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Evaluation and rationalization methodology for the acquisition of packaging capital equipment and services

Craig E. Densmore

EVALUATION AND RATIONALIZATION METHODOLOGY FOR THE ACQUISITION OF PACKAGING CAPITAL EQUIPMENT AND SERVICES

By

Craig E. Densmore

A Thesis

Submitted to the

Department of Packaging Science

College of Applied Science and Technology

In partial fulfillment of the requirements

for the degree of

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Certificate of Approval

M.S. DEGREE THESIS

The M.S. Degree thesis of Craig E. Densmore
has been examined and approved
by the thesis committee as satisfactory
for the thesis requirements for the
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May 17, 2001

Evaluation and Rationalization Methodology for the Acquisition of Packaging Capital Equipment and Services

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ABSTRACT

The development of proactive methods for the evaluation, selection, standardization, and rationalization of capital equipment and services used in the medical device industry will benefit equipment/process interchangeability and will result in lower costs of goods (COG). Reduced exposures to legal and regulatory issues are also expected. At the time this study began, senior management believed staff should have the latitude to make continuous improvements initiated without the burden of a corporate regulatory, engineering, quality, or procurement oversight, as long as each facility continued to meet or exceed appropriate performance standards and government regulations.

This work seeks to document the technical, quality, commercial, legal, and supplier assessment tools that can ease the selection, acquisition, and ownership of capital equipment. The development of a standardized set of supplier engagement tools, created cross-functionally, has enabled groups from different business units, cultures, countries, and continents to form consensus opinions when projects were led according to this planned methodology.

Thesis Permission Release

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COLLEGE OF APPLIED SCIENCE AND TECHNOLOGY

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May 17, 2001

DEDICATION

This thesis is dedicated to my grandparents, Gertrude and Merton S. Williams; my parents, Donald and Dorothy Densmore; and my wife, Barbara. They all supported and encouraged me throughout the years of my life to seek and attain the highest levels of education. Further, it is dedicated to my daughters, Catherine and Carly, who may not have received immediate attention while Dad was preoccupied; and to my friends, who may have thought me too engrossed in my education.

ACKNOWLEDGEMENTS

I would like to express my thanks to the many professionals who assisted in the development of this thesis. Special thanks are due my good friend, John M. Robortella, for his help and encouragement. Let it be known that the faculty and staff of the Department of Packaging Science played *the* paramount role in my educational experience by having created a stimulating atmosphere in which to learn.

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INTRODUCTION

This researcher arrived at an international medical device manufacturer and was confronted with inconsistent methods that were being used in the selection, specification, engagement, and contracting of supplier/partners for the enterprise. These conflicting business approaches encompassed packaging machinery, auxiliary process equipment used in manufacture, contract manufacturing services of packaged products, technical service agreements, and consulting agreements for the development and manufacture of medical devices and related sterile solutions. The patient may utilize these products to maintain good ocular health.

In this researcher's opinion, each of the individual major manufacturing locations had expanded as a result of new product development, strategic deployment for economic efficiencies, or technology introductions. At the time that this situation was identified, it became apparent that the individual manufacturing locations were constrained only by corporate Standard Operating Procedures (SOP's) for manufacture, the individual facility's SOP's, ISO 9001 assessments, current Good Manufacturing Practices (cGMP's), or European Union (EU) and United States FDA regulations.

This continued platform development took place subsequent to the original research and development, scale-up feasibility studies, pilot line proof of principle, and multiple clinical trails had been conducted. Senior management's philosophy, in place at the origination of this review, was that each plant administrator and his or her associated staff should be allowed the latitude to make continuous improvements without the burden of a corporate regulatory, engineering, quality, or procurement review. The premise assumed that each facility

continued to meet or exceed the appropriate governmental regulations for safety and efficacy.

Within a short period of time, however, the corporation's financial, engineering, quality, and procurement departments determined that these practices added additional expense to the corporation's cost of goods (COG). Additionally, legal and regulatory groups questioned whether these practices were subjecting the corporation to excessive legal liability for a lack of equivalence of manufacturing procedures, as required by various worldwide regulatory agencies. This lack of standardization created higher costs of manufacturing platforms due to the loss of procurement leverage for the acquisition of production manufacturing equipment, packaging machinery, inspection, metrology equipment, and shop floor data collection systems in a more comprehensive strategic atmosphere. The procurement establishment documented that the lowest total cost of ownership over the expected capital depreciation cycle of such equipment was not being realized. Validation timelines and therefore expense were also lengthier, slowing regulatory approval and commercial introduction. Loses due to unrealized market opportunities occurred. Validation processes included Factory Acceptance Testing (FAT), Installation Qualification (IQ), Operational Qualification (OQ), and Production Qualification (PQ). Unrealized market opportunities could take several paths. One was that patients who would have been potential new consumers of the corporation's products were not introduced to them by their medical practitioner due to the lack of regulatory approval. Another was the lost or deferred sales to competitors who had a sharper understanding of the marketplace and who executed their strategies more efficiently to bring equivalent products to market. A third instance was the shortened life cycle of entire product manufacturing platforms due to

new entries emerging from the research and development (R&D) pipeline. These new introductions could be from within the company's own research and development groups or from other competitors in the market sector.

Medical device manufacture within this firm had expanded from the northeastern United States to the southeastern United States and further to multiple sites in South America, Europe, and Asia. In the case of several of these sites, commercial trade barriers had led to the development of smaller, less efficient manufacturing facilities that were more difficult to economically support due to the lack of multiple core competencies that were needed to operate these facilities. These core competencies were maintained only at the corporate technology center in the United States. Sterile solution manufacture had grown from the two strategic facilities in the southeastern United States and Italy to include facilities in India, Indonesia, and China due to a similar rationale of cost avoidance due to excessive barriers to entry in each country.

RATIONALE

During the earliest portion of this review, senior management's objectives were centered on new product research and development activities in addition to the pilot implementation of the next generation of medical devices. Within this cultural atmosphere, capital equipment procurement personnel developed informal strategic internal alliances, first and foremost with the machinery automation engineering group, and secondarily with manufacturing plant packaging and process engineering site representatives.

The capital equipment procurement process had been a reactive support function at the beginning of this researcher's review. New positions were created when management identified that there were multiple economic advantages for early commercial involvement to manage capital acquisitions and standardization. These positions were transitioned to non-traditional procurement personnel with engineering, manufacturing, and supply chain skill sets that supported the methodology of the total cost of ownership. Few direct reporting relationships or lines of authority were in place. The newly reorganized capital equipment procurement group struck out to develop a strategy to provide higher levels of services beyond the internal customer's previous expectations.

The second step of the implementation of the capital acquisition strategy involved the capital procurement group taking the earliest successes to plant engineering and research project teams in the form of in-service training. This training soon became an ingrained and accepted process within U.S. operations when functional managers received immediate positive impacts to their project budgets and timelines.

The third portion of strategy execution involved the support of the offices of Regulatory Affairs and Quality Assurance that supported Capital Best Practices concepts. This resulted in the implementation of standard Capital Best Practices and the supplier engagement tool set at all manufacturing facilities worldwide. This formalization was the key to equivalence in manufacturing platforms for both locations inside and outside the United States. Historically non-United States plants had been the least receptive to commercial procurement standardization. Packaging and allied support machinery were now to be acquired utilizing cross-functional teams and discrete selection processes.

IMPLEMENTATION

In conjunction with other cross-functional team members, this researcher developed and documented a set of supplier engagement tools to facilitate consensus and avoid variance in manufacturing methods and procedures among the worldwide units. Additionally, commercial relationships between the company and its supplier/partners were standardized.

These engagement tools were based on a recognized business process flow with checkpoints for evaluation and control. The major steps include:

- Identification of the need for a material or service
- Convene the Supply Based Management Team, consisting of the core competencies of Quality, Procurement, Technical, Operations, Engineering, and Regulatory
- Establish supplier requirements packages by the appropriate team members
- Determine if existing suppliers can meet the specified demand
- Identify existing suppliers for evaluation; if the current supply base is not adequate, evaluate additional suppliers
- Define requirements and specifications for Request for Quotation and distribute to selected suppliers
- Evaluate suppliers against the requirements/protocols
- Draft supplier evaluation reports
- Determine if acceptance criteria have been met
- Development a recommendation of the selected supplier
- Select and negotiate with the preferred supplier
- Finalize the supply agreement

- Update the Approved Supplier List with current information
- Define the type and extent of control to be exercised over the supplier (self certification, required acceptance testing, etc.)
- Assess supplier performance on an ongoing basis
- Document results of ongoing performance in supplier master file

The team developed fifteen Supplier Engagement Tools to aid in the standardization and selection. The legal, quality, and regulatory groups required some of the tools, while others were used to quantify supplier capabilities and remove subjective personal opinions from the evaluation process.

A brief summary of each tool and its potential application will now be discussed.

Unilateral Confidentiality Agreement: Mandates that the supplier/partner will not share confidential or proprietary information outside of the relationship with the company (Appendix I)

Bilateral Confidentiality Agreement: Mandates mutual confidentiality of intellectual property by both the company and the supplier/partner; useful for the protection of the supplier which may have proprietary expertise and knowledge in a particular field (Appendix II)

Supplier Profile: Collects basic information for database input and provides the company with the basic due diligence for the assessment of the commercial viability of the supplier/partner (Appendix III)

Strategic/Extended Evaluation Report: In-depth evaluation of a supplier/partner for longer-term relationships, mission-critical assignments, or large commercial exposure (Appendix IV)

Request for Quotation: Standardized form for the reporting of a supplier/partner's price and service proposals to the company (Appendix V)

Selection Matrix: Provides the team members with the opportunity to assess the supplier/partner's qualifications in various areas. This method was developed by this researcher to substantially reduce the subjective nature of supplier selection, allowing objective full team participation in the decision making process. Later in this review, one such selection process will be evaluated and discussed. This matrix is not a static document. It is expected that pertinent selection items & weights will be added or omitted for each new selection process. The important factor is that the team members define these criteria prior to final development of the specification to allow for the most unbiased selection process to take place. (Appendix VI)

Standard Terms and Conditions of the Purchase Order: The generic company contract used in a variety of applications. (Appendix VII)

Terms and Conditions of Sale of Capital Equipment: An extended set of company requirements for the purchase of capital equipment. This provides requirements upon both the company and the supplier/partner that supercede a standard purchase order, such as:

- Penalties for late delivery
- Specific warranty requirements
- Compliance with health and safety regulations
- Ownership rights of intellectual property
- Procedures for changes in the scope of the contract
- Project management reporting requirements
- Requirements for the publication of manuals and drawings
- Definition of spare parts and their availability

- Installation requirements
- In service status to define final payment schedule
- Rights and requirements for subcontracting (Appendix VIII)

User Requirement Specification (URS): Defines the purpose or use of a specific piece of equipment or service, including its applicability; key objectives and benefits; comparison with existing equipment; operational content; performance parameters; general requirements for operation, maintenance, and documentation; and the acceptance criteria that will be utilized for factory acceptance testing. This becomes a vital component of the Supplier Engagement Tools because it establishes the standardized information that the supplier/partners need to provide to the company for the team's evaluation of the supplier's proposal. (Appendix IX)

Consulting Agreement: Establishes requirements for consultants retained on fee-based defined deliverable projects versus flat fee or hourly-charged projects. (Appendix X)

Technical Service Agreement: Typically a shorter-term agreement that calls for defined deliverables or equipment of a prototype nature in which the company and the supplier/partner have input. (Appendix XI)

Contract Manufacturing Agreement: A contract that establishes the requirements of a supplier/partner for the delivery, quality, price, and regulatory compliance when manufacturing finished goods for the company. (Appendix XII)

Supply Agreement: This is similar to the Contract Manufacturing Agreement. It provides specifications for the purchase of raw materials and requires the supplier/partner to comply with applicable laws, regulations, and acts in the manufacture of medical devices. (Appendix XIII)

Certified Supplier Assessment/Business Review Process: A quality assessment tool used annually by the company to assess the viability and continuous improvement of preferred long-term supplier/partners. (Appendix XIV)

Supplier Selection: In this phase the team finalizes and collects the data that determined and justified the selection of the supplier/partner for a particular project or role. (Appendix XV)

MEASUREMENT AND EVALUATION

OF A PROJECT SPECIFIC APPLICATION

The processes established by this researcher and discussed above were used in practice when the company chose to upgrade and purchase its sterilization equipment in a majority of the operating units in the United States and abroad.

At the beginning of the project, a committee of fifteen staff members was established to provide their individual requirements for the new sterilization equipment. These included such parameters as cycle times, internal capacity, warranties, price, etc. Many of the committee members had preconceived ideas and recommendations for supplier selection, in some cases based on their own personal preferences.

The first step in the process was the development of a user requirement specification by the technical subcommittee. This review included visits to worldwide manufacturers of this type of equipment, supplier presentations, and demonstrations. This research data was then evaluated and compared with the company's requirements.

To remove the subjectivity from the decision-making process, this researcher developed a format to collect, organize, and rank the raw data. The categories and their related subcategories were to be weighted and ranked in accordance with the company's requirements, prior to receipt of the supplier/partners' proposals.

Description	Weight	Scale 1-5
Cost and delivery	20%	
System price		5
Delivery schedule		4

Description	Weight	Scale 1-5
Proposal evaluation	**25%**	
Technical concept		5
Production rate (capacity)		5
Commonality to other facility equipment		4
Floor space utilization		3
Conformance to specifications		3
Ease of maintenance		3
Safety and guarding		3
Timeliness to RFQ		3
Conformance to RFQ		3
Fit to facility resources		3
Degree of flexibility		2
Proposal completeness		2
Supplier/proposal professionalism		1

Description	Weight	Scale 1-5
Past performance evaluation	**40%**	
System functionality/ capability		5
Maintenance costs		5
On-time delivery		4
Spare parts availability		4
Training (presentation and material)		4
Documentation		4
Synergy with team		4
Service		3
Drawings		3
Start-up assistance		2
Amount of outsourced (engineering)		1
Amount of outsourced (fabrication)		1

Description	Weight	Scale 1-5
Business evaluation	**15%**	
Supplier capacity (facility/floor space)		5
Supplier size (sales volume)		4
Design engineering resources		4
Controls engineering resources		4
Project management		3
Supplier location		3
Experience in medical/ Pharmaceutical		1

Weighted Scale 1 equals the lowest rank; weighted Scale 5 equals the highest rank

Specifications and requests for quotations were issued to five medical sterilization equipment manufacturers who had been identified

by the original subcommittee. Two suppliers who could not meet the requirements declined to submit proposals.

When proposals were received, each committee member was asked to evaluate them, compare them with the matrix, and submit a written ranking for each category. This data was collected and input by this researcher into a previously developed spreadsheet. The results were tabulated and are shown in Appendix XX of this document.

The three participating suppliers received rankings of 94 percent, 77 percent, and 51 percent, respectively.

CONCLUSION

Following an evaluation of the raw data and its rankings, the committee unanimously selected the supplier with the highest ranking (94 percent) to provide on-going company requirements for medical sterilization equipment. The methodology developed by this researcher and used in this real-world application virtually removed personal preference and predispositions to the decision-making process.

When the success of the this process was communicated throughout the enterprise, its use was formalized and included in the company's Policies and Procedures Manual and it remains in use as of this writing as an efficient and objective method to select a variety of supplier/partners in various categories.

UNILATERAL CONFIDENTIALITY AGREEMENT

This AGREEMENT effective as of <DATE>, by and between **MEDICAL DEVICE INCORPORATED** (and applicable to the locations listed on Attachment A, which may be changed or amended from time to time), a corporation of the State of New York, <ADDRESS> USA (hereinafter referred to as "MEDICAL DEVICE") and Insert complete name & address of supplier (hereinafter referred to as "RECIPIENT").

WHEREAS, MEDICAL DEVICE represents that it now has, or may in the future develop or acquire, certain ideas, concepts, data, or other information which in whole or in part is or will be considered proprietary, in particular, but not limited to, information on the following subject(s): contact lenses, eye care solutions, inter-ocular devices, spectacles, surgical eye procedures & instruments, laser eye treatments, pharmaceutical products and pharmaceutical delivery devices for the eye (hereinafter agreed to as "Confidential Information").

WHEREAS, in order for RECIPIENT to review technical and/or business information as an Independent (Consultant/Contractor/Supplier) it is necessary for MEDICAL DEVICE to disclose Confidential Information to RECIPIENT.

NOW, THEREFORE, the parties agree as follows:

1. This Agreement provides only for the handling and protecting of Confidential Information provided to RECIPIENT and shall not be construed as a further commitment or obligation by either party.

2. RECIPIENT shall preserve the confidentiality of all Confidential Information received hereunder. RECIPIENT will disclose the Confidential Information only to those within its own organization who need to have such Confidential Information for the sole purpose of assisting MEDICAL DEVICE as set forth above. RECIPIENT shall not otherwise use, copy, or disclose such Confidential Information.

3. RECIPIENT shall not be liable for disclosure of any Confidential Information and the non-use obligations of this Agreement shall not apply to any such Confidential Information if the same:

a. is now in or hereafter comes into the public domain without breach of this Agreement and through no fault of RECIPIENT, or

b. is properly and lawfully known to RECIPIENT prior to the effective date of this Agreement and free of any obligation of confidence to MEDICAL DEVICE , which RECIPIENT can prove from its written records, or

c. is disclosed by RECIPIENT with the written approval of MEDICAL DEVICE , or

d. subsequent to disclosure hereunder, is lawfully received from a third party whose rights therein are without any restriction to disseminate such Confidential Information.

4. This Agreement shall not be construed as granting by implication, estoppel or otherwise, any right in or license under any present or future inventions, trade secrets, trademarks, copyrights, or patents,

owned or controlled by MEDICAL DEVICE.

5. This Agreement may be terminated by either party by giving thirty (30) days written notice to the other party. However, RECIPIENT's obligations to protect previously received Confidential Information shall, except as qualified by Paragraph 3, survive for (recommended minimum five (5) years) from the date of receipt of such Confidential Information. When this Agreement expires or is terminated, RECIPIENT shall return to MEDICAL DEVICE (or provide evidence of destruction of) all Confidential Information of MEDICAL DEVICE within RECIPIENT's possession or control and all copies, regardless of medium in or on which it is copied or stored.

6. This Agreement is non-assignable except with the prior written approval of MEDICAL DEVICE.

7. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York without reference to its conflict of law or choice of law rules.

8. This Agreement contains the entire understanding relative to the protection of Confidential Information covered by this Agreement and supersedes all prior and collateral communications, reports, and understandings, if any, between the parties regarding such Confidential Information. No modifications to any provision hereof shall be binding unless in writing and signed by the parties.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

<INSERT NAME/FIRM> <INSERT COMPLETE ADDRESS>	MEDICAL DEVICE INCORPORATED by and through its <BLANK>
Signature: _____	Signature: _____
Name Printed: _____	Name Printed: _____
Title: _____ (Authorized Representative)	Title: _____ (Authorized Representative)

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ATTACHMENT A

List all locations of Medical Device, Inc. including addresses

BILATERAL CONFIDENTIALITY AGREEMENT

AGREEMENT effective <INSERT DATE>, by and between Medical Device, Incorporated (and applicable to the locations listed on Attachment A, which may be changed or amended from time to time) <insert address>(hereinafter referred to as "MEDICAL DEVICE") and <INSERT COMPANY NAME, and Complete Address> (hereinafter referred to as <INSERT RECIPIENT NAME>.

WHEREAS, MEDICAL DEVICE represents that it now has, or may in the future develop or acquire, certain ideas, concepts, data, or other information which in whole or in part is or will be considered by MEDICAL DEVICE to be proprietary and confidential (hereinafter "MEDICAL DEVICE Confidential Information"), including but not limited to information on the following subject(s): contact lenses, eye care solutions, inter-ocular devices, spectacles, surgical eye procedures & instruments, laser eye treatments, pharmaceutical products and pharmaceutical delivery devices for the eye (hereinafter agreed to as "Confidential Information").

WHEREAS, <INSERT RECIPIENT NAME> represents that it now has, or may in the future develop or acquire certain ideas, concepts, data, or other information which in whole or in part is or will be considered by <INSERT RECIPIENT NAME> to be proprietary and confidential (hereinafter "<INSERT RECIPIENT NAME> Confidential Information"), including but not limited to information on the following subject(s): _____.

WHEREAS, MEDICAL DEVICE and <INSERT RECIPIENT NAME> are desirous of exploring the possibility of entering into a new and/or maintaining

an existing business relationship with each other and MEDICAL DEVICE is willing to provide <INSERT RECIPIENT NAME> with access to MEDICAL DEVICE Confidential Information, and <INSERT RECIPIENT NAME> is willing to provide MEDICAL DEVICE access to <INSERT RECIPIENT NAME> Confidential Information, all in order to aid MEDICAL DEVICE and <INSERT RECIPIENT NAME> in reaching a decision concerning such potential contractual arrangement(s).

NOW, THEREFORE, in consideration of the premises, and the mutual covenants contained herein, the parties agree as follows:

1. The MEDICAL DEVICE Confidential Information and the <INSERT RECIPIENT NAME> Confidential Information may sometimes hereinafter be referred to as "Confidential Information".

2. This Agreement provides only for the handling and protecting of Confidential Information and shall not be construed as a teaming, joint venture, or other such arrangement.

3. MEDICAL DEVICE represents and warrants to <INSERT RECIPIENT NAME> that it has the right to enter into this Agreement and disclose the MEDICAL DEVICE Confidential Information to <INSERT RECIPIENT NAME> pursuant to this Agreement, and that it is not a party to any other agreement or under any obligation to any third party that would prevent it from entering into this Agreement.

4. <INSERT RECIPIENT NAME> represents and warrants to MEDICAL DEVICE that it has the right to enter into this Agreement and disclose Confidential Information to MEDICAL DEVICE pursuant to this

Agreement, and that it is not a party to any other agreement or under any obligation to any third party that would prevent it from entering into this Agreement.

5. In order for Confidential Information to be covered by this Agreement (a) any written information (including information stored on tapes and disks) must be prominently identified on the face thereof as Confidential Information to the disclosing party by appropriate legend, stamp or other marking, and (b) any oral information must be described in reasonable detail in writing, identified as Confidential Information and transmitted to the receiving party within thirty (30) days of the date of oral disclosure to the receiving party.

6. The receiving party shall take all reasonable steps to preserve any and all Confidential Information received from the disclosing party pursuant to this Agreement. The receiving party will disclose the Confidential Information only to those employees, agents and consultants whose work requires such disclosure and who have agreed in writing to maintain such Confidential Information in confidence. The receiving party shall not otherwise use, copy or disclose (either internally or to third parties) such Confidential Information.

7. Notwithstanding any other provisions of this Agreement, the receiving party shall not be liable for disclosure of any Confidential Information of the disclosing party and the non-use obligations shall not apply to any such Confidential Information if the same:

a. is not identified as Confidential Information in accordance with this Agreement, or

b. is now in or hereafter comes into the public domain without breach of this Agreement and through no fault of the receiving party, or

c. is properly and lawfully known to the receiving party prior to the effective date of this Agreement without an obligation of confidentiality to the other party, or

d. is disclosed by the receiving party with the written approval of the disclosing party, or

e. subsequent to disclosure hereunder, is lawfully received by the receiving party from a third party whose rights therein are without any restriction to disseminate the Confidential Information, or

f. is developed by employees, agents, or consultants of the receiving party independently of and without reference to any Confidential Information of the disclosing party, or

g. is communicated by the disclosing party to a third party free of any obligation of confidence.

8. The disclosure of MEDICAL DEVICE Confidential Information by MEDICAL DEVICE to <INSERT RECIPIENT NAME> and the disclosure of <INSERT

RECIPIENT NAME> Confidential Information by <INSERT RECIPIENT NAME> to MEDICAL DEVICE shall not result in any obligation on the part of either party to enter into any future agreement relating to such Confidential Information or to undertake any other obligation not set forth in a written agreement signed by the parties hereto. Neither the execution and delivery of this Agreement nor the delivery of any Confidential Information hereunder shall be construed as granting by implication, estoppel or otherwise, any right in or license under any present or future invention, trade secret, trademark, copyright, or patent, now or hereafter owned or controlled by either party hereto.

9. The primary but non-exclusive points of contact for the transmission and control of Confidential Information exchanged hereunder, are:

FOR <INSERT COMPANY NAME>	FOR MEDICAL DEVICE:
Name Printed: _____	Name Printed: _____
Title: _____	Title: _____
(Authorized Representative)	(Authorized Representative)

Each party may change its primary point of contact by written notice to the other party.

10. This Agreement may be terminated by either party by giving thirty (30) days written notice to the other party. However the receiving party's obligation to protect previously received Confidential Information shall survive for <INSERT # OF YEARS> (Minimum five (5) years) from the date of receipt of such Confidential Information.

11. All Confidential Information identified in accordance with the provisions of Paragraph 7, which is provided by the disclosing party to the receiving party shall remain the property of the disclosing party and shall be returned to the disclosing party upon written request. Neither the receiving party's failure to return or destroy, nor the disclosing party's failure to request such return or destruction, shall relieve the receiving party of its confidentiality obligations under this Agreement.

12. This Agreement is non-assignable and any attempt or purported assignment of any rights hereunder by either party shall be null and void, except that either party may assign the Agreement to a successor or assignee of its business division to which this Agreement pertains, provided that appropriate notice is given to the other party.

13. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York without reference to its conflict of law or choice of law rules.

14. The Agreement contains the entire understanding relative to the protection of the type of Confidential Information covered by this Agreement and supersedes all prior and collateral communications, reports, and understandings, if any, between the parties regarding such Confidential Information. No modifications, or additions to any provision hereof shall be binding unless in writing and signed by the parties. This agreement shall apply in lieu of and notwithstanding any specific terms contained in any legend or statement associated with any particular Confidential Information

exchanged, and the duties of the parties shall be determined exclusively by the terms and conditions herein.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

<INSERT COMPANY NAME> INCORPORATED	MEDICAL DEVICE INCORPORATED
Signature: _____	Signature: _____
Name Printed: _____	Name Printed: _____
Title: _____ (Authorized Representative)	Title: _____ (Authorized Representative)

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ATTACHMENT A

List all locations of Medical Device, Inc. including addresses

MEDICAL DEVICE BASELINE SUPPLIER PROFILE

DATE: _____

_____

LEGAL NAME _____
LEGAL STRUCTURE _____
CORRESPONDENCE ADDRESS _____
CITY/STATE/ZIP CODE _____
COUNTRY _____
BUSINESS CONTACT: _____
STATE OF INCORPORATION OR
BUSINESS REGISTRATION: _____

REMITTANCE ADDRESS:
(IF DIFFERENT THAN ABOVE) _____
CITY/STATE/ZIP CODE _____
COUNTRY _____

ANNUAL SALES ($): _____ YEAR ESTABLISHED: _____

DIVISION OR AFFILIATIONS
WITH OTHER PARENT FIRMS: _____

CHIEF EXECUTIVE OFFICER (CEO)/PRESIDENT: _____
CHIEF FINANCIAL OFFICER (CFO): _____
PLANT OR GENERAL MANAGER: _____

FEDERAL EMPLOYERS ID #: _____ DUNS #: _____

FDA SITE REGISTRATION #:
(IF APPLICABLE) _____

ISO REGISTRATION(S): _____ REGISTRAR: _____
LAST ASSESSMENT DATE: _____

MINORITY OWNED: YES _____ NO _____
MINORITY CATEGORY: _____
WOMEN OWNED: YES _____ NO _____
% OF OWNERSHIP: _____
EEOC EQUAL OPPORTUNITY FORM: YES _____ NO _____
(IF YES, ATTACH)

GLOBAL OPERATIONS PARTNERS/
DIVISIONS/JOINT VENTURES: _____

COMMUNICATION METHODS:
TELEPHONE: _____ FAX: _____
E-MAIL: _____ INTERNET: _____

MEDICAL DEVICE BASELINE SUPPLIER PROFILE

TOLL FREE #: _____ TOLL FREE FAX #: _____

SPARE PARTS COST/POLICY:
(% MARKED UP FROM OEM) _____

CONFIDENTIALITY AGREEMENT: _____
ON FILE: _____ EXPIRATION DATE: _____

LEADING EDGE TECHNOLOGIES:(WHAT SPECIFIC STRENGTHS DOES YOUR FIRM POSSESS)

_____

_____

_____

COMPUTER & ELECTRONIC INTERFACE CAPABILITIES: _____

_____

INVOICING PROCEDURES: _____

_____

PAYMENT TERMS: _____

_____

ADVISE OF ANY DEBT(s) (BEYOND TERMS), JUDGEMENT(s) OR TAX LIEN(s)

_____

DISCOUNT POLICY FOR MULTIPLE UNITS OR ANNUAL SALES VOLUMES: _____

_____

MODULARITY & INTERCHANGEABILITY OF EQUIPMENT DESIGNS: _____

_____

WILLINGNESS TO COMPLY W/STANDARD B&L TERMS & CONDITIONS: _____

_____

PROJECT MANAGEMENT CAPABILITIES & METHODS: _____

_____

CONTROL PROCEDURES FOR CUSTOMER OWNED SUPPLIES, DRAWINGS & EQUIPMENT:

_____

DOCUMENT & CHANGE CONTROL PROCESS (AS BUILT STATUS): _____

_____

LEAD-TIME (IN WEEKS FOR CUSTOMARY PROJECTS): _____

PERCENTAGE OF PROJECTS COMPLETED ON SCHEDULE: _____

DOCUMENTED QUALITY PROCEDURES: _____

MEDICAL DEVICE BASELINE SUPPLIER PROFILE

JOINT COST REDUCTION PROCESS: (HOW ARE THEY DOCUMENTED) _____

_____

FACILITY OPERATES UNDER GOOD MANUFACTURING PRACTICES (GMP's) RELATED TO MEDICAL DEVICES, PHARMACEUTICALS, FOOD/COSMETICS OR N/A: _____

_____

RELATIONSHIPS WITH OTHER EYE CARE, PHARMACEUTICAL OR MEDICAL DEVICE: MANUFACTURING ORGANIZATIONS _____

_____

DOES THE FACILITY RECEIVE REGULAR AND PERIODIC QUALITY SYSTEM ASSESSMENTS FROM THESE OUTSIDE ORGANIZATIONS: _____

_____

NUMBER OF MAJOR CUSTOMERS: _____

INDUSTRY BREAKDOWN: _____

_____

SIZE OF FACILITIES (SQ. FT.): _____

- ASSEMBLY _____
- MANUFACTURING _____
- MACHINING/FABRICATION _____
- OFFICE _____

TOTAL EMPLOYEES: _____

- ADMINISTRATIVE _____
- ENGINEERING _____
- PROCUREMENT _____
- CLERICAL _____
- MANUFACTURING _____

NUMBER OF:

- ENGINEERS/DISCIPLINE _____
  - MECH. _____
  - ELECTRICAL _____
  - CONTROLS _____
  - OTHER _____
- CAD OPERATORS _____
- DEDICATED PROJECT MANAGERS _____
- CONTROL TECHNICIANS _____

- PROGRAMMERS
  - MACHINE CONTROLS _____
  - SYSTEMS SUPPORT _____

MEDICAL DEVICE BASELINE SUPPLIER PROFILE

NUMBER OF UNION OR COLLECTIVE BARGAINING EMPLOYEES: _____

UNION(S) INVOLVED _____

_____

CONTRACT DATE(S) EXPIRATION _____

_____

EXPANSION PLANNING _____

_____

BUSINESS PLAN (FIVE YEAR VISION FOR THE CORPORATION) _____

_____

_____

_____

Medical Device, Inc.

STRATEGIC/EXTENDED ENTERPRISE EVALUATION REPORT

Date: _____

Report Prepared By: _____
_____
_____

Position: _____
_____
_____

Organizational Information

General Information

1. Production Location
Supplier Name:
Number and Street:
City and State:
Country:
Phone: ( )
Fax:
E:mail:
Contact: (Names and Contacts – attach Organizational Chart):
Name/Title/Phone/Fax #/Pager #/Mobile Phone #
Facility Manager:
Sales:
Engineering:
Materials Manager:
Finance:
Quality Assurance:

2. **Headquarters Location** [If different]
Supplier Name:
Number and Street:
City and State:
Country:
Phone: ( )
Fax:
E-mail:
Contact: (Names and Contacts – attach Organizational Chart):
Name/Title/Phone/Fax #/Pager #/Mobile Phone #

3. Please provide a signed confidentiality agreement from you in our file (attach):
4. Please provide a copy of your standard and/or specialized purchase agreement:
5. Please provide a copy of your standard and/or specialized lease agreement:
6. Please provide a copy of your standard and/or specialized terms and conditions:

[Exchange equivalent MEDICAL DEVICE, INC. documentation as appropriate]

7. What type of communication means you possess (explain):
   Web site:
   Teleconference:
   Video conference:
   Electronic mail:
   Voice Mail:
   Paging System:
   Language translation capabilities:

8. What type of planning system does management use (explain: Demand Planning, MRP, etc.):
9. What type of forecasting system software does management use (explain):
10. How closely does your forecast equate to actual plan (measure):
11. Does your firm make to order, make to plan, make to inventory (explain)
12. Employee Demographic:
    Direct:
    Exempt:
    Contract/Temporary:
    Has firm filled EEOC-1 equal opportunity form?
    (If Yes, please attach/If No, please state reason)
13. Work Schedule:
    Hours:
    Shifts:
    Days Worked:
    National Holiday Schedule:
    Union Shop (Yes/No)?:
    Contract Expiration Date?:

14. Business Type:
    Corporation:
    Partnership:
    Proprietorship:
    Subsidiary:
    Indicate Parent Company:
    Woman/Minority Owned Business:
        Woman Owned:
            % Of Ownership:
        Minority Owned:
            Minority Category:
        Small Business:
15. Year Established:
16. Type of Service and/or Products:
    Primary: %
    Secondary: %
    Specializing: %
17. Facilities:
    Total Area, square feet
    % Utilized
    Type of Building: (eg. 3 stories, brick, air conditioned, etc.)
        Sprinklered
        Alarmed
        Manned security
    Own or Lease:
        Lease Expiration Date:
18. Is adequate safety and fire containment equipment available:
19. Are good safety practices in place and followed:
20. What value amount of inventory is on hand:
21. Production Capacity:
    (Explain:)

Financial Information

1. Dun & Bradstreet Number:
2. Bank Name:
   Location:
   Account Number:
   Telephone Number:
   Fax Number:
   Swift Code:
3. Federal Identification Number (US Firms):
4. Copy of Direct Payment Permit (US Firms Please Attach):
5. Trade References Name (at least three):
   Address:
   City, State, Country, Zip:
   Phone and Fax Number:
6. Financial Data (Past Three years):
   10Ks:
   Annual Reports:
   Financial Statements:
   Liquidity Ratios:
7. Percentage of Last Years Sales to MEDICAL DEVICE, INC.:
   This Years Sales Forecast:
   Percentage of this Years Sales to MEDICAL DEVICE, INC. Forecasted:
8. What is Supplier's long Term Business Strategy:
   Does it match our current and future needs:
   Is there willingness and financial capability for full service supplier:
   Is there short term capacity to meet our needs:
   Is there ability to expand capacity to meet our long term needs:
   Would there be a need for future capital expenditures to support Medical Devices' requirements?

9. Describe your commitment and involvement to a continuous improvement process:
10. Describe your labor/management relationship (strike risk assessment):
11. Describe how company issues and goals are communicated to all levels:
12. Please list major customers names, percent of business and industry type (attach):
13. Please list other divisions of MEDICAL DEVICE, INC. Corporation, which you have done business:
14. Please list other Divisions of MEDICAL DEVICE, INC. Corporation, which you currently do business:

15. Other items for evaluator's review:
    Unusual employee turnover in Key Positions
    Requests for expedited payments, major downpayments
    Small Customer Base
    Loss of Major Customer
    Major Litigation
    Sudden change in quality or delivery
    Reluctance to purchase lower level material
    High number of business failures in this industry
    Safety/OSHA violations
16. Insurance policy info and coverage:
    (Cert. Filed with MEDICAL DEVICE, INC. Risk Mgt.?)
17. Disaster recovery plan:
18. Backup of documentation for intellectual property and operational items:
19. Can firm manufacture in a confidential manner:
    (Explain method)

Supply Chain Information

Quoting Process & Price Determination and Control

1. What methods does supplier use to determine selling price:
2. Is willingness to enter into Cost Analysis to establish value verified prices:
3. What cost reduction/cost control programs do they have in place:

Order Control

1. Is there real-time order tracking?
   Web based?
2. What is standard order placement lead-time:
3. Will supplier use a forecasted/short lead-time program and/or JIT:
4. Does supplier participate in any CPFR [Collaborative Planning Forecast & Replenishment] programs?
5. Does order processing system provide timely feedback on status of orders:
6. Does the order processing system allow for changes in customer orders:
   Engineering Change Orders [ECO's], Purchase Order Changes
7. Is there a system to keep customer drawings and other documentation up to date:
8. Is there internal tracking of on-time delivery performance:
9. How is on time defined:
10. What is percentage of on-time (attach documentation):

Procurement, Production and Inventory Control

1. Describe inventory procurement, control and planning systems:
2. Describe production scheduling and capacity planning systems:

3. Describe material flow and work-in-process tracking system:
4. Dose the supplier have a rating system for their suppliers (please explain):

Handling, Storage, Packaging and Shipping

1. What are procedures to identify status of material in stock, age/shelf-life control:
2. What is the closest commercial airport:
3. Distance from them to use:
4. Are storage areas secured from unauthorized personnel (explain):
5. Are items checked for damage, count, and indicate final inspection before shipped:
6. How are requested methods of shipment adhered to (explain):
   Conformance to customer shipping method communicated (explain):
7. Can the supplier support our JIT/CPFR program (explain):
8. Does the supplier have in-house packaging design capability (explain):
9. Can they package to support dock-to-sip requirements (explain):
10. How is your product packed and handled to preserve quality (explain):
11. Does the supplier have bar coding capabilities for outbound shipments (explain):

Measures

1. Do you measure customer satisfaction (document):
2. How do you measure inventory turns (document):
3. How is your cycle time measured (document):
4. How are your lead times tracked (documented):
5. How do you track profit vs. operating expense:

Technical Information

Research & Development

1. Do you have research and development capabilities:
2. Please describe from above:
3. Explain types of specialty expertise gained through development activities:
4. Have you partnered on joint development activities (give references):
5. Give a description of your research and development process and resources:

Engineering & Design for Capital Equipment Acquisitions

1. Please give a copy of written machine specification (attach):
2. What manuals are available (explain):
   - Operator:
   - Installation:
   - Service:
   - Training:
   - Recommended Spare Parts:
3. Are statistics on mean time between failure (MTBF) available (explain):
4. Are statistics on mean time to repair (BTTR) available (explain):
5. Will supplier repair, replace or modify any equipment not performing to spec:
   - For what period:
6. Please give a copy of suppliers standard written warranty (attach):
7. What is the warranty period (days, months):
8. When does the warranty start (explain):
9. What does the warranty cover (explain):
   - Parts only:
   - Parts and Labor:
   - On site warranty support:
   - Deport warranty support:
10. Can warranty period or coverage be extended by negotiation (explain):
11. Can warranty period or coverage be extended at a premium change (amount):
12. What is warranty recovery process (explain):
    - Return Authorization Number Required (explain):
    - Who is contact (name, telephone, fax, address & e-mail):
    - What is estimated turn around time on warranty claims (days):
13. What is the labor recovery procedure (explain):
14. What is the emergency parts turn around procedure (explain):
15. Will supplier warranty remain in effect if we modify the equipment (explain):
16. Will the supplier modify the equipment that is under warranty (explain):
17. What will the effect be to suppliers warranty, for customer modifications, to the unmodified portion of the equipment (explain):
18. Will the supplier rebate the warranty portion of the price (percentage):
19. Please give a list of recommended spares (attach):
20. If not available, can the supplier create this list (explain):
21. What are prices associated with recommended spares (explain):
22. What is spare parts order procedure (explain):
23. Are parts identified in a manual or other document (explain):
24. Who is the contact (name, telephone, fax, and address):
25. What is the normal lead time (days):
26. What is the emergency parts procedure (explain):
27. Is service training available (explain):
28. Is operator training available (explain):
29. Is service and operator training included as part of the equipment price (explain):

30. If not, what is the price:
31. Where is training available (options):
    Manufacturers location (where, duration):
    Buyers location (change, travel expense):
    Field location (change, travel expense):
32. What is the recommended Operator Preventative Maintenance procedure & schedule:
33. What is the recommended Service Preventative Maintenance procedure & schedule:
34. Are any special tools required to operate this product (explain):
35. Are any special tools required to service this product (explain):
36. Are any of these tools supplied as part of the product cost (explain):
37. What type of CAD/CAM capabilities do you possess:
38. What is suppliers level of willingness to meet MEDICAL DEVICE, INC. document control procedures (explain):
39. How well do they integrate with the systems of customers and suppliers:
40. What type of file transfer processes do you use:
41. What type of file conversion processes do you use:
42. Describe your drawing control system:
43. Are specifications available for the product to be processes by this equipment:
44. What are the environmental limitations to store and operate this equipment:
45. Are there special considerations in the storage or handling of this equipment:
46. Are there hazardous materials involved in the construction or use of the equipment:
47. Are MSDS sheets provided with all applicable materials:
48. How do you tie your design to manufacturing processes (explain):
49. Does supplier meet industrial design and ergonomic design capabilities (explain):

Production Equipment, Tooling and Capabilities

1. Type, condition, age, etc. (attach equipment list if available):
2. Special or unique equipment (include description/condition):
3. Is any equipment dedicated to specific jobs (explain):
4. Other capabilities (explain):
5. Typical complexity of parts currently in production (explain):
6. Geometric tolerance (true positioning) capability (explain):
7. Metric capability (explain):
8. What is the supplier's part size range:
9. Is supplier willing to make added equipment/people investment if req'd (explain)

Tooling

1. Design (who):
   - In-house responsibility (name and position):
   - Subcontract responsibility (name and position):
2. Build (who):
   - In-house responsibility (name and position):
   - Subcontract responsibility (name and position):
3. Design reviewed by:
4. Tool maintenance program (explain):
5. How are tools identified:
   - Part #:
   - Tool #:
   - Other #:
6. What are the standard tooling payment terms (explain):

Manufacturing Process Control

1. How are manufacturing processes controlled (explain):
   - Processes documented:
   - No major process changes made without customer approval:
   - Properly trained and certified operators:
   - Approved sub-contractors:
   - In-process inspections:
2. How are ECO's indicated and checked on routings and drawings (explain):
3. Who is responsible for ECO updates (explain):
   - Routings:
   - Drawings:
4. How are production changes implemented in the production process (explain):
5. Are material certification records kept on file when required (describe):
6. Do you have a way to trace & identify products moving through facility (explain):
7. How do you determine time required per unit (document accuracy):
8. How do you define and determine capacity bottlenecks (explain):

9. How do you define set up/conversion time (how monitored):
10. Describe your set up time reduction plan (measured achievement):
11. How flexible is your manufacturing concept (explain):
12. Describe your lead time reduction plan (measured achievement):
13. Describe your cost reduction process (measured achievement):

Statistical Process Control

1. What type of statistical process controls does the supplier utilize (explain):
2. Can they supply control results to use (explain):

Subcontract Process Control

1. What processes are normally sub-contracted (explain):
2. What is your sub-contractor evaluation process (explain):
3. How are your sub-contracted activities monitored and reported (explain):
4. Is your prior customer approval secured (explained):
5. Is sub-contractor prepared to certify process were certificates of compliance are req'd:
6. Does supplier inspect material and parts from the sub-contractor (explain):

Inspection, Calibration and Control of Equipment

1. Describe the supplier's periodic calibration and maintenance procedure:
2. Is the equipment checked and approved prior to use (explain):
3. Is equipment marked and can it be identified to calibration records and dates (explain):
4. What is the procedure for calibration of mechanical and electrical equipment available:
5. Is test and inspection equipment available to control all special processes (explain):
6. Is inspection equipment used by production calibrated (explain):

Quality System

1. Do you have an ISO or any other nationally or internationally recognized certification (explain, dates):
2. If applicable, when were you last assessed by a regulatory agency or notified body? What were the results of the inspection? Please attach copy of last assessment.
3. Do other customers conduct audits of your quality system? (who, when):
4. Do you have a documented quality system?
5. Do you have a Quality Manual? (Please attach)
6. Please provide organizational chart.
7. Describe the reporting organizational relationship for the quality organization.
8. Do you have established procedures that address the specific sections of the ISO 9001/9002 quality system standard?

9. Do you operate under Good Manufacturing Practices per Title 21 CFR (Code of Federal Regulations)?
10. Do you conduct management reviews of the quality systems? Please attach report from most recent management review.
11. Do you have an internal audit program? How is information from this system utilized?
12. Do you have a corrective and preventive action system? Please describe.

Document Control

1. Do you have a formal, documented process to control documents?
2. How are changes to documents controlled?
3. How are documents from customers maintained and changes controlled?
4. Are you able to receive specifications electronically?
5. Do you provide for confidential document handling?

Design Control

1. Are design control processes established for your operation?
2. Do established procedures exist governing design activities?
3. How are customer needs incorporated in design requirements?
4. How are design changes controlled?
5. Do you have processes governing design input, output, review, verification, validation and transfer? Explain.
6. Are design history files maintained?

Safety Compliance and Agency Approval

1. What approvals do you obtain (explain)?
2. What are your safety standards (attach)?
3. What agencies do you use for approval (list)?
4. What type of safety/flammability/environmental assessment is done on products?
5. Note if supplier has had any reportable environmental incidents (explain):
6. Does supplier possess adequate credentials and permits for the goods and services supplied (attach)?

Medical Device, Inc.

Request for Quotation
XXXXXXX
Due Date XX/XX/20XX
8:30 AM

XXX X, 20__

X Supplier
X
X
X
X

Medical Device invites you to submit pricing on our requirements as follows:

Project Scope:
X
X
X
X
X
X
[Attachments]

Capacity Volumes: See individual options for estimated requirements.

Option 1

Option 2

Option 3

Medical Device Supplied

(Components, parts, tooling, etc. for process)

Confidentiality

Successful suppliers will be required to sign confidentiality agreements as required by Medical Device prior to award of this contract. Information contained in this Request for Quotation, engineering drawings, formulations and any other information obtained during this process may only be utilized for the preparation of your proposal. At no time will you or any employees, agents or suppliers divulge the information contained in these documents, which Medical Device considers proprietary and confidential.

Specifications

Any and all information presented herein, including drawings, specifications, instructions, policies, engineering guides, etc., which are a part of this request, or disclosed during the selection process, are the property of Medical Device, and shall not be duplicated nor disclosed.

Supplier Profiles

Please complete the Supplier Profile attached and return it with this proposal.

Time is of the Essence

Please provide your quotation information to Medical Device by XXX X, 20__ via fax or Email by 8:30 AM.

Response to Request for Quotation

Response to this Request for Quotation commits neither Medical Device nor the respondent. Any costs incurred in preparation of this proposal are totally the responsibility of the respondent.

Suppliers not able to submit a proposal are requested to inform Medical Device, via electronic or written response, of their regrets and interest in future work in order to be considered for future solicitations for quotations. Regrets should be directed to the address above.

Alternate Submissions

To be considered, all proposals must be prepared in accordance with these specifications. However, suppliers may offer alternates they believe will result in an operational savings, cost avoidance, improvement in process, or improvement to MEDICAL DEVICE products. In submitting alternates, supplier shall list all exceptions or deviations (if any) taken to this Request for Quotation. Failure to do so may eliminate your alternate quotation. The submission of alternate quotations is requested when improvements can be substantiated and must accompany the original submission. Please keep alternate proposals separate.

Thank you in advance for your prompt attention to these matters.

Highest regards,

XX
Authorized Agent
Procurement & Sourcing

Examples
Enc: MEDICAL DEVICE Confidentiality Agreement
MEDICAL DEVICE Terms & Conditions
MEDICAL DEVICE Supplier Profile
MEDICAL DEVICE DWG #, Part #, Specification #

Medical Device, Inc. **Supplier Evaluation - Weights**

Project: Sterilizers **Example**

Cost & Delivery Evaluation			20%
Item	Description	Weight (1-5)	Weight (%)
1	System Price	5	11.1%
2	Delivery	4	8.9%
3			0.0%
4			0.0%
5			0.0%
Total		9	20.0%

Proposal Evaluation			25%
Item	Description	Weight (1-5)	Weight (%)
1	Technical Concept	5	3.1%
2	Production Rate (Capacity, CT)	5	3.1%
3	Commonality to Other Facility Equipment	4	2.5%
4	Floor Space Utilization	3	1.9%
5	Conformance to Specifications	3	1.9%
6	Ease of Maintenance	3	1.9%
7	Safety & Guarding	3	1.9%
8	Timeliness to RFQ	3	1.9%
9	Conformance to RFQ	3	1.9%
10	Fit to facility resources	3	1.9%
11	Degree of Flexibility	2	1.3%
12	Proposal Completeness	2	1.3%
13	Supplier/Proposal Professionalism	1	0.6%
14			0.0%
15			0.0%
16			0.0%
17			0.0%
18			0.0%
19			0.0%
20			0.0%
Total		40	25.0%

Cost & Delivery Evaluation **20%**

Medical Device, Inc. **Supplier Evaluation - Weights**

Past Performance Evaluation **40%**

Item	Description	Weight (1-5)	Weight (%)
1	System Functionality/Capability	5	5.0%
2	Maintenance Costs	5	5.0%
3	On-time Delivery	4	4.0%
4	Spare Parts Availability	4	4.0%
5	Training (Presentation & Material)	4	4.0%
6	Documentation	4	4.0%
7	Synergy with Team	4	4.0%
8	Service	3	3.0%
9	Drawings	3	3.0%
10	Start-up Assistance	2	2.0%
11	Amount of Outsource (Engineering)	1	1.0%
12	Amount of Outsource (Fabrication)	1	1.0%
13			0.0%
14			0.0%
15			0.0%
16			0.0%
17			0.0%
18			0.0%
19			0.0%
20			0.0%
Total		40	40.0%

Business Evaluation **15%**

Item	Description	Weight (1-5)	Weight (%)
1	Supplier Capacity (Facility/Floor Space)	5	3.1%
2	Supplier Size (Sales Volume)	4	2.5%
3	Design Engineering Resources	4	2.5%
4	Controls Engineering Resources	4	2.5%
5	Project Management	3	1.9%
6	Supplier Location (Proximity)	3	1.9%
7	Experience in Medical/Pharmaceutical	1	0.6%
8			0.0%
9			0.0%
10			0.0%
11			0.0%
12			0.0%
13			0.0%
14			0.0%
15			0.0%
16			0.0%
17			0.0%
18			0.0%
19			0.0%
20			0.0%
Total		24	15.0%

Medical Device, Inc.

Project: Sterilizers

Input Data

Example

Cost & Delivery Evaluation

Item	Description		Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	System Price		4	1	5		
2	Delivery		5	2	4		
3		0					
4		0					
5		0					
Total							

Proposal Evaluation

Item	Description		Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	Technical Concept		4.75	3.125	3.5		
2	Production Rate (Capacity, CT)		5	4	4		
3	Commonality to Other Facility Equipment		4.874	1	1.25		
4	Floor Space Utilization		5	5	5		
5	Conformance to Specifications		5	3	4		
6	Ease of Maintenance		5	3	3		
7	Safety & Guarding		4	4	4		
8	Timeliness to RFQ		4	4	4		
9	Conformance to RFQ		4	2	2		
10	Fit to facility resources		4	4	3		
11	Degree of Flexibility		4.375	2.375	4.125		
12	Proposal Completeness		4	3	3		
13	Supplier/Proposal Professionalism		5	3	4		
14		0					
15		0					
16		0					
17		0					
18		0					
19		0					
20		0					
Total							

Project: Sterilizers

Example

Past Performance Evaluation

Item	Description		Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	System Functionality/Capability		4.25	3.875	4		
2	Maintenance Costs		4.625	3	4.875		
3	On-time Delivery		5	2	4		
4	Spare Parts Availability		5	2	2		
5	Training (Presentation & Material)		4	2	2		
6	Documentation		5	2	4		
7	Synergy with Team		5	3	3.75		
8	Service		5	1	3		
9	Drawings		3	1	2		
10	Start-up Assistance		4	3	4		
11	Amount of Outsource (Engineering)		4	4	4		
12	Amount of Outsource (Fabrication)		5	5	5		
13		0					
14		0					
15		0					
16		0					
17		0					
18		0					
19		0					
20		0					
Total							

Business Evaluation

Item	Description		Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	Supplier Capacity (Facility/Floor Space)		5	3	5		
2	Supplier Size (Sales Volume)		5	2	4		
3	Design Engineering Resources		5	3	4		
4	Controls Engineering Resources		5	2	4		
5	Project Management		5	5	5		
6	Supplier Location (Proximity)		5	1	3		
7	Experience in Medical/Pharmaceutical		5	3	3		
8		0					
9		0					
10		0					
11		0					
12		0					
13		0					
14		0					
15		0					
16		0					
17		0					
18		0					
19		0					
20		0					
Total							

Medical Device, Inc. **Supplier Evaluation Score**

Project: Sterilizers **Example**

Cost & Delivery Evaluation

Item	Description	Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	System Price	8.9%	2.2%	11.1%	0.0%	0.0%
2	Delivery	8.9%	3.6%	7.1%	0.0%	0.0%
3	0	0.0%	0.0%	0.0%	0.0%	0.0%
4	0	0.0%	0.0%	0.0%	0.0%	0.0%
5	0	0.0%	0.0%	0.0%	0.0%	0.0%
Total		**17.8%**	**5.8%**	**18.2%**	**0.0%**	**0.0%**

Proposal Evaluation

Item	Description	Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	Technical Concept	3.0%	2.0%	2.2%	0.0%	0.0%
2	Production Rate (Capacity, CT)	3.1%	2.5%	2.5%	0.0%	0.0%
3	Commonality to Other Facility Equipment	2.4%	0.5%	0.6%	0.0%	0.0%
4	Floor Space Utilization	1.9%	1.9%	1.9%	0.0%	0.0%
5	Conformance to Specifications	1.9%	1.1%	1.5%	0.0%	0.0%
6	Ease of Maintenance	1.9%	1.1%	1.1%	0.0%	0.0%
7	Safety & Guarding	1.5%	1.5%	1.5%	0.0%	0.0%
8	Timeliness to RFQ	1.5%	1.5%	1.5%	0.0%	0.0%
9	Conformance to RFQ	1.5%	0.8%	0.8%	0.0%	0.0%
10	Fit to facility resources	1.5%	1.5%	1.1%	0.0%	0.0%
11	Degree of Flexibility	1.1%	0.6%	1.0%	0.0%	0.0%
12	Proposal Completeness	1.5%	1.1%	1.1%	0.0%	0.0%
13	Supplier/Proposal Professionalism	1.9%	1.1%	1.5%	0.0%	0.0%
14	0	0.0%	0.0%	0.0%	0.0%	0.0%
15	0	0.0%	0.0%	0.0%	0.0%	0.0%
16	0	0.0%	0.0%	0.0%	0.0%	0.0%
17	0	0.0%	0.0%	0.0%	0.0%	0.0%
18	0	0.0%	0.0%	0.0%	0.0%	0.0%
19	0	0.0%	0.0%	0.0%	0.0%	0.0%
20	0	0.0%	0.0%	0.0%	0.0%	0.0%
Total		**24.6%**	**17.2%**	**18.3%**	**0.0%**	**0.0%**

Past Performance Evaluation

Item	Description	Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	System Functionality/Capability	4.3%	3.9%	4.0%	0.0%	0.0%
2	Maintenance Costs	4.6%	3.0%	4.9%	0.0%	0.0%
3	On-time Delivery	4.0%	1.6%	3.2%	0.0%	0.0%
4	Spare Parts Availability	4.0%	1.6%	1.6%	0.0%	0.0%
5	Training (Presentation & Material)	3.2%	1.6%	1.6%	0.0%	0.0%
6	Documentation	4.0%	1.6%	3.2%	0.0%	0.0%
7	Synergy with Team	4.0%	2.4%	3.0%	0.0%	0.0%
8	Service	3.0%	0.6%	1.8%	0.0%	0.0%
9	Drawings	1.8%	0.6%	1.2%	0.0%	0.0%
10	Start-up Assistance	1.6%	1.2%	1.6%	0.0%	0.0%
11	Amount of Outsource (Engineering)	0.8%	0.8%	0.8%	0.0%	0.0%
12	Amount of Outsource (Fabrication)	1.0%	1.0%	1.0%	0.0%	0.0%
13	0	0.0%	0.0%	0.0%	0.0%	0.0%
14	0	0.0%	0.0%	0.0%	0.0%	0.0%
15	0	0.0%	0.0%	0.0%	0.0%	0.0%
16	0	0.0%	0.0%	0.0%	0.0%	0.0%
17	0	0.0%	0.0%	0.0%	0.0%	0.0%
18	0	0.0%	0.0%	0.0%	0.0%	0.0%
19	0	0.0%	0.0%	0.0%	0.0%	0.0%
20	0	0.0%	0.0%	0.0%	0.0%	0.0%
Total		**36.3%**	**19.9%**	**27.9%**	**0.0%**	**0.0%**

Business Evaluation

Item	Description	Getinge Castle	Kuhlmann SBM	Amsco	Supplier D	Supplier E
1	Supplier Capacity (Facility/Floor Space)	3.1%	1.9%	3.1%	0.0%	0.0%
2	Supplier Size (Sales Volume)	2.5%	1.0%	2.0%	0.0%	0.0%
3	Design Engineering Resources	2.5%	1.5%	2.0%	0.0%	0.0%
4	Controls Engineering Resources	2.5%	1.0%	2.0%	0.0%	0.0%
5	Project Management	1.9%	1.9%	1.9%	0.0%	0.0%
6	Supplier Location (Proximity)	1.9%	0.4%	1.1%	0.0%	0.0%
7	Experience in Medical/Pharmaceutical	0.6%	0.4%	0.4%	0.0%	0.0%
8	0	0.0%	0.0%	0.0%	0.0%	0.0%
9	0	0.0%	0.0%	0.0%	0.0%	0.0%
10	0	0.0%	0.0%	0.0%	0.0%	0.0%
11	0	0.0%	0.0%	0.0%	0.0%	0.0%
12	0	0.0%	0.0%	0.0%	0.0%	0.0%
13	0	0.0%	0.0%	0.0%	0.0%	0.0%
14	0	0.0%	0.0%	0.0%	0.0%	0.0%
15	0	0.0%	0.0%	0.0%	0.0%	0.0%
16	0	0.0%	0.0%	0.0%	0.0%	0.0%
17	0	0.0%	0.0%	0.0%	0.0%	0.0%
18	0	0.0%	0.0%	0.0%	0.0%	0.0%
19	0	0.0%	0.0%	0.0%	0.0%	0.0%
20	0	0.0%	0.0%	0.0%	0.0%	0.0%
Total		**15.0%**	**8.0%**	**12.5%**	**0.0%**	**0.0%**

Medical Device, Inc.

Project: Sterilizers

Supplier Evaluation - Summary

Example

Rank	Vendor	Cost & Delivery	Proposal Evaluation	Past Performance	Business Evaluation	Total Score
		20%	25%	40%	15%	100%
1	Supplier D	0%	0%	0%	0%	0%
2	Getinge Castle	18%	25%	36%	15%	94%
3	Amsco	18%	18%	28%	13%	77%
4	Kuhlmann SBM	6%	17%	20%	8%	51%
5	Supplier E	0%	0%	0%	0%	0%

STANDARD FORM PURCHASE ORDER

TERMS AND CONDITIONS

1. **Acceptance.** The terms and conditions as listed herein shall prevail unless otherwise agreed to in writing by the Buyer. Acceptance of this order is expressly limited to the terms and conditions herein. Seller's assent to all of these terms and conditions shall be conclusively presumed from any conduct by Seller which recognizes the existence of a contract, including shipment of any part of this order.

2. **Complete Agreement.** The terms and conditions of this Purchase Order are the only terms and conditions governing this order and are the final expression and shall constitute the complete and exclusive statement of the agreement between Buyer and Seller with respect to the products and/or services provided by Seller hereunder. Reference to Seller's bids and proposals, if noted on this Purchase Order, shall not affect the provisions hereof, unless specifically provided to the contrary herein and no other agreement or quotation or any acknowledgment of Seller in any way modifying any of said provisions or adding additional terms or conditions will be binding upon Buyer unless made in writing and signed by Buyer's authorized representative. This order shall be construed in accordance with the laws of the State of New York.

3. **Delivery.** TIME IS OF THE ESSENCE OF THIS CONTRACT. If delivery of items or rendering of services is not completed by the time provided for or established herein, Buyer reserves the right without liability, in addition to and without waiving any of its other rights and remedies, to terminate this order by notice effective when received by Seller, as to any or all stated items not yet shipped or services not yet rendered, and to purchase substitute items or services elsewhere and charge the Seller with any loss or damage incurred by Buyer. Seller shall not be liable for damages however, resulting from delays due to causes beyond its reasonable control, such as acts of God, fires, strikes and acts of the Government, provided such delay is not due to the fault or negligence, in whole or in part, of Seller or its vendors, contractors, suppliers or agents. Seller is responsible for providing prompt notification to Buyer of delivery delays. Any provision herein for delivery of items or the rendering of services by installments shall not be construed as making the obligations of Seller severable. Buyer reserves the right to return early deliveries or excess or short shipments at Seller's expense.

4. **New Materials.** Except as to any supplies and components which the specifications contained herein specifically provide need not be new, the Seller represents that the supplies and components to be provided are new (not used or reconditioned, and not of such age or so deteriorated as to impair their usefulness or safety).

5. **Title to Goods, Risk of Loss.** Goods shall be delivered to Buyer at its address specified in this order. Unless otherwise explicitly provided for in this order, title and risk

of loss to goods shall pass to Buyer only at the time and place of delivery at Buyer's facility.

6. **Billing, Packaging and Shipping.** All items shall be suitably packed in containers for protection in shipment and storage in accordance with requirements of common carriers and in a manner to secure lowest transportation costs. No additional charges shall be made to Buyer therefor unless otherwise stated on the face hereof. No charge shall be made for drayage or storage unless agreed upon in writing by the Buyer. Unless otherwise specified herein, Seller shall properly mark each package with Buyer's order numbers and where multiple packages comprise a single shipment, each package shall also be consecutively numbered. Purchase order number and package numbers shall be shown on packing slips, bills of lading, and invoices. Packing slips must accompany each shipment.

7. **Inspection, Rejection of Goods.** All goods furnished hereunder shall be subject to inspection, and Seller shall be given notice of any defects other than latent defects within a reasonable time after receipt of the goods and all records required to be furnished therewith. Buyer may reject or require the prompt correction, in place or otherwise, of any goods which are found not to conform in all respects to (a) Buyer's specifications, drawings, blueprints and data, (b) Seller's warranties, and each of them, whether express or implied, or (c) any other instructions or requirements contained in this Purchase Order. Buyer may, in addition to any other rights it may have, prepare for shipment and ship such goods to Seller, require Seller to remove them or direct their correction in place, and the expense of any such action, including transportation both ways, if any, shall be borne by Seller. If Seller fails promptly to remove such goods or to proceed promptly to replace or correct them, Buyer may replace or correct such goods at the expense of Seller, including any excess cost. Payment for any or all of the goods or services supplied hereunder shall not constitute acceptance by Buyer.

8. **Warranty.** Seller warrants that all goods and services to be furnished hereunder will conform to the designs, specifications, drawings, samples or other descriptions referred to in this Purchase Order, will perform as specified herein, will be manufactured in accordance with any applicable Good Manufacturing Practices, and will be merchantable, of good quality, and free from defects in material, design and workmanship (including damage due to unsatisfactory packing by Seller), and to the extent that Seller knows or has reason to know of the purpose for which the goods are intended, will be fit for such purpose. The warranties contained herein shall run to Buyer and its customers and users of Buyer's products or services, and shall survive inspection, acceptance and payment. Seller agrees to indemnify and save Buyer harmless of and from all losses, liability, damages and expenses of any nature, including reasonable attorneys' fees, which may be sustained by or claimed against Buyer arising out of defects, omissions or negligence in the manufacture of goods or furnishing of services hereunder.

9. **Prices.** Unless otherwise specified herein, prices are F.O.B. Buyer's plant, at the location indicated on the face hereof, will be invoiced as set forth herein or if not stated on this order, at the price last paid by Buyer to Seller for similar goods or services, including all customs and duties and sales, use, excise, retailer's occupation and/or

other taxes payable by reason of this transaction; and are firm, fixed prices. Charges on goods sold F.O.B. shipping point shall be prepaid and invoiced. No insurance or premium transportation charges will be allowed unless authorized by the Buyer in writing.

10. **Set-Off.** Buyer shall be entitled to set-off any amount owing at any time from Seller to Buyer against any amount payable at any time by Buyer to Seller.

11. **Intellectual Property.** Any material, including but not limited to artwork, design, sketch, audiotape, videotape, photograph, advertising copy, publicity material, packaging or other creative material, created for or at the request of Buyer in any form whatsoever (the "Material"), including but not limited to any Material incorporating Buyer's trademark(s), shall constitute work-made-for-hire under the copyright laws of the United States and shall be the sole and exclusive property of Buyer. Buyer shall be the author and copyright holder of the Material. In the event Seller retains any interest in the Material (in whole or in part) Seller irrevocably grants, assigns and transfers to Buyer free and clear of any compensation all rights with respect thereto and will execute any document necessary to convey such title to Buyer.

12. **Intellectual Property Indemnity.** Seller agrees to forever defend, indemnify and hold harmless Buyer, its successors and assigns and any of its customers and all persons claiming under Buyer from and against any and all claims, actions, loss, damage and expense of any kind, including without limitation reasonable attorneys' fees and costs, by reason of actual or alleged infringement or contributory infringement of any United States or foreign Letters Patent, copyrights, trademark or tradedress rights (collectively "Intellectual Property") arising in any way out of or connected with this Purchase Order, including without limitation by reason of the manufacture, delivery, use or sale of goods supplied under this Purchase Order, and Seller agrees to defend at its own expense any and all actions or proceedings charging infringement of said Intellectual Property that may be brought against the Buyer or any of its customers or all persons claiming under Buyer and to pay all costs and damages that may be assessed or incurred in every such action. This provision shall apply notwithstanding that any of said claims, actions or suits shall ultimately be determined to be unjustified or to have been unfounded.

13. **Compliance With Laws.** Seller warrants that all goods or services called for herein have been produced or performed in compliance with all applicable federal and state laws, rules and regulations, including without limitation, those pertaining to working conditions, payment of labor, and manufacture, branding, labeling, registration and shipment of goods. Without limiting the foregoing, Seller agrees, with respect to the goods or services to be supplied, to comply with the provisions of the Occupational Safety and Health Act (the "Act") and the standards and regulations issued thereunder, or any other federal, state or local law or regulation of the same or similar nature, and further certifies that all items furnished under this Purchase Order will conform to and comply with said Act, standards and regulations, and other applicable laws or regulations, so far as the same pertain to the use of the goods or services as intended under this order.

14. **Non-Discrimination.** Seller shall comply (unless exempt) with Executive Order 11246, as amended, and all rules and regulations issued thereunder, as amended, including, without limiting the generality of the foregoing, sending Buyer an executed certificate of non-segregated facilities, complying with the Equal Employment Opportunity Clause which is made a part hereof, completing and filing all required reports including form EEO-1 and implementing an Affirmative Action Program.

15. **Assignment.** Neither this Purchase Order nor any payment hereunder are assignable or transferable, nor shall Seller sublet or subcontract any or all of the performance of services or production of goods called for hereunder without Buyer's prior written approval.

16. **Changes.** Buyer may, at any time, by written order make changes or additions within the general scope of this Purchase Order. If any such change causes any increase or decrease in the cost of, or the time required for performance of this Purchase Order, Seller shall notify Buyer in writing and an appropriate equitable adjustment will be made in the price or time of performance, or both, by written modification of this Purchase Order. Any claim by Seller for such adjustment must be asserted within 30 days, or such other period as may be agreed upon in writing by the parties, after Seller's receipt of notice of change. Nothing herein shall excuse Seller from proceeding with the Contract as changed. Seller shall not make a material change or process change without notification to Buyer. This provision shall not in any way relieve Seller of its obligation to provide goods or services in conformance with the designs, specifications, drawings, samples or other descriptions referred to in this Purchase Order.

17. **Termination.** Buyer (in addition to any remedy for Seller's default) shall have the right to terminate this order in whole or in part, without cause, upon notice in writing to the Seller. Seller shall thereupon as directed cease work and deliver to the Buyer all completed and partially completed goods or materials and work in progress, or otherwise dispose of such goods and materials, as directed by Buyer, and the Buyer shall pay the Seller the following which shall be Buyer's exclusive liability to Seller for such termination and which in no event shall exceed the total price provided for herein.

a) The price provided in the order for all goods which have been completed prior to termination and which are accepted by Buyer.

b) The actual expenditures on the uncompleted portion of the order including reasonable cancellation charges paid by the Seller on account of commitments made under the order.

Notwithstanding the preceding sentence, if Seller ceases to conduct its operation in the normal course of business, including inability to meet its obligations as they mature, or if any proceeding under the bankruptcy or insolvency laws is brought by or against Seller, or a receiver for Seller is appointed or applied for or an assignment of substantially all the assets of Seller for the benefit of creditors is made by Seller, Buyer may terminate this order without liability, except for deliveries previously made or for goods covered by

this order then completed and subsequently delivered in accordance with the terms of this order.

18. **Confidentiality.** Any specifications, drawings, sketches, models, samples, tools, technical information, methods, processes, techniques, shop practices, formulas, compounds, compositions, research data, marketing and sales information, customer lists, plans, know-how, trade secrets, or data, written, oral or otherwise (all hereinafter designated "Information") furnished to Seller hereunder or in contemplation hereof shall remain Buyer's property. All copies of such Information in written, graphic, computer disk or other tangible form shall be immediately returned to Buyer without cost upon completion of this order. The Information shall be kept confidential by Seller, shall be used only in the filling of Buyer's order, or in performing hereunder, and may be disclosed or used for other purposes only upon such terms as may be agreed upon between Buyer and Seller in writing. No information furnished by Seller to Buyer shall be considered by Seller to be confidential or proprietary unless specifically agreed to in writing by Buyer. Further, Seller shall not release to third parties any advertising, photographs or other like information concerning this order without Buyer's written consent.

19. **Non-Waiver.** Buyer's failure at any time to require strict performance by Seller of any of the provisions herein shall not waive or diminish Buyer's right thereafter to demand strict compliance therewith or with any other provision. Waiver of any default shall not waive any other default. Buyer shall not be deemed to have waived any rights hereunder unless such waiver is in writing and signed by a duly authorized officer of Buyer.

20. **Gratuities.** It shall be deemed a default subject to possible termination if it is found that gratuities (in the form of entertainment, gifts, or otherwise) were offered or given by the Seller to any officer or employee of Medical Devices, its affiliates or subsidiaries with respect to the awarding, amending or the making of any determination with respect to the performing of this Purchase Order.

21. **Buyer's Property.** Unless otherwise provided herein, or in any other written agreement between the Buyer and Seller, all items, materials, facilities, tools, jigs, dies, fixtures, patterns or equipment furnished or paid for by the Buyer shall be Buyer's property and Seller shall bear the risk of loss thereof, and damage thereto, normal wear and tear excepted, while such property is in Seller's possession. Property covered by this provision shall be suitably protected, segregated and marked as the property of Buyer, shall not be moved from Seller's premises without written Buyer approval, and shall be immediately delivered to Buyer upon request.

22. **Liability for Injuries**. Seller shall take reasonable precautions to prevent the occurrence of any injury to person or property (including the goods and services provided hereunder) and Seller shall defend, indemnify and hold Buyer harmless against any claims, actions, losses, damages or expenses (including reasonable attorneys fees and costs) by reason of injuries to persons (including death) or damage to property arising out the activities of Seller, its agents, representatives, employees, or contractors,

except to the extent that any such injury or damages are due directly and solely to Buyer's negligence. Seller shall maintain at its sole cost and expense with insurance companies having a current A.M. Best rating of A- or better, policies meeting the following minimum insurance requirements, the compliance or non-compliance with which shall not be construed to limit or affect Seller's obligation or liability:

Insurance Requirements

A. Workers' Compensation Insurance in accordance with statutory requirements, as applicable, including Employer's Liability with limits of liability not less than $1,000,000 each accident/disease. The policy shall include a waiver of subrogation in favor of Buyer.
B. Commercial General Liability insurance including coverage for products/completed operations with annual limits of liability not less than $1,000,000 per occurrence; $1,000,000 general aggregate; and $3,000,000 products/completed operations aggregate and the policy shall include Medical Devices Incorporated and its subsidiaries as an additional insured. This insurance shall be primary and any insurance maintained by Buyer shall be considered excess over Seller's insurance.
C. Automobile Liability insurance in an amount not less than $1,000,000 per occurrence and the policy shall include Medical Devices Incorporated and its subsidiaries as an additional insured.
D. "All-risk" property insurance covering all equipment, merchandise and all other items belonging to Seller on Buyer's premises. The policy shall include a waiver of subrogation in favor of Buyer.
E. All policies shall be so written that Buyer will be notified of cancellation or restrictive amendment at least 30 days prior to the effective date of such cancellation or amendment. Certificates from the insurance carrier stating the limits of liability and expiration date shall be filed with Buyer before operations are begun. If the initial insurance expires prior to completion of the work, renewal certificates shall be furnished before the date of expiration.
F. Seller shall require each of its subcontractors to procure and maintain, until the completion of that subcontractor's work, insurance of the type and to the limits specified in paragraphs A to D inclusive above. It shall be the responsibility of the Seller to insure that all its subcontractors comply with all of the insurance requirements contained herein relating to such subcontractors.
G. Seller agrees to protect, defend, indemnify and save Buyer harmless against any and all liens and encumbrances arising out of or in connection with performance of the services and to keep Buyer's premises free from all such liens and encumbrances.
H. The treatment and care of injuries sustained by Seller's employees shall be and remain the responsibility of Seller as provided in this contract; provided however, that any of Buyer's first aid facilities will be made available to Seller's employees in emergency cases which are the direct result of accidents occurring on Buyer's premises during authorized work hours. Buyer shall incur no liability for, and Seller hereby agrees to indemnify Buyer against any causes of action, claim, liability, or cost including attorney's fees, arising in whole or in part out of the furnishing of such first aid facilities to Seller's employees or out of the failure to furnish such facilities.

TERMS & CONDITIONS

OF SALE

BETWEEN

MEDICAL DEVICE INCORPORATED

AND

CONTRACT

Medical Device Terms & Conditions of Sale

This Agreement is made by and between MEDICAL DEVICE INCORPORATED, a New York corporation with an office at <ADDRESS> ("BUYER") and xxxxxxxxx corporation with offices at XXXXXX ("SELLER").

In consideration of the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. ACCEPTANCE
   The terms and conditions as listed herein shall prevail unless otherwise agreed to in writing by the BUYER. Acceptance of purchase orders is expressly limited to the terms and conditions herein. SELLER's assent to all of these terms and conditions shall be conclusively presumed from any conduct by SELLER which recognizes the existence of a contract, including shipment of any order in whole or part of these orders.

2. SCOPE
   SELLER will provide the equipment, machine(s), items and/or services, all as described in any purchase order accepted by SELLER (the "Contract Product"), in conformance with the specifications set forth in such purchase order. BUYER shall not be required to purchase a minimum amount of Contract Product, and shall not be required to purchase Contract Product in excess of that reflected in a purchase order submitted by BUYER to SELLER.

3. PRICE
   BUYER will pay SELLER for the Contract Product as described in such purchase order(s).

4. DELIVERY
   If delivery of items or rendering of services are not completed by the mutually agreed time frame between the BUYER and SELLER, BUYER reserves the right without liability and without waiving any of its other rights and remedies (i) to terminate the order by notice effective when received by SELLER, (ii) or BUYER may deduct, from the purchase order price, two percent (2%) after fifteen (15) days delinquency from the mutually agreed upon delivery date. Further penalties will accrue at a rate of an additional one percent (1%) for each seven (7) calendar days, past the 31st day of delinquency beyond the mutually agreed upon delivery date. Ten percent (10%) shall be the maximum amount deducted from the gross contract price or purchase order due to SELLER's delinquency. If SELLER has not delivered Contract Product the BUYER is permitted to purchase substitute items or services elsewhere without further liability to SELLER. SELLER shall not be liable for damages however, resulting from delays due to causes beyond its reasonable control, such as acts of God, fires, strikes and acts of the government, provided such delay is not due to the fault or negligence, in whole or in part, of SELLER or its SELLER's, contractors, SELLER's or agents. SELLER is responsible for providing prompt notification to BUYER of delivery delays. Any provision herein for delivery of items or the rendering of services by installments shall not be construed as making the obligations of SELLER severable. BUYER reserves the right to return early deliveries or excess or short shipments at SELLER's expense. BUYER shall not penalize SELLER for any delay caused by the failure of BUYER to deliver to SELLER any services or components upon a mutually agreed schedule. Any such delay upon the part of the BUYER shall extend the required delivery on a "day for day" basis.

5. NEW MATERIALS
   Except as to any supplies and components which the specifications contained herein specifically provide need not be new, the SELLER represents that the supplies and components to be provided are new (not used or reconditioned, and not of such age or so deteriorated as to impair their usefulness or safety).

Medical Device Terms & Conditions of Sale

6. BILLING, PACKAGING AND SHIPPING
All items shall be suitably packed in containers for protection in shipment and storage. No additional charges shall be made to BUYER therefor unless otherwise stated on the face of a purchase order. SELLER shall properly mark each package with BUYER's order numbers and where multiple packages comprise a single shipment, each package shall also be consecutively numbered. Purchase order number and package numbers shall be shown on packing slips, bills of lading, and invoices. Packing slips, required export documentation, and commercial invoice must accompany each shipment.

7. INSPECTION, REJECTION OF GOODS
All goods furnished hereunder shall be subject to inspection, and SELLER shall be given notice of any defects, other than latent defects, within a reasonable time after receipt of the goods and all records required to be furnished therewith. BUYER may reject or require the prompt correction, in place or otherwise, of any goods which are found not to conform in all respects to (a) BUYER's specifications, drawings, blueprints and data, (b) SELLER's warranties, and each of them, whether express or implied, or (c) any other instructions or requirements contained within the Purchase Order as otherwise agreed to by the parties. In the event of defective or nonconforming goods, BUYER may, in addition to any other rights it may have, prepare for shipment and ship the goods to SELLER, require SELLER to remove them or direct their correction in place, and the expense of any such action, including transportation both ways, if any, shall be borne by SELLER. If SELLER fails promptly to remove such goods or to proceed promptly to replace or correct them, BUYER may replace or correct such goods at the expense of SELLER, including any excess cost. Payment for any or all of the goods or services supplied hereunder shall not constitute acceptance by BUYER.

8. WARRANTY
SELLER warrants that all goods and services to be furnished hereunder will have clear title, conform to the designs, specifications, drawings, samples or other descriptions referred to in the applicable Purchase Order(s), will perform as specified herein, will be manufactured in accordance with any applicable Good Manufacturing Practices and will be free from defects in material, design and workmanship. The warranties contained herein shall run to BUYER and shall survive inspection, acceptance and payment.

Warranty period shall commence upon successful use, operation and acceptance as specified by the BUYER. The warranty period shall include a period of three hundred sixty-five (365) days, upon referenced written acceptance. Days shall be defined as up to and including twenty-four hours of operation unless otherwise noted in any BUYER purchase order.

9. DATE RECOGNITION
SELLER warrants that the Contract Product(s)' processing capability will correctly recognize and process four-digit year-dates, including the correct recognition and processing of February 29 during leap years, and that the Contract Product(s) will continue to function properly with regard to dates before, during, and after the transition year 2000.

10. LIABILITY/INDEMNIFICATION
SELLER shall indemnify and hold BUYER harmless from any and all claims, losses, damages, liability or expenses (including reasonable attorneys fees and costs) whether incurred in a third party action or in an action to enforce this agreement, that may arise out of or be connected with (i) its' provision of Contract Product(s) under this Agreement, except to the extent caused by BUYER'S negligence or (ii) SELLER's in breach of any warranty or term of this agreement.

Medical Device Terms & Conditions of Sale

11. COMPLIANCE WITH LAWS
SELLER assumes full responsibility for compliance with all applicable laws, rules and regulations including, but not limited to, those regarding all services completed or goods supplied shall be performed and completed in compliance the following standards:

A. Electrical
OSHA Subpart-S 29 CFR 1910.300-.399
NFPA 70 & 79
NEC (latest version)
B. Machine Guarding
OSHA Subpart-O 29 CFR 1910.211 .222

12. CONFIDENTIALITY
Any specifications, drawings, sketches, models, samples, tools, technical information, methods, processes, techniques, shop practices, formulas, compounds, compositions, research data, marketing and sales information, customer lists, plans, know-how, trade secrets, or data, written, oral or otherwise (all hereinafter designated "information") furnished to SELLER hereunder or in contemplation hereof shall remain BUYER's property. All copies of such information in written, graphic or other tangible form shall be immediately returned to BUYER without cost upon completion of that order. The information shall be kept confidential by SELLER, shall be used only in the filling of BUYER's order, or in performing hereunder, and may be disclosed or used for other purposes only upon such terms as may be agreed upon between BUYER and SELLER in writing. No information furnished by SELLER to BUYER shall be considered by SELLER to be confidential or proprietary unless specifically agreed to in writing by BUYER. Further, SELLER shall not release to third parties any advertising; photographs or other like information concerning an order without BUYER's written consent.

13. INTELLECTUAL PROPERTY
SELLER agrees to forever defend, indemnify and hold harmless BUYER, its successors and assigns and any of its customers and all persons claiming under BUYER from and against any and all claims, actions, loss, damage and expense of any kind, including without limitation reasonable attorneys' fees, by reason of actual or alleged infringement or contributory infringement of any United States or foreign Letters Patent, copyrights or trademark rights arising in any way out of or connected with the Purchase Order(s), including without limitation by reason of the manufacture, delivery, use or sale of goods supplied under the Purchase Order(s), and SELLER agrees to defend at its own expense any and all actions or proceedings charging infringement of said Letters Patent, copyrights or trademark rights that may be brought against the BUYER or any of its customers or all persons claiming under BUYER and to pay all costs and damages that may be assessed or incurred in every such action. This provision shall apply notwithstanding that any of said claims, actions or suits shall ultimately be determined to be unjustified or to have been unfounded. . BUYER agrees to waive this section should any portion of the process or design be specified by the BUYER, in drawings or detailed specification as to construction or process, not the SELLER.

14. RELATIONSHIP
SELLER offers Contract Product to BUYER as an independent provider and nothing herein shall be deemed to constitute or render the parties as joint ventures, partners or employer and employee and BUYER shall have no right or obligation with respect to any employee, agent or representative of SELLER.

Medical Device Terms & Conditions of Sale

15. CHANGES IN WORK
BUYER reserves the right to make changes in the Contract Product and BUYER's internal processes which may effect the performance and/or completion of the Contract Product, as described herein. Upon receipt by SELLER of BUYER's written notification of a contemplated change, SELLER shall:

A. Provide a written estimate for the increase or decrease in cost attributable to the contemplated change.
B. Notify BUYER in writing of any estimated change in the completion date, occasioned by the change.
C. Advise BUYER in writing if the contemplated change will affect SELLER's ability to meet the completion dates or schedules of this Project.
D. BUYER agrees to reimburse SELLER for any and all parts made obsolete by changes requeste by BUYER. BUYER will also reimburse SELLER for labor costs effected by said changes.
If BUYER so instructs in writing, SELLER shall suspend work on that portion of the Contract Product affected by a contemplated change, pending BUYER's decision to proceed with said change.
If BUYER elects to make the change, BUYER shall issue a change order for said change and SELLER shall not commence work until such written change order has been issued. If SELLER commences work without a written change order, submitted by the BUYER's Purchasing Department, SELLER does so at their own risk of non-payment.
SELLER shall not make any changes to the Contract Product without prior written approval of BUYER.

16. TERMINATION
BUYER (in addition to any remedy for SELLER's default) shall have the right to terminate an order in whole or in part, without cause, upon thirty (30) days written notice to the SELLER. SELLER shall thereupon as directed cease work and deliver to the BUYER free and clear of any lien, claim or encumbrance all completed and partially completed goods or materials and work in progress, or otherwise dispose of such goods and materials, as directed by BUYER, and the BUYER shall pay the SELLER the following which shall be BUYER's exclusive liability to SELLER for such termination and which in no event shall exceed the total price provided for herein.

A. The price provided in the applicable order for all Contract Product which have been completed prior to termination and which are accepted by BUYER.

B. The actual expenditures on the uncompleted portion of the applicable order including reasonable cancellation charges paid by the SELLER on account of commitments made under the order.

Notwithstanding the preceding sentence, if SELLER ceases to conduct its operation in the normal course of business, including inability to meet its obligations as they mature, or if any proceeding under the bankruptcy or insolvency laws is brought by or against SELLER, or a receiver for SELLER is appointed or applied for or an assignment of substantially all the assets of SELLER for the benefit of creditors is made by SELLER, BUYER may immediately terminate an order without liability, except for deliveries previously made or for goods covered by the corresponding order then completed and subsequently delivered in accordance with the terms of that order.

17. GRATUITIES
It shall be deemed a default subject to possible termination if it is found that gratuities (in the form of entertainment, gifts, or otherwise) were offered or given by the SELLER to any officer or employee of Medical Device with respect to the awarding, amending or the making of any determination with

respect to the performing of the Purchase Order(s).

18. BUYER'S PROPERTY
Unless otherwise provided herein, or any other written agreement between the BUYER and SELLER, all items, materials, facilities, tools, jigs, dies, fixtures, patterns or equipment furnished or paid for by the BUYER shall be BUYER's property and SELLER shall bear the risk of loss thereof, and damage thereto, normal wear and tear excepted while such property is in SELLER's possession. Property covered by this provision shall be suitably protected, segregated and marked as the property of BUYER, shall not be moved from SELLER's premises without written BUYER approval, and shall be immediately delivered to BUYER upon request.

19. NOTICES
All notices hereunder must be in writing. These notices shall be deemed duly given upon delivery if delivered by hand (against receipt) or three (3) days after posting, if sent registered mail at the address given on the signatory page, return receipt requested to:

In the case of notices given by BUYER: In the case of notices given by:

Or to whomever else the parties may designate by notice pursuant to this Section. Notices hereunder may be sent by FAX to the following numbers:
BUYER: (Area Code)_____ _____

20. PROJECT MANAGEMENT
SELLER shall supply BUYER with a periodic production status report in a form acceptable to BUYER for each period starting with the acceptance of this contract through and including the *in service* date of the final items under the purchase order. Each status report shall be sent by the SELLER to agreed BUYER representative(s).

21. MANUALS
Maintenance and installation manuals are to be supplied, in English and any site required language as specified by BUYER, at time of delivery of Contract Product, one (1) manual per Contract Product purchased will be supplied by SELLER. SELLER shall deliver one (1) set of "as built" drawings for each Contract Product delivered. This drawing package shall be delivered to a specified BUYER representative within two (2) weeks of delivery of each Contract Product. Drawing package shall be provided on appropriate substrate (paper, blueprint, etc.) as well as on computer disk in a computer program approved by BUYER (AutoCAD).

22. SPARE PARTS
A spare parts listing including part specifications and drawings shall be supplied to BUYER purchasing within thirty (30) days of receipt of the items listed in the order(s). Part specifications and drawings shall be provided on appropriate substrate (paper, blueprint, etc.) as well as on computer disk in a computer program approved by BUYER. Said parts list shall include approved SELLER's/ manufacturers for each part. A complete price list shall be provided.

23. RIGHTS TO TECHNOLOGY
A. Definitions:

"SELLER Background Technology" shall mean all technology, technical information, software, inventions, patent applications and patents which SELLER owns or has legal right to license and which

were (1) made or discovered prior to the Effective Date of this Agreement, or (2) made or discovered independently of the project but after the Effective Date of this Agreement.

"Project Technology" shall mean all technology, technical information, software, inventions, patent applications, and patents, which relate to the Scope of Work and were made by or on behalf of SELLER during the performance of this Agreement. Project Technology shall not include SELLER Background Technology.

B. All rights, title and interest (including ownership of copyright and patent rights) to Project Technology shall belong to and be the property of BUYER, and SELLER hereby assigns any and all of its rights in Project Technology to BUYER. SELLER agrees to make any assignments and execute documents (at BUYER's expense) as necessary to effect BUYER's title hereto in all countries of the world.

C. All documents and materials (including reports, data, drawings, plans, prints, articles, information, records, etc.) prepared by SELLER in performance of its duties hereunder shall be deemed "work made for use" hereunder U.S. Copyright laws, shall belong to and be the exclusive property of BUYER and shall outlive this Agreement. SELLER hereby assigns to BUYER, all copyrights that SELLER has to such documents and materials.

D. SELLER grants to BUYER and its subsidiaries a non-exclusive, perpetual, irrevocable, worldwide, paid-up license to use SELLER's Background Technology as reasonably necessary to utilize those Project Technology(s).

21. INSTALLATION
Unless otherwise agreed, upon receipt of equipment at BUYER facility, SELLER will send a qualified representative to install said equipment and insure equipment performs to design specifications. SELLER will also provide this start-up assistance at rates as agreed between BUYER and SELLER. SELLER will remain on-site at BUYER until problem(s) have been resolved and Contract Product is functioning to the stated claims and specifications of the Contract Product. In the event that SELLER's engineers must leave due to pre-arranged circumstances, circumstances agreed to by both parties, family illness, death and etc., a fully competent replacement must be expeditiously dispatched. SELLER's engineer is expected to travel with whatever tools are deemed necessary by the engineer to ensure equipment acceptance.

22. IN SERVICE
The equipment is to be considered "in service" and the warranty period effective upon final written acceptance by BUYER that equipment meets the stated claims, specifications and is operating to the satisfaction of BUYER.

23. NO ASSIGNMENT & SUBCONTRACTING
Contract Product(s) is to be provided by SELLER and cannot be delegated without the prior written consent of BUYER. However, BUYER shall permit subcontracting of reasonable outside services and specialty operations without written consent when, no such individual service shall exceed ten (10%) percent of the total price for the Contract Product(s). Not with standing any permitted subcontracting, SELLER shall remain fully responsible for Contract Product.
SELLER shall provide confidentiality statements from its subcontractors substantially in the form set forth in Section 13 of this document provided by BUYER by SELLER.

24. INSURANCE
During the term of this agreement SELLER shall, at its sole cost and expense, procure and maintain:

a. Commercial General Liability insurance including coverage for products/completed operations with annual limits of liability in an amount not less than $1,000,000 per occurrence; $1,000,000 general aggregate; and $3,000,000 products/completed operations aggregate, or their equivalent in non-US locations. This insurance shall also name Medical Device Incorporated and its subsidiaries as an additional insured. This insurance shall be primary and any insurance maintained by BUYER shall be considered excess over SELLER's insurance.
b. Workers' Compensation insurance in accordance with statutory requirements including Employer's Liability with limits in an amount not less than $1,000,000 each accident/disease, or its equivalent in non-US locations. The policy shall include a waiver of subrogation in favor of BUYER.
c. Automobile insurance in an amount not less than $1,000,000 per occurrence, or its equivalent in non-US locations which shall include Medical Device Incorporated and its subsidiaries as an additional insured.
d. Property insurance covering all equipment, merchandise and all other items belonging to SELLER while situate on BUYER's premises. Such insurance shall be written on an "all risk" of physical loss or damage basis, for the full replacement cost value and in amounts that meet any coinsurance provisions of the policy. Both BUYER and SELLER hereby agree to have their respective property insurance companies waive any rights of subrogation that such companies may have against the other, as the case may be. As long as such waivers of subrogation are contained in their respective insurance policies, BUYER and SELLER hereby waive any right that either may have against the other on account of any loss or damage to their respective property to the extent such loss or damage is insurable under policies of insurance for fire and all risk coverage, theft, or other similar instance.

All insurance policies required hereunder shall be endorsed to provide BUYER with no less than 30 days prior written notice in the event of cancellation, non-renewal or material changes. The insurance company(s) providing these policies shall have a current A.M. Best rating of A- or better, and shall be licensed to do business in the applicable jurisdiction. A certificate of insurance evidencing such insurance coverage will be provided to BUYER upon execution of this agreement and no less than 14 days prior to renewal of said insurance policies. The certificate of insurance shall indicate that the above 30 day notice provision applies. If either party elects to self-insure, its rights and obligations under subrogation shall be limited by the terms of this provision as if actual insurance policies had been purchased from an unaffiliated insurance company.

General:

25. SEVERABILITY
In the event that any section or part of this Agreement shall be found to be void or unenforceable, such section or part shall be deemed to be superfluous and the remainder of the Agreement shall remain in full force and effect.

26. YEAR 2000 WARRANTY
Supplier warrants that the machine(s)' processing capability will correctly recognize and process four-digit year-dates, including the correct recognition and processing of February 29 during leap years, and that the machine(s) will continue to function properly with regard to dates before, during, and after the transition year 2000.

27. CHOICE OF LAW
This Agreement shall be governed by the laws of New York without regard to its provisions regarding conflicts of laws.

Medical Device Terms & Conditions of Sale

28. NON-WAIVER
No rights of either party arising under this Agreement or any provision hereof shall be waived except in writing. A waiver by any party of any of its rights hereunder or any breach of this Agreement shall not be construed as a waiver of its future rights or any other right or any other breach.

29. ENTIRE AGREEMENT, MODIFICATION
This Agreement, together with any and all purchase orders submitted by BUYER and accepted by SELLER authorized hereto, constitutes the entire agreement between the parties, superseding any prior agreement, whether written or verbal. The terms of this Agreement may be modified only by mutual written agreement. To the extent that any term, condition or requirement listed on the reverse side of the BUYERS purchase order presented to SELLER conflicts with the terms and conditions of this Agreement, the terms and conditions of this Agreement shall control.

(remainder of page intentionally left blank)

Medical Device Terms & Conditions of Sale

Authorized Medical Device Signatory:

_____

(Signature)

Authorized SELLER'S Signatory:

_____

(Signature)

(remainder of page intentionally left blank)

Descriptive Title

USER REQUIREMENTS SPECIFICATION (URS)

REV. *X.X*

(Here is where you can put comments on drafts. I.E. highlight all changed items from the previous revisions when circulating for comment. Use Italic & font colors to do this. Then you change all fonts back when publishing the new revision for sign-off.)

The Maroon & Italic items are instructions that need to be deleted when using this template to create a URS for publication. Template = URS REV 3

Green & Underlined items are examples

Open Items in Red

Document Owner:
Name
Address questions to:
Name (xxx)-xxx-xxxx
Owner's tile
XXXXXXXXXX, XXX

URS first created on: *Date*
Approved on _____*Date*_____
Copy Printed: 08/07/01at 7:36 PM

Document Abstract

This document provides the functional specification for the ***DESCRIPTIVE TITLE*** Equipment. This system *(main purpose> i.e. produces, extracts, edges, cartons...etc.*
_____.

Security Notice

This document contains information of a proprietary nature and is classified XXXXXXXXXX, XXX Proprietary and Confidential. It is not to be shared with any other XXXXXXXXXX, XXX or Supplier's employees other than those working on the ***DESCRIPTIVE TITLE*** project with a predetermined need to know.

Version Notice

This is revision *X.X* it was printed from an on-line system and must only be used for reference purposes. You can retrieve a copy of the current version by contacting the author.

Please preserve the integrity of the User Requirement Specification by destroying any obsolete versions and not removing any pages from this printed copy. A comment form is provided at the end of the document for your suggestions on the process document content and format.

Document Control Section

The Table of Contents, END-OF-DOCUMENT entry indicates the last page of this document.

Document revisions will be summarized in the table below in chronological sequence. A section follows that lists the details of change since the document was first released.

Change Date	By Whom	Change Description
Date	*Name*	Creation of first draft, Rev *X.X*

Table 1. URS Change Summary

Document Change Approvers

The following must review and approve any changes.

Function	Name	Signature / Date
XXXXXXXXX, XXX	*Xxxxx Xxxxxx*	
XXXXXXXXXX, XXX	*Xxxxx Xxxxxx*	
XXXXXXXXXX, XXX	*Xxxxx Xxxxxx*	
XXXXXXXXXX, XXX	*Xxxxx Xxxxxx*	
XXXXXXXXXX, XXX	*Xxxxx Xxxxxx*	
Supplier's Name	*Xxxxx Xxxxxx*	
Supplier's Name	*Xxxxx Xxxxxx*	
Supplier's Name	*Xxxxx Xxxxxx*	
Supplier's Name	*Xxxxx Xxxxxx*	

Table 2. Approvers of Change to the URS

Document Approvals

Document Approvals are acquired and maintained by the document owner.

Complete System Functional Specification Document Set

The ***DESCRIPTIVE TITLE*** System is described completely by the set of User Requirements Specification documents below: *(this is to be used when this specification is describing a system's requirements which is made up of several pieces of equipment; if not N/A this section)*

1. *URS #1*
2. *URS #2*
3. *URS XXXXX (this document)*

Preface

The Table of Contents, END-OF-DOCUMENT entry indicates the last page of this document.

Purpose

The purpose of this User Requirements Specification is to document the desired capability of equipment necessary to perform *Descriptive Title* process.

Audience

The intended audience for this document is those XXXXXXXXXX, XXX and *Supplier's Name (may have multiple suppliers)* employees involved with the *Descriptive Title* process.

Format

This document is organized in an ISO compatible format using Microsoft Word *X.X.* It contains a title page, front matter, a preface section, the body of the document and appendices.

Contact

If you have any comments on this document, or suggestions for process improvements, please send them to *Owner's Name* at XXXXXXXXXX, XXX. A comment form is provided at the end of the document.

Contents

Contents continued

Tables

1.0 Descriptive Content

1.1 Purpose

Describe the overall objectives for building this equipment/system.

1.2 Applicability

Describe the product(s) that will be processed by this equipment/system.

1.3 References

In each subsection below there will be specs that always apply. Also you will need to add pertinent specs for each specific project This may be an all encompassing list that is in each URS Doc for a given project.

1.3.1 Embedded References

The following document files are electronically embedded in this document

a) XXXXXXXXXX, XXX Documents: ***(Always embed the latest revision available!!!!)***

- "Programming Standards InTrack V3.1 / InTouch V6.0" – D120IT60.DOC
- "Standards Checklist - InTrack V3.1 / InTouch V6.0" – D120IT-1.DOC
- "Programming Standards Visual Basic V5.0" – D120VB-R.DOC
- "Equipment Safety & Environmental Review Program (Red Tag)" – TDSNE009.DOC
- "Cumulative Trauma Disorder Reduction Program" – TDSNE026.DOC
- "Documentation Requirements for XXXXXXXXXX, XXX System Builds" – DOCPKG02.DOC
- "Preferred Components" – PRECOMP1.DOC

b) Industry Standards:

- "NIOSH Lifting Equation Worksheet" – NIOSHLT1.XLS for British Standard units & NIOSHLT2.XLS for metric units.

NOTE: If cases where XXXXXXXXXX, XXX's standards are more stringent than industry standards, XXXXXXXXXX, XXX's standards are to supercede.

1.3.2 Supplied References

Hard copies of the following documents are supplied with this Functional Requirement.

- "Process Failure Mode & Effect Analysis – VC-PRO-1402" – PRO1402.doc
- "F.M.E.A. worksheet" – FM14-06.xls
- "Ergonomics Policy" – VCPOLX1.DOC
- Applications Manual for the Revised NIOSH Lifting Equation

If these documents are not provided please contact the author.

1.3.3 Internet References

- NFPA 70 & 79 (latest version) – Contact the NFPA to obtain the latest version copy.
  Web address: http://www.nfpa.org/
  Inside the US: 800-344-3555
  Outside the US: (508)-895-8300
- OSHA Subpart-S 29 CFR 1910.300 - .399: http://www.osha.gov/comp-links.html
- OSHA Subpart-0 29 CFR 1910.211 .222: http://www.osha.gov/comp-links.html
- Medical Devices current Good Manufacturing Practices:
  http://www.access.gpo.gov/nara/cfr/waisidx/21cfr820.html

Building Codes

- NYCRR Title 9 Uniform Building Codes:
  http://www.westgroup.com/htbin/westgroup/westgroup.exe?FNC=NonItemDescriptionPage__Aresult_htm___23450___1722

CE Marking

- Official Journal of the European Communities
  europa.eu.int
- New Approach standardization in the European internal market
  www.newapproach.org

2.0 Overview

This section gives an overview of ***DESCRIPTIVE TITLE*** Project and what is required of it.

2.1 Background

A general description of the history and basis of this build project. Intent here is to give a flavor of what is transpiring not detail.

2.2 Key Objectives and Benefits

A brief description hitting major items is required here.

2.3 Comparison with Existing Equipment

A brief comparison with any existing equipment builds that will bring possible insight to this project.

2.4 Scope of Supply

The supplier shall supply the equipment to meet the requirements specified within this document except where noted.

2.5 Open Issues

A complete listing of all open issues and plans for closure. Appendix X will be used to track closure of open items with any existing equipment builds that will bring possible insight to this project.

The above items shall be confirmed through risk reduction programs, process capability testing before the process is transferred to manufacturing, and reconfirmed during validation testing on XXXXXXXXXX, XXX's manufacturing floor.

See appendix D for open item tracking information.

3.0 Operational Content

3.1 System Operation Overview

Give the supplier a vision of the desired system's operational characteristics. Be careful not to describe a solution; that's the supplier's job.

3.2 Entry

Describe the start point and handoff/interface. Be sure to define the responsibility for that handoff and the performance metrics associated with this starting point. All mechanical, electrical and Shop Floor Information System (SFIS) interface should be included.

3.3 Includes

Step by step descriptions of each required area. Make sure to define specific key parameters for each step as required. (I.e. operating ranges and run tolerances)

3.3.1 *Step Description*

3.3.2 *Step Description*

3.3.3 *Step Description*

3.4 Exit

Describe the end point and handoff/interface. Be sure to define the responsibility for that handoff and the performance metrics associated with this end point. All mechanical, electrical and Shop Floor Information System (SFIS) interface should be included.

3.5 Excludes

Describe items that are not contained in this specification but are part of the project. This makes the supplier aware of the other equipment/systems that this build is associated with but not in the scope.

This Functional Requirement excludes:

3.6 Performance Parameters

Describe the items that are measurable and the criteria to be met. You can point to or embed a separate document where these parameters are spelled out or describe them as in the example that follows.

A number of operational parameters are critical to project success. All desired operational parameters will be confirmed through a pre-delivery qualification (PDQ) before the equipment is shipped from the supplier's floor to XXXXXXXXXX, XXX. The PDQ document and acceptance criteria will be developed before the completion of the equipment (see section 5.0 Acceptance Criteria for a draft outline of the PDQ). The equipment will be re-qualified and validated as a system at XXXXXXXXXX, XXX.

3.6.1 Availability

The target availability for the equipment is at least 95%, measure over an 8-hour shift period. This means that the equipment shall be available for automated running for at least 7.6 hours per 8-hour shift.
The total time the equipment is unavailable for automated running because of scheduled servicing, cleaning, and other planned support functions shall not be greater than 0.4-hours per 8-hour shift.

3.6.2 Reliability & Uptime

Process Performance Index (PPI)
The Process Performance Index (PPI) expresses the overall performance of equipment.

⇨ **PPI = %Uptime x %Utilization x %Efficiency x %Yield**

Where:

⇨ $\%\text{Uptime} = \frac{\text{Available Hours - Downtime}}{\text{Available Hours}}$

- Available hours is defined in section 3.6.1
- Downtime from technical problems (mechanical, electrical or process problems).

⇨ $\%\text{Utilization} = \frac{\text{Uptime Hours – (Stoppages)}}{\text{Uptime Hours}}$

- Uptime Hours = Available Hours – Downtime
- Stoppages from operational reasons (set-up, excess WIP, breaks, raw mat'ls, meetings etc)

⇨ $\%\text{Efficiency} = \frac{\text{Total Quantity Produced}}{\text{Theoretical Output x (Available Hours - Downtime - Stoppages)}}$

⇨ $\%\text{Yield} = \frac{\text{Quantity of Good Parts Produced}}{\text{Total Quantity Produced}}$

3.6.3 PPI Targets

The target PPI levels for this equipment are as follows:

- %Uptime = 95%
- %Utilization = 95%
- %Efficiency = 85%
- %Yield = 95%

Using the PPI formula from section 3.5.2 gives
PPI = 0.95 x 0.95 x 0.85 x 0.95 = **0.73**

4.0 General Requirements

In general, the equipment will be in compliance with FDA, USDA & cGMPs.

4.1 Equipment Functions

4.1.1 Modes of Operation

Describe in general terms the desired levels of automation and operation. This is a high level overview! Try to give the flavor; is it pneumatics or servos, palm buttons or autofeeding?

This process requires a mixture of automated and operator tasks.

The normal mode of operation for automated equipment shall be continuous, automated running with minimal human intervention.

Other modes of automated operation shall be provided for the following purposes:

- Start-up
- Pause and resume
- Error prompting and reconciliation.
- Intervention for emergency stop, problem solving, etc.
- Stop, shut-down and equipment clearance.

4.1.2 Failure

The supplier shall conduct an FMEA (Failure Modes and Effect Analysis) on their supplied system, produce an FMEA document and hold a review with the customer. The supplier's analysis will encompass both Equipment Design Failures and Safety Failures. XXXXXXXXXX, XXX's project engineer(s) will analyze the areas of Process and Lot Integrity.

The supplier will use XXXXXXXXXX, XXX's "Process Failure Mode & Effect Analysis, #VC-PRO-1402" procedure for conducting the FMEA (see attached document "PRO1402.doc" and the corresponding worksheet "FM14-06.xls"). *Note: This document, although originally created for process evaluations, can be applied to design & safety evaluations as well.*

The latest revision level of these documents should be attached. These can be obtained through XXXXXXXXXX, XXX Document Control (GDMS).

Describe in general terms the desired levels of failure/error detection and expected actions.

- In the event of any failure, the equipment shall behave in a predictable and safe manner.
- Whenever possible, the equipment shall automatically record and display the reason for failure and/or stoppage.
- If the main electricity supply fails (or partially fails), the equipment shall shut down in a "fail-safe" manner. When the supply becomes available again, the equipment shall not resume operation until the operator is present and has checked all the necessary parameters.
- If other supplies (listed in section 4.7) fail, or are outside usable limits, the equipment shall detect the failure, take appropriate action or limit the operation of the equipment, and provide the necessary alarm signals and diagnostic messages.
- Whenever possible, the equipment shall not completely shut down but be capable of resuming operation in as short a time as possible.

4.1.3 Alerting the User to Problems

Describe in general terms the desired levels of error notification and display.

The equipment shall have means of alerting the user to problems encountered during automatic or manual running.

A three-color beacon shall be used to indicate the machine status (red – alarm, yellow – warning, green – OK).

A text display local to the machine shall give indication of the nature of the problem.

4.1.4 Security

Describe what restrictions/privileges are required for program and parameter access.

The equipment shall be configured such that only authorized users can give instructions and data to the equipment or change the program or parameters within it.

4.2 Electrical Controls

This section describes the process equipment's electrical control requirements.

4.2.1 Data I/O

Describe all input and output requirements desired.

Data Input

The equipment may be required to read data in all of the following forms:

- Data from the user via a keypad or other manual input device
- Data from external units (digital/analog)
- Data from external databases

- start processing lot instruction
- pause instruction
- shutdown instruction
- resume instruction

Data Output

The equipment shall have means of outputting data of the following types:

- Data and error messages warning of deteriorating behavior or explaining a stoppage

The equipment may be required to output data using the following means:

- Displaying information to the user on local indicators
- Displaying information to the user on a screen / text display
- Sending data by direct electrical connection to external units
- Sending data to external databases for Device History Record (DHR) and historical purposes.

Output data includes, but is not limited to:

- processing time
- alarm signals (i.e. jam, stoppage etc)
- warning signals (i.e. services status, materials status etc)

4.2.2 Build Standards

List here any additional standards that may apply to the project over and above the usual standards.

See "Compliance with Laws" in the XXXXXXXXXX, XXX Terms & Conditions Document.

4.2.3 Interfaces

Describe all interfaces/interactions with the equipment/system.

The proposed manufacturing equipment has four types of interfaces:

- interface with operator
- interfaces with other process stages
- interfaces with other process stages within the stage
- Interfaces with other supporting structures

4.2.3.1 Interface with Operator

The equipment shall have an interface for a human user. It shall be able to give different levels of access to different categories of users. For example, the different levels might be for the following activities:

- routine operation (operator)
- intervention for problem solving (operator, engineering)
- scheduled or unscheduled servicing (maintenance, engineering)
- changes or upgrading (set-up, engineering)

4.2.3.2 Interfaces with other process stages

4.2.3.3 Interfaces with stations within the stage

4.2.3.4 Interfaces with lens supporting structures

4.2.4 Software

The PLC shall be

The Operator/Machine Interface shall be Wonderware InTrack V3.1/InTouch V6.0 with optional Microsoft Visual Basic V5.0 applications if desired. See embedded documents below for InTrack V3.1 / InTouch V6.0 and Visual Basic programming standards.

InTrack V3.1/InTouch V6.0 Standards

d120it60.doc

InTrack V3.1/InTouch V6.0 Standards Checklist

D120IT-1.DOC

Visual Basic V5.0 Standards

D120VB-R.DOC

See section 4.11 for more details.

4.3 Mechanical Specifications

4.3.1 General Build Standards

- The equipment must be finished to a high standard using food grade materials for product contact components.
- Parts should be manufactured of anodised aluminium, brushed stainless steel or white Delrin where cleaning is likely to be required.
- Where applicable, parts must resist attack from monomer and IPA.
- Parts must be compatible with the process environment.

- Frames may be fabricated. Mild steel should be painted with Rittal Beige #RAL 7032 – 60 degree or using Sherwin-Williams: # F 63 PXA 00 w/Catalyst # W/V66V44 & Reducer # 84.
- The machine frame will be equipped with easily adjustable levelling feet.
- Stainless steel fasteners should be used on all parts. Hexagon head screws should be used in all areas requiring cleaning.
- A "best effort" should be made to standardise fasteners for size in order to reduce the tools required to maintain the equipment.
- Specific materials shall be approved by XXXXXXXXXX, XXX (particulate shall not be generated between materials).
- All parts shall be specified in metric units. Metric fasteners, hardware and components shall be used if at all possible. Exceptions must be agreed to in writing.

4.3.2 Lubrication

XXXXXXXXXX, XXX prefers that the amount of components requiring lubrication be kept to a minimum. If the equipment must require lubrication XXXXXXXXXX, XXX personnel must approve all proposals. For a proposal to be entertained the following requirements must be met:

- All proposed lubricants shall meet FDA & USDA requirements for food manufacturing environments.
- All equipment shall have a lubricating system for all sliding & rotating components requiring lubrication. The system shall distribute the appropriate amount of lubricant in the required areas and shall be automatic.
- Where lubrication failure could cause immediate damage to the equipment, automatic safety devices shall be incorporated to which will prevent such damage.
- Lubrication reservoirs shall be equipped with visual level indicators and all filler caps and other lubrication points shall be identified as to the type of lubricant used.
- Lubrication reservoir capacity shall be sufficient for a minimum of 120 hours of continuous equipment run time.
- Any equipment with PLC or PC control shall electronically monitor the reservoir levels, grease points via distribution blocks, line pressure in lubrication systems, etc. This will be done such that any malfunction of the lubrication system can be detected and its location definitively indicated to the operator.

4.4 Environmental

The requirements for the environment in which the process equipment shall work are defined below.

4.4.1 System Wide Requirements

The system wide requirements are as follows.

4.4.1.1 Operation to Full Specification

The equipment shall be capable of operating to its full specification in the following conditions:

- Ambient temperature range: 15 to 30^{0}C
- Ambient humidity range: 5 to 80% relative humidity (non-condensing)
- The noise level must be less than 80dB at any location 1.0m from the machine and 1.5m above the floor.

4.4.1.2 Physical Conditions to Control

- Particulate contamination of the product and environment
- Static electricity on the product or any material handling interfaces which could attract particulate

Particulate generating materials, handling or processes shall not be used. The machine shall not generate contaminate that will violate a Class 100k environment.

4.4.1.3 Layout

The physical layout of the shop floor will have an impact on operator ergonomics (see section 4.5 – Safety), process flow, service runs, etc.

When installed and ready to run, the equipment shall preferably occupy a space, which is not greater than *XX long and XX wide.*

Restrictions on the vertical dimensions of the equipment when installed are as follows:

- A maximum overall height of 2m.
- A ground clearance of at least 0.20m shall be provided underneath the equipment
- The equipment shall not require continuous manual work:

  above a height of 1.25m relative to the floor level

  below a height of 0.60m relative to the floor level

4.4.1.4 Storage & Transportation

The equipment shall be capable of being moved through six-foot wide hallways and five-foot wide double doors.

Appropriate care shall be given in the packing of equipment to prevent damage during storage or transit.

- Surfactants shall be used to prevent damage from moisture.
- All components that have the possibility of moving shall be secured. High inertia components shall be locked down.
- Consultation with the XXXXXXXXXX, XXX project engineer and procurement agent is required before storage or transport.

The equipment shall be capable of tolerating the following conditions without damage during storage or transit:

- Ambient temperature range: minus 15 to plus 45^{0}C
- Ambient humidity range: 10 to 90% relative humidity (non-condensing)

4.4.2 Chemicals

The process equipment shall be capable of handling and processing the following materials without inducing any degradation in the system process and/or components:

4.5 Safety

The supplier shall conduct a safety review on the supplied equipment, to an agreed document, and hold a review with the customer.
The equipment shall comply with all safety regulations that are legally enforceable at the place of use and on the date of installation.
The machine shall be installed in XXXXXXXXXX, XXX XXXXX.

The safety guarding on the equipment shall be user-friendly for:

- routine operation of the equipment
- manual intervention for cleaning and maintaining
- manual intervention for clearing faults

In general the guarding must follow the guidelines in the "Compliance with Laws" section in the XXXXXXXXXX, XXX Terms & Conditions Document.

The equipment must dissipate self induced electrostatic charges providing protection to personnel, product and equipment.

The process equipment shall comply with XXXXXXXXXX, XXX's "Equipment Safety & Environmental Review Program (Red Tag)" guidelines # TD-SNE-PRO-009. See embedded document TDSNE009.doc below.


TDSNE009.doc

The process equipment shall comply with XXXXXXXXXX, XXX's "Cumulative Trauma Disorder Reduction Program" #TD-SNE-PRO-026. See embedded document TDSNE026.doc below.


TDSNE026.DOC

The process equipment shall comply with XXXXXXXXXX, XXX Vision Care's "Ergonomics Policy" #VC-POL-2202. See attached document VCPOLX1.doc.
The latest revision level of this document should be attached. This can be obtained through XXXXXXXXXX, XXX Document Control (GDMS).

Any operator tasks that involve lifting shall be evaluated using the NIOSH lifting equation (see "Applications Manual for the Revised NIOSH Lifting Equation"). When

evaluating lifting tasks use the spreadsheets provided below - NIOSHLT1.XLS for British Standard units or NIOSHLT2.XLS for metric units.


NIOSHLT1.XLS


nioshlt2.xls

List here any additional standards that may apply to the project over and above the previously mentioned standards.

See section 4.1.2 – Failure – for additional safety items.

4.6 Quality

Describe all standards and product performance criteria needed to be met.

4.6.1 System Outputs

4.6.1.1 Lens Specifications

4.6.1.2 Clinical Performance

TO BE DETERMINED

4.6.1.3 Physical Testing

4.6.2 Product & Lot Integrity

Specify desired technologies, configurations, inputs and, outputs required to maintain integrity.

N/A

These systems will be evaluated in a FMEA as described in section 4.1.2 in this document.

4.7 Facility Requirements

Specify location of the facility that the system will reside in and specify the utilities supplied.

The process equipment will be installed in XXXXXXXXXX, XXX's XXX.

The utilities supplied at this facility are:

- Electrical small loads – 120 volt, 60 Hz, single phase
- Electrical large load – 480 volt, 60 Hz, 3 phase, 3 conductor
- Compressed air – XX psi gage pressure dew-point of X^0C
- Chilled water – X^0C
- Steam – XX psi gage

Equipment Reconfiguration for other Global Locations

Provisions shall be made by the supplier for conversion of the equipment to U.K. electrical supplies (i.e., 230 volts & 50 Hz). The supplier is expected to provide both electrical and mechanical designs for this option so that it may be easily retrofitted to the machine at any time.

4.8 Metrology

Key Parameters must be monitored and controlled by devices that need to be calibrated. This must be done prior to any PDQ or acceptance run. In this section you can specify the responsibility of the supplier and XXXXXXXXXX, XXX as it relates to Key Pparameters.

- Gauges used for measuring and/or controlling key parameters are critical gauges. These critical gauges will have current calibration stickers attached throughout the development period. Repeatability and Reproducibility (R&R) studies will be performed on all critical gauges prior to machine qualifications.
- Each gage must have a completed calibration worksheet (included as an attachment to the calibration procedure) prior to the acceptance testing. Calibration procedures must be written and approved prior to execution. Training of XXXXXXXXXX, XXX personnel for the calibration procedures will be included as part of the installation qualification.

4.9 Maintenance

The equipment shall be designed and constructed for ease of maintenance & calibration. The equipment shall provide means whereby a person performing servicing or repair can enter details of the situation and relevant measurements into maintenance log in the machine.

4.9.1 Access

All parts, which the user needs to service or adjust (for operation or for maintenance), shall be easily seen and easily reachable without injury or 'repetitive strain': See also the restrictions on the size and layout of the machine as described in section 4.5.

4.9.2 Cleaning

The equipment shall be designed such that the user can perform cleaning easily, effectively, and efficiently.
Wherever possible, the equipment shall enable cleaning to be performed in-situ, i.e. without the need to remove parts from the equipment.
Note that there is no general requirement for the equipment to tolerate washing, rinsing or hosing with significant quantities of water or other liquid-cleaning agents.

4.10 Documentation

The supplier is expected to deliver:

- Functional specification
- FMEA
- Safety review
- Technical file relating to CE-mark, if XXXXXXXXXX, XXX should decide at a future date to CE-mark the machine.
- Build Documentation Package

- See the embedded document below for complete documentation delivery package requirements.


DOCPKG02.DOC

Note: The supplier shall supply complete documentation of the facilities required to install the equipment no later than 45 days prior to its scheduled arrival at XXXXXXXXXX, XXX. See docpkg02.doc above.

4.11 Preferred Components

Use listed components unless a better solution on a given application exists. However, XXXXXXXXXX, XXX must agree to any variance from the component list in writing.

See embedded document below.


precomp1.doc

Also >This section is where you would reference any MRO inventory parts lists that you may want the supplier to use. This allows the project not to needlessly add to your spares inventory. You can refer to the list or embed it here on a per project basis.

4.12 Training

The supplier is expected, at a minimum, to conduct system specific training at their manufacturing facility to equipment operators and maintenance personnel. This must be included in the cost of the equipment and may be broken out as a separate line item.

The training of equipment operators and maintenance personnel should cover all items listed in the "Operations / Maintenance Documentation" section of the "DOCPKG02.DOC" file embedded in section 4.10. The training will be "hands-on." A knowledgeable individual employed by the supplier will train and the equipment operators and maintenance personnel in each and every procedure contained in said documentation.

4.13 Project Management

See "Project Management" section of the Terms & Conditions Document

4.14 Spare Parts

See embedded document **docpkg02.doc** in section 4.10 of this document for complete documentation delivery package requirements for spares.

Note: The project engineer must work out a plan with the program manager and plant facility receiving this equipment for spares required through build, debug, start-up, acceptance and validation. This is a crucial step in ensuring that timelines and budgets are met in any implementation.

5.0 Acceptance Criteria

Specify the plan and or criteria here or in an embedded document. ***The acceptance criteria should test if the functional requirements were met! Does it answer the URS?***

XXXXXXXXXX, XXX personnel will generate a final acceptance-testing document with content input from the selected vendor of the XXXXXXX equipment. This document will be referred to as a Pre-Delivery Qualification (PDQ) protocol. The PDQ will address, but not be limited to, the following items:

(a) Safety Compliance – verification that items resulting from the FMEA have been resolved, ergonomics, NEC, NFPA, etc.
(b) Review of Equipment Functionality – mechanical operation, control system review, etc.

Appendix A. Distribution List

This process document is distributed to:

Name	*Company*

Appendix B. Process Base Line

Appendix C. Engineering Drawings

Appendix D. Open Items

List open items here. When an item is closed, change the font in the document and strike it out in the list. Do not delete it, so there will be a record of what has transpired.

Section No.	*Item Description*

Appendix E. Project Check List

ITEM	N/A	Date Complete	Action Items
PROJECT MANAGEMENT			
Terms & Conditions Signed			
Project Management Progress Report Schedule			
Functional Specification Approved			
Acceptance Criteria Approved			
SAFETY COMPLIANCE			
FMEA Completed			
Ergonomics Compliance			
Cumulative Trauma Compliance			
NIOSH Lifting Compliance			
CODE COMPLIANCE ELECTRICAL			
OSHA Subpart – S 29 CFR 1910.300 - .399			
NFPA 70 & 79			
NEC (latest version)			
CODE COMPLIANCE MECHANICAL			
OSHA Subpart – O 29 CFR 1910.211 .222			
SOFTWARE			
InTrack/InTouch Standards Compliance			
Visual Basic Standards Compliance			
GENERAL REQUIREMENTS			
FDA, USDA & cGMP Compliance			
Documentation Check List Complete			
Technical File Relating to CE-mark			

Comments Form

If you found errors in this document, or want to provide suggestions on its content or format, please send your comments to the document owner:

Electronic Comments to: Email: *Owner's email address*

FAX Comments to: *Owner's Fax No. XXX-XXX-XXXX*

Internal Mail Comments to: *Owner's Company Mail address*

Name:_____

Organization:_____

Location:_____

Phone:_____

Node ID:_____

Document Approval Form

This form is to be used by an approver that can not attend a review or sign the original document. This can be sent to the document owner in lieu of signing the original.

User Requirements Specification – Descriptive Title

Name: _____
Document Name/Number:
Edition:

As an approver of the document entitled:

***Descriptive Title*-User Requirements Specification (URS)**

Owned By: *Owner's Name* Dept. Owner's Department

I concur with the contents as reviewed on _____

I non-concur with the contents as reviewed on:_____

Reasons:_____
_____
_____
_____

Name:_____
_____
Signature

The following section is for use by the document owner if necessary:

Action Plan:_____
_____
_____

Date for Closure:_____

End of Document

CONSULTING AGREEMENT

This Agreement made and entered into this _____ day of _____, 200__, is between MEDICAL DEVICE, INC. INCORPORATED, a corporation of the State of New York, having an address at One MEDICAL DEVICE Place, _____ (hereinafter "MEDICAL DEVICE") and _____, a corporation of the State of _____ *(or partnership, individual, etc.)*, having an address at _____ (hereinafter "CONSULTANT").

WHEREAS, CONSULTANT is recognized for expertise in the area of _____ _____; and

WHEREAS, MEDICAL DEVICE desires to retain CONSULTANT to assist MEDICAL DEVICE in _____ (hereinafter "FIELD OF AGREEMENT") and CONSULTANT wishes to so assist MEDICAL DEVICE, all subject to the terms and conditions hereof.

NOW, THEREFORE, for and in consideration of the mutual premises and covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto, intending to be legally bound hereby, do mutually agree as follows:

MEDICAL DEVICE hereby engages CONSULTANT for the purposes of giving advice, on-site services, making recommendations, providing information, development and otherwise generally acting in a consulting capacity in matters connected with, relating to, and/or arising out of the FIELD OF AGREEMENT all as set forth in Exhibit A. *(This is deliverables list)*

1. CONSULTANT accepts such engagement and agrees to use best efforts to provide the above services. CONSULTANT warrants that all services provided under this Agreement shall be performed in a professional and workmanlike manner. CONSULTANT is authorized to perform such services on the instruction of and will report to _____ or a designated alternate.

2. MEDICAL DEVICE shall pay CONSULTANT at the rate of $_____ per _____ for services performed. CONSULTANT will bill MEDICAL DEVICE monthly in a form suitable to MEDICAL DEVICE and with such supporting documentation as MEDICAL DEVICE may reasonably require. *(Payment can be per hour or per project, depending on circumstances. Payment against deliverable hurdles is preferred if circumstances allow. Description of reimbursement for travel expenses, etc. as appropriate)*

4. CONSULTANT warrants that CONSULTANT has the full and unrestricted right to disclose to MEDICAL DEVICE any information CONSULTANT makes available to MEDICAL DEVICE under this Agreement.

5. CONSULTANT agrees that during the term of this agreement and for a period of one (1) year from the termination of this agreement that it will not, directly or indirectly, render its services to any entity or corporation whose products are in direct competition with any

products of MEDICAL DEVICE, INC. Incorporated or any of its subsidiaries. Without limiting the foregoing, MEDICAL DEVICE shall consider, on an as requested basis, modifications to these restrictions where it believes the competitive impact on MEDICAL DEVICE, INC. to be minimal or otherwise manageable. In the event of a breach by CONSULTANT of its obligations hereunder during the terms of this agreement, MEDICAL DEVICE, INC. Incorporated, together with such other remedies it may elect, shall have the option of immediately terminating the agreement without notice. This provision shall survive the termination of the contract by either party and, in the event of a breach, MEDICAL DEVICE, INC. Incorporated shall be entitled to all legal and equitable remedies available to it without limitation.

6. CONSULTANT acknowledges that this Agreement creates a confidential relationship between CONSULTANT and MEDICAL DEVICE that is the basis upon which MEDICAL DEVICE will allow CONSULTANT to have access to MEDICAL DEVICE's commercially valuable, proprietary and confidential information, including but not limited to, information stored within the computer systems of MEDICAL DEVICE. CONSULTANT shall hold such information in strict confidence and shall not disclose same to a third party or use such information in any way except as provided for in this Agreement.

7. CONSULTANT agrees to keep confidential and not, without the prior written consent of MEDICAL DEVICE, to publish, disclose to any third party or use (except for purposes of performance under this Agreement) (a) any business information or plans of MEDICAL DEVICE, (b) technical information provided by MEDICAL DEVICE to CONSULTANT in connection with the performance of CONSULTANT's duties hereunder, and (c) any documentation and materials specifically developed or prepared by CONSULTANT in performance of CONSULTANT's duties under this Agreement (collectively, the "Confidential Information"). The obligations of this paragraph do not pertain to information which is generally known or hereafter becomes generally known to the public through no fault of CONSULTANT, or which is possessed by CONSULTANT, without direct or indirect derivation from MEDICAL DEVICE, prior to the Effective Date of this Agreement, or is disclosed by CONSULTANT with the written approval of MEDICAL DEVICE, or subsequent to disclosure hereunder, is lawfully received from a third party whose rights therein are without any restriction to disseminate such Confidential Information. CONSULTANT's obligations to protect Confidential Information shall survive for five (5) years from the date of receipt or generation of such Confidential Information. CONSULTANT will require that all its employees assigned to and/or working within the FIELD OF AGREEMENT for MEDICAL DEVICE are subject in writing to the same confidentiality restrictions as set forth in this Agreement.

8. In performing under this Agreement, CONSULTANT shall act at all times as an independent contractor. Nothing contained herein shall be construed or applied so as to create the relationship of principal and agent or employer and employee between MEDICAL DEVICE and CONSULTANT. CONSULTANT shall not make any commitment or incur any charges or expense in the name of MEDICAL DEVICE. The term "CONSULTANT" as used herein shall include all employees, agents and representatives of _____.

9. While assigned to MEDICAL DEVICE's premises, CONSULTANT shall abide by and conform to the MEDICAL DEVICE rules and regulations observed by MEDICAL DEVICE's employees.

10. CONSULTANT shall indemnify and hold MEDICAL DEVICE harmless from and against any loss, cost, damage, expense (including reasonable attorneys' fees and court costs, whether arising out of a third party action or an action to enforce this Agreement), claim or other liability (including injuries and death to persons carrying out CONSULTANT's responsibilities or MEDICAL DEVICE employees) (collectively "Damages") to the extent such Damages arise from or are related to CONSULTANT's performance or failure to perform under this Agreement and/or the negligence, intentional acts or omissions of CONSULTANT's employees, agents, representatives or contractors.

11. INSURANCE. *(if circumstances warrant)* CONSULTANT agrees to maintain at its sole cost and expense, an insurance policy or policies of commercial liability insurance in an amount not less than $_____ in the aggregate. Such insurance shall provide coverage for contractual liability and MEDICAL DEVICE shall be included as an additional insured. CONSULTANT also agrees to maintain workers' compensation insurance in accordance with statutory requirements. A certificate of insurance shall be provided to MEDICAL DEVICE prior to the commencement of this Agreement and upon renewal of said policy(s). The certificate shall include a notice of cancellation, non-renewal of 30 days.

12. All rights, title, and interest to all technology, technical information, and inventions, patent applications, and patents which relate to the FIELD OF AGREEMENT and were made by CONSULTANT under this Agreement, shall belong to and be the property of MEDICAL DEVICE. CONSULTANT agrees, without further payment by MEDICAL DEVICE, to make any assignments and execute documents as are necessary to effect MEDICAL DEVICE's title hereto in all countries of the world.

13. All documents and materials (including, but not limited to, reports, data, drawings, plans, prints, articles, information, records, etc.) prepared by CONSULTANT in the performance of its duties hereunder will constitute works-made-for-hire and shall belong to and be the exclusive property of MEDICAL DEVICE and shall be surrendered by CONSULTANT to MEDICAL DEVICE upon request at the termination of this Agreement. CONSULTANT hereby assigns to MEDICAL DEVICE all rights of copyrights that CONSULTANT has to such documents and materials.

14. Unless sooner terminated as provided herein, this Agreement shall terminate at such time that *(all deliverables as set forth on Exhibit A are provided to MEDICAL DEVICE)* either party gives at least sixty (60) days prior written notice of termination. However, the obligations of CONSULTANT in Paragraphs _____ shall survive any termination of this Agreement.

15. Services under this Agreement are to be performed by CONSULTANT and cannot be delegated without prior written consent of MEDICAL DEVICE. MEDICAL DEVICE reserves the right to terminate this Agreement upon written notice if in MEDICAL DEVICE's sole discretion CONSULTANT is unable to perform the services required under this Agreement or if CONSULTANT is in breach of any material term of this Agreement. Upon termination of this Agreement, MEDICAL DEVICE shall be liable for payment obligations only to the extent that services have been provided.

16. CONSULTANT shall be fully responsible for payment of all state and federal income taxes, social security taxes, and for any other taxes or payment which may be due and owing by CONSULTANT as the result of fees or amounts paid by MEDICAL DEVICE under this Agreement, and CONSULTANT shall indemnify and hold harmless MEDICAL DEVICE for any such payment which may be due and owing by CONSULTANT.

17. During the term of this Agreement, the parties can, upon written agreement, add new areas to the FIELD OF AGREEMENT. Any services performed in the new areas will be subject to all of the conditions and restrictions set forth in this Agreement.

18. None of the provisions of this Agreement may be waived, changed, modified, amended or altered, except by an instrument in writing signed by both parties.

19. If any provision of this Agreement should be declared invalid or unenforceable for any reason by a court of competent jurisdiction, such provision or portion shall be considered separate and apart from the remainder of this Agreement, which shall remain in full force and effect.

20. This Agreement shall be governed by the laws of the State of New York, without regard to its provisions regarding conflicts of laws.

21. The Effective Date of this Agreement is _____, 200__.

22. This Agreement constitutes the entire agreement and understanding between CONSULTANT and MEDICAL DEVICE with respect to the subject matter of this Agreement. To the extent that the terms of any purchase order or other document conflicts with the terms of this agreement, this Agreement shall control.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

MEDICAL DEVICE, INC. INCORPORATED	CONSULTANT
Signature: _____	Signature: _____
Name Printed: _____	Name Printed: _____
Title: _____	Title: _____
Date: _____	Date: _____

(remainder intentionally left blank)

EXHIBIT A

[Deliverables List]

TECHNICAL SERVICES AGREEMENT

THIS AGREEMENT is made as of _____, 200X, by and between MEDICAL DEVICE INCORPORATED, a corporation of the State of New York, by and through its <DIVISION> <ADDRESS> ("MEDICAL DEVICE, INC.") and (individually and collectively, the "Contractor").

WHEREAS, Contractor has proposed to design, construct and deliver to MEDICAL DEVICE, INC. a certain XXXX, as more fully described below; and

WHEREAS, MEDICAL DEVICE, INC. desires to engage Contractor to conduct the work and services as further described herein, and Contractor desires to accept such engagement.

NOW THEREFORE, the parties hereby agree as follows:

1. DESCRIPTION OF WORK

1.1 MEDICAL DEVICE, INC. hereby engages Contractor to design, construct and deliver the system in accordance with the specifications set forth in (the "Project").

1.2 Contractor accepts such engagement and agrees to provide the DELIVERABLES described in XXXX, under the terms and conditions set forth herein.

1.3 The Project may be amended during the term of this Agreement only upon prior, express written agreement of Contractor and MEDICAL DEVICE, INC.. In the event that MEDICAL DEVICE, INC. and Contractor agree to modify the Project, MEDICAL DEVICE, INC.'s liability to Contractor for the modified Project shall not exceed payment of the aggregate sum as negotiated by MEDICAL DEVICE, INC. and Contractor as a condition of the modification.

1.4 All work performed by Contractor under this Agreement shall be done in compliance with MEDICAL DEVICE, INC.'s standard Terms and Conditions, as set forth in Attachment XXXX

2. PAYMENT

2.1 MEDICAL DEVICE, INC.'s sole liability to Contractor shall be payment of the fixed amounts according to the following payment schedule as more fully described in Attachment XXXX:

a. XXXX upon signing of this Agreement and receipt of supplier invoice by MEDICAL DEVICE, INC. Accounts Payable;

b. A progress payment of XXXX upon delivery, installation and acceptance by MEDICAL DEVICE, INC. of the system;

c. A progress payment of (_____) upon receipt of XXXX satisfactory to MEDICAL DEVICE, INC. for the use and operation of the system in form and substance acceptable to MEDICAL DEVICE, INC.;

d. In addition, MEDICAL DEVICE, INC. shall pay Contractor at the time of XXXX; and

e. In no event shall MEDICAL DEVICE, INC.'s liability for services and materials exceed the aggregate sum of XXXX

2.2 Contractor shall bill MEDICAL DEVICE, INC. in a form suitable to MEDICAL DEVICE, INC. and with such supporting documentation as MEDICAL DEVICE, INC. may reasonable require. Invoices shall be sent to MEDICAL DEVICE, INC.'s Accounts Payable Department as specified on the Purchase Order accompanying this Agreement.

3. REPAYMENT OBLIGATION. In consideration of MEDICAL DEVICE, INC.'s advance payment to Contractor under Section 2.1(a), XXXX does hereby covenant and agree that such payment shall not be deemed earned unless and until the Project shall have proceeded to the point of delivery, installation, and acceptance as defined herein. In the event XXXX shall fail to advance the Project to such stage (within the timeframes set forth in Attachment XXXX), MEDICAL DEVICE, INC. shall have the right to demand repayment in full of such payment upon notice as set forth herein.

4. TERM; TERMINATION

4.1 The work shall commence upon Contractor's receipt of the first payment provided under Section 2.1(a), and unless terminated earlier in accordance with this Agreement, shall remain in effect until the Project is completed.

4.2 MEDICAL DEVICE, INC. shall have the right to terminate this Agreement by providing Contractor written notice of termination. The effective date of termination shall be thirty (30) days following receipt of the written notice of termination.

4.3 The effect of termination is as follows:

a. In the event of termination of this Agreement by MEDICAL DEVICE, INC., MEDICAL DEVICE, INC.'s sole liability to Contractor shall be payment for all services performed up until the date of termination (subject to the limitations contained in Section 3), not to exceed the agreed aggregate sum.

b. In the event of expiration or termination of this Agreement for any reason whatsoever, the obligations under this Agreement shall survive for purposes set forth herein, including Sections 5, 6, 7, 9 and 10.

5. WARRANTY

5.1 Contractor represents and warrants to MEDICAL DEVICE, INC. that:

a. Its services hereunder shall be performed in a diligent, workmanlike and professional manner consistent with good engineering practices and all services and equipment furnished or developed hereunder shall be as represented by Contractor to MEDICAL DEVICE, INC.; and

b. It has full power to enter into and fully perform this Agreement without conflict with any other Agreements, and that no service or equipment furnished or developed hereunder will in any way knowingly infringe upon or violate any rights of any third person, including, without limitation, rights of patent, trade secret, trademark or copyright.

6. INDEMNITY

6.1 Contractor shall, at its own expense, defend, indemnify and hold harmless MEDICAL DEVICE, INC. against any claims, losses, damages, costs or expenses resulting from property damage or injuries (including death) caused by the acts or omissions of its agents or employees.

Limits of Liability

Bodily Injury	$1,000,000	each person
	3,000,000	each occurrence
	3,000,000	aggregate products
Property Damage	$3,000,000	each accident
	3,000,000	aggregate operations
	3,000,000	aggregate protective
	3,000,000	aggregate products
	3,000,000	aggregate contractual

The Comprehensive General Liability Policy shall provide insurance for the Contractor for Bodily Injury and Property Damage to third persons arising out of:

1. Work performed by the Contractor himself with his own employee ("premises-operations")

2. Work performed by his subcontractors, called "sublet work" or "Independent Contractors"
("Contractor's Protective Liability")

3. Contractor's Liability assumed under this Contract, called "Hold Harmless" clauses or indemnity agreement ("Contractual Liability Insurance")

4. Products Liability coverage covering the completed building or installation or products furnished ("Products Liability Insurance" for the manufacturer and "Completed Operations
Liability Insurance" for the Contractor)

5. The coverage shall be extended to include protection against property damage caused by explosion, collapse of structures and damage to underground pipes and utilities ("XCU" coverage)

Comprehensive Automobile Liability Insurance covering Bodily Injury and Property Damage as follows:

Limits of Liability

Bodily Injury	$	1,000,000	each person
		3,000,000	each accident
Property Damage	$	1,000,000	each accident

6.2 Each party shall, at its own expense, defend, indemnify and hold harmless the other, against any claims, losses, damages costs or expenses based upon or resulting from any breach of any representation or warranty of the indemnifying party contained in this Agreement.

7. CONFIDENTIALITY

7.1 Contractor acknowledges that this Agreement creates a confidential relationship between Contractor and MEDICAL DEVICE, INC. that is the basis on which MEDICAL DEVICE, INC. will allow Contractor to have access to MEDICAL DEVICE, INC.'s commercially valuable, proprietary, and confidential information. Contractor shall hold such information, including all information and equipment (including drawings and the like) developed by Contractor for MEDICAL DEVICE, INC. herein, in strict confidence and shall not disclose such information to any third party or use such information in any way except as provided for in this Agreement. This obligation shall not apply to information which is or may become generally known to the public. Contractor shall safeguard all materials, but not limited to written documents, drawings, electronic files, software and other other data communications supplied by MEDICAL DEVICE, INC., and shall not copy or duplicate such materials except as

specifically permitted herein, and shall return all such materials to MEDICAL DEVICE, INC. upon completion of the services hereunder or upon MEDICAL DEVICE, INC.'s request.

7.2 The Contractor shall be fully responsible for payment of all state and federal income taxes, social security taxes, and for any other taxes or payment which may be due and owing by the Contractor as the result of fees or amounts paid by MEDICAL DEVICE, INC. under this Agreement, and the Contractor shall indemnify and hold MEDICAL DEVICE, INC. harmless from any such payment which may be due and owing by the Contractor.

8. INDEPENDENT CONTRACTOR STATUS

8.1 Work performed by Contractor for MEDICAL DEVICE, INC. under this Agreement shall be in Contractor's capacity as an independent contractor and not as agent or representative of MEDICAL DEVICE, INC.. It is expressly understood that this undertaking does not constitute a joint venture. Contractor shall not enter into and is not authorized to enter into any contract or commitment on behalf of MEDICAL DEVICE, INC..

9. EXCLUSIVE RIGHTS

9.1 All documents and materials (including reports, data, drawings, plans, prints, articles, information, records, etc.) prepared by Contractor in performance of its duties hereunder, including all items described in Attachments A and B, shall belong to and be the exclusive property of MEDICAL DEVICE, INC. and shall be surrendered by Contractor to MEDICAL DEVICE, INC. upon request at the termination of this Agreement or completion of the Project, whichever is earlier. Contractor hereby assigns to MEDICAL DEVICE, INC., all rights of copyrights that Contractor has to such documents and materials.

9.2 All rights, title, and interest (including ownership of copyright) to all technology, technical information, software, inventions, patent applications, and patents which relate to the Project and were made by or on behalf of Contractor during the performance of this Agreement (hereinafter "PROJECT TECHNOLOGY"), shall belong to and be the property of MEDICAL DEVICE, INC.. Contractor hereby assigns any and all of its rights in PROJECT TECHNOLOGY to MEDICAL DEVICE, INC.. Contractor agrees to make any assignments and execute documents (at MEDICAL DEVICE, INC.'s expense) as are necessary to effect MEDICAL DEVICE, INC.'s title hereto in all countries of the world.

10. OWNERSHIP OF EQUIPMENT

10.1 During the Project, if MEDICAL DEVICE, INC. shall purchase specific materials (e.g., hardware and software) necessary for Contractor to complete the Project.

All such purchases shall be made on standard MEDICAL DEVICE, INC. purchase orders, subject to prior approval by the Project Manager. The materials necessary for the completion of the Project are more fully set forth in Attachment ?????.

10.2 Contractor shall hold all materials purchased in trust for MEDICAL DEVICE, INC., and without any right, title or interest in or to the same. Contractor acknowledges and agrees that MEDICAL DEVICE, INC. has and shall have all right, title and interest in or to the equipment, as well as all accessions to, or substitutes or replacements for, the equipment. Contractor shall bear all risk of and reimburse and hold harmless MEDICAL DEVICE, INC. for and against any injury related to the use, operation or assembly of the equipment or loss or destruction of or to any of the equipment occurring during the delivery of the equipment to or from Contractor and when in the possession of Contractor.

10.3 Contractor represents and warrants that:

a. it shall not sell, lease, assign, transfer, pledge, or otherwise transfer or encumber the equipment or deal with it as its own;

b. the equipment shall be located at the Contractors primary address and shall not be moved without the prior written authorization of MEDICAL DEVICE, INC.;

c. it shall use the equipment solely for use in the PROJECT;

d. it shall permit MEDICAL DEVICE, INC. to inspect the equipment at Contractor's place of business, and provide assurances that the equipment has not been moved, at MEDICAL DEVICE, INC.'s request; and

e. upon completion of the Project shall return the equipment to MEDICAL DEVICE, INC. in good working condition, normal wear and tear excepted.

11. NOTICES; PROJECT ADMINISTRATION

11.1 All notices shall be in writing, shall be effective upon receipt, and shall be addressed to the Project Managers listed below. MEDICAL DEVICE, INC. may change its designated Project Manager by providing written notice to Contractor.

For Contractor:

For MEDICAL DEVICE, INC.: **Technical Issues**
XXXX
MEDICAL DEVICE, INC. Incorporated
Phone:
Fax:
E-mail:

Commercial Issues
MEDICAL DEVICE, INC. Incorporated
Phone:
Fax:
E-mail:

12. GENERAL PROVISIONS

12.1 Assignment. The services to be provided by Contractor hereunder are of a personal nature. This Agreement shall not be assigned in whole or in part without the written consent of MEDICAL DEVICE, INC.. The duties, obligations, rights and remedies under this Agreement are in addition to and not in limitation of those otherwise imposed or available by law.

12.2 Non-Waiver. The failure by either Party to require strict performance or to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppel with respect to any subsequent breach or with respect to any provision thereof. A Party shall not be deemed to have waived any rights hereunder unless such waiver is in writing and signed by an authorized officer of the Party claimed to have waived.

12.3 Severability. If any provision hereof shall be determined to be invalid or unenforceable, the validity and effect of the other provisions of this Agreement shall not be affected thereby.

12.4 Entire Agreement; Amendments. This Agreement, including any attachments hereto, constitutes the entire agreement and understanding between the Parties with respect to the subject matter of this Agreement and supersedes all prior and collateral communications, reports, and understandings, if any, between the Parties. To the extent any provision of this Agreement conflicts with any attachment hereto, the terms of this Agreement shall be controlling. None of the provisions of this Agreement may be waived, changed or altered, except by an instrument in writing signed by authorized representatives of both parties.

12.5 Applicable Law. This Agreement shall be governed by the laws of the State of New York without reference to its conflict of law or choice of law rules.

12.6 Publicity. Neither Party shall use the name, trademark, trade name or other designation of the other Party in any advertising, publicity or other promotional activity without prior written permission.

IN WITNESS HEREOF, the parties hereto have caused this Agreement to be executed by its duly authorized offices on the date set forth below.

MEDICAL DEVICE, INC. INCORPORATED by and through its <XXXX> Division (MEDICAL DEVICE, INC.)	CONTRACTOR
By: _____	By: _____
Date: _____	Date: _____
Title:_____	Title: _____

(remainder left intentionally blank)

CONTRACT MANUFACTURING
SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement"), dated as of _____, 20XX, by and between _____ ("Supplier") and MEDICAL DEVICE Incorporated ("MEDICAL DEVICE").

WITNESSETH

WHEREAS, MEDICAL DEVICE does currently or desires in the future to market, distribute and sell certain products under trademarks owned by MEDICAL DEVICE; and

WHEREAS, MEDICAL DEVICE desires to engage Supplier as a source of supply for the product(s) (as more particularly defined herein below), and Supplier desires to manufacture and supply such products to MEDICAL DEVICE, subject to and in accordance with the terms of this Agreement; and

WHEREAS, this Agreement may be used for supply of product to MEDICAL DEVICE and its wholly owned subsidiaries.

NOW, THEREFORE, in consideration of the foregoing premises, the respective representations, warranties, covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

ARTICLE I

DEFINITIONS

Unless otherwise defined in this Agreement, all capitalized terms used herein shall have the following meanings:

1.1 Batch Records. "Batch Records" shall mean batch records developed by the Supplier in the course of manufacturing separate lots of the Products.

1.2 cGMP. "cGMP" means the current good manufacturing practice regulations promulgated by FDA pursuant to the FDC Act. For Products that are drugs, the relevant regulations shall include 21 CFR 211. For Products that are MEDICAL DEVICE, the relevant regulations shall include 21 CFR 820.

1.3 Facility. "Facility" shall mean the Supplier's facility located at _____.

1.4 Equipment. "Equipment" shall mean any equipment or machinery purchased by Supplier or provided by MEDICAL DEVICE to Supplier specifically for the purpose of manufacturing Product. Equipment shall be installed, qualified and verified by Supplier at Supplier's Facility, subject to MEDICAL DEVICE's prior written approval.

1.5 FDA. "FDA" means the Food and Drug Administration of the United States of America and/or any other governmental or regulatory agencies as may regulate or control the sale of drugs in the Territory.

1.6 FDC Act. "FDC Act" means the Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated pursuant thereto.

1.7 Product(s). "Product(s)" shall mean those finished product(s) described on a schedule 1.7, a form of which is attached hereto and any and all mutually agreed additions or deletions which MEDICAL DEVICE may make with respect thereto during the term of this Agreement. It is anticipated that multiple Products may be sourced from Supplier pursuant to this Agreement, meaning that multiple schedules 1.7 may exist.

1.8 Raw Materials. "Raw Materials" shall mean all raw materials, supplies components and packaging necessary to manufacture the Products in accordance with the Specifications.

1.9 Specifications. "Specifications" as it relates to each Product shall refer to the Raw Materials, manufacturing, labeling, packaging, quality assurance testing, and other specifications for each Product, and any and all improvements, modifications, additions and deletions which MEDICAL DEVICE may make with respect thereto during the term of this Agreement. Such improvements, modifications, additions and deletions to the Specifications shall only be effective when approved by MEDICAL DEVICE in writing. The Specifications for each particular product shall be set forth in the relevant schedule 1.7.

1.10 Technology. "Technology" shall mean the technical knowledge, Specifications and any other know-how owned by MEDICAL DEVICE relating to the manufacture of the Products, including any confidential and proprietary information which MEDICAL DEVICE owns or controls pertaining to the manufacture of the Products.

ARTICLE II

TERM

2.1 Term. The term of this Agreement shall commence on the date hereof and shall continue for a term of five (5) years unless extended or terminated in accordance with the terms of this Agreement (the "Term").

2.2 Option Years. MEDICAL DEVICE shall have the right to extend this Agreement for additional periods of one (1) year each (the "Renewal Year(s)") by delivery of written notice to Supplier at least thirty (30) days prior to the end of the Term or any Renewal Year. Each Renewal Year shall be subject to the terms and conditions hereof unless otherwise agreed in writing by the parties. For purposes of this Agreement "Term" shall refer collectively to the Term under Section 2.1 hereof and the Renewal Year(s) under section 2.2 hereof.

ARTICLE III

SUPPLY OF PRODUCTS

3.1 Supply. During the Term, Supplier shall manufacture and supply to MEDICAL DEVICE Product, as and when ordered by MEDICAL DEVICE, in accordance with the ordering, manufacturing, delivery, payment and other provisions hereof. This is not a requirements contract and Supplier is not awarded any exclusive right to manufacture any one or more Product.

3.2 Resources. During the Term, Supplier agrees to devote sufficient organizational, financial and personnel resources necessary to perform its obligations under this Agreement, including maintaining capacity to manufacture and deliver to MEDICAL DEVICE Products as described at Section 3.1 hereof.

3.3 Adherence to Specifications. During the Term, Supplier shall manufacture the Products in strict accordance with the Specifications and cGMPs. In the event MEDICAL DEVICE desires to make changes that are required by the FDA or other regulatory body that affects or impacts manufacturing, testing or the supply of Product, MEDICAL DEVICE shall provide written notice to Supplier prior to making any such change and shall consult with Supplier regarding such change, and Supplier shall make any such change. During the term of this Agreement, if MEDICAL DEVICE desires to amend or make changes to any applicable regulatory filings or any other changes that are not required by the FDA that affects or impacts the manufacturing, testing or supply of Product, MEDICAL DEVICE shall provide written notice to Supplier of such proposed change and shall consult and obtain Supplier's written approval regarding such change. Supplier's approval shall not be unreasonably withheld, and MEDICAL DEVICE shall pay to Supplier such increased out-of-pocket costs to manufacture Product(s).

3.4 Raw Materials. Supplier shall be responsible for securing, inspecting and releasing adequate Raw Materials based upon MEDICAL DEVICE's requirements as contained in purchase orders submitted by MEDICAL DEVICE. MEDICAL DEVICE shall provide Raw Material specifications and may recommend suppliers. In certain instances, MEDICAL DEVICE may insist on a specific supplier to be used for Raw Material. In such an event, the suppliers will be specified in the relevant schedule 1.7.

3.5 Testing and Inspection of Product. Supplier shall conduct all quality control and other tests required to insure that Product as manufactured meets the mutually agreed upon Specifications. The cost of all such analysis, testing and evaluation shall be borne by Supplier. Supplier shall provide MEDICAL DEVICE with a Certificate of Analysis for each lot of Product, such Certificate of Analysis being in the form as attached in Schedule 3.5.

ARTICLE IV

ORDERING AND PRICES

4.1. Ordering/Quantities. Upon execution of this Agreement, MEDICAL DEVICE shall submit to Supplier a forecast listing MEDICAL DEVICE's requirements for Products for the subsequent twelve (12) months, on a rolling basis, with the first three (3) months constituting a firm Purchase Order

("Purchase Order") and the remaining nine (9) months a non-binding forecast of MEDICAL DEVICE's projected requirements for Products. Each month thereafter MEDICAL DEVICE will submit subsequent rolling forecasts constituting a firm Purchase Order for the next three (3) months and non-binding forecasts for the subsequent nine (9) months. Order quantities should approximate full batch sizes understanding there may be yield gain/loss incurred during the manufacturing process.

4.2. Excess Quantities. Notwithstanding anything contained herein to the contrary, MEDICAL DEVICE may submit a Purchase Order for quantities in excess of the quantities specified in MEDICAL DEVICE's firm portion of the forecast, and Supplier shall accept and satisfy such orders subject to Supplier's production capacity.

4.3 Prices. The prices for Product(s) sold to MEDICAL DEVICE shall be as set forth in each Schedule 1.7 (the "Prices"). Prices shall remain fixed during the Term, provided Prices may be modified based on changes in Supplier's cost to manufacture Product.Supplier shall supply MEDICAL DEVICE with not less than ninety (90) days prior written notice of any such prices change accompanied by written documentation of such change, such change to be effective for any Purchase Order submitted after the date the price change becomes effective. Any price changes must be mutually agreed to by the parties.

4.4 Payment Terms. MEDICAL DEVICE shall pay for each order within forty-five (45) days of receipt of Supplier's invoice. The parties shall consider moving to electronic settlement of invoices provided appropriate capability exists.

ARTICLE V

DELIVERY

5.1 Shipment/Delivery Requirements. All Product(s) shall be properly packed, marked and shipped in accordance with Specifications and instructions for shipping and packaging included in the MEDICAL DEVICE Purchase Order in a format previously agreed upon by the parties. Shipments shall be routed by Supplier in accordance with the Purchase Order. Unless otherwise agreed in writing by the parties, each firm order of the Products shall be delivered to MEDICAL DEVICE's specified receiving dock by the date provided in each purchase order. Supplier, because of unforeseen transportation issues may deliver Product within three (3) days prior to the Purchase Order date and one (1) day later than Purchase Order date. MEDICAL DEVICE may deduct two (2%) percent of the invoice price for each ten (10) days delay of Product beyond the date specified in each Purchase Order.

5.2 Alternate Delivery Point. At the request and expense of MEDICAL DEVICE, Supplier shall ship any of the Products ordered by MEDICAL DEVICE by such carrier or carriers as MEDICAL DEVICE may designate to such warehouse, facility or other location, as MEDICAL DEVICE may designate. Such shipping instructions as provided by MEDICAL DEVICE to Supplier shall be reasonable. If Supplier fails to comply with the shipping instructions as specified by MEDICAL DEVICE resulting in excess transfer and/or storage charges, such excess charges shall be the responsibility of Supplier.

5.3 Terms. Shipping terms shall be F.O.B. Supplier's shipping dock, freight collect.

ARTICLE VI

INSURANCE: RISK OF LOSS

6.1 During the term of this agreement Supplier shall, at its sole cost and expense, procure and maintain:

(a) Commercial General Liability insurance including coverage for products/completed operations with annual limits of liability in an amount not less than $1,000,000 per occurrence; $1,000,000 general aggregate; and $3,000,000 products/completed operations aggregate, or their equivalent in non-US locations. This insurance shall also name MEDICAL DEVICE Incorporated and its subsidiaries as an additional insured. This insurance shall be primary and any insurance maintained by MEDICAL DEVICE shall be considered excess over Supplier's insurance.

(b) Workers' Compensation insurance in accordance with statutory requirements including Employer's Liability with limits in an amount not less than $1,000,000 each accident/disease, or its equivalent in non-US locations. The policy shall include a waiver of subrogation in favor of MEDICAL DEVICE.

6.2. During the term of this agreement MEDICAL DEVICE shall procure and maintain Global Transit insurance including warehouse to warehouse coverage for all property in transit in which MEDICAL DEVICE has an insurable interest, with limits of $4,000,000 per shipment, or its equivalent in non-US locations. Further,

Supplier shall not procure this coverage for shipments to MEDICAL DEVICE nor charge MEDICAL DEVICE for such coverage, but will be responsible for notifying MEDICAL DEVICE no less than 72 hours in advance of any single shipment which will exceed the $4,000,000 limit, so MEDICAL DEVICE may place the necessary additional insurance coverage.

6.3. During the term of this agreement Supplier shall notify MEDICAL DEVICE in writing within 24 hours of a major business interruption and/or natural catastrophe that may prevent or delay the delivery of goods to MEDICAL DEVICE.

6.4. All insurance policies required hereunder shall be endorsed to provide MEDICAL DEVICE with no less than 30 days prior written notice in the event of cancellation, non-renewal or material changes. The insurance company(s) providing these policies shall have a current A.M. Best rating of A- or better, and shall be licensed to do business in the applicable jurisdiction. A certificate of insurance evidencing such insurance coverage will be provided to MEDICAL DEVICE upon execution of this agreement and no less than 14 days prior to renewal of said insurance policies. The certificate of insurance shall indicate that the above 30-day notice provision applies.

6.5 Risk of Loss. Unless otherwise agreed by the parties hereto all risk of loss or damage to the Products from any cause whatsoever shall be borne by Seller until delivery of the Products to, and acceptance by, MEDICAL DEVICE or MEDICAL DEVICE's carrier at the F.O.B. Shipping Point.

ARTICLE VII

ACCEPTANCE AND CLAIMS

7.1 Inspection/MEDICAL DEVICE Quality Control Tests.

(a) All of the Products shall be received subject to MEDICAL DEVICE's inspection and may be rejected if found not to conform to the Specifications or otherwise fail to be as warranted hereunder. Within thirty (30) days of delivery to MEDICAL DEVICE, MEDICAL DEVICE may undertake its own quality control tests to ensure that the Products delivered have been manufactured by Supplier in accordance with the terms of this Agreement. MEDICAL DEVICE shall be deemed to have accepted each order delivered if supplier does not receive written notice to

the contrary within the same thirty (30) day period. Such acceptance is subject to revocation upon later discovery of any latent defect in any of the Products delivered.

(b) Subject to MEDICAL DEVICE's written request, prior to releasing Products satisfying Purchase Orders hereunder, Supplier shall deliver to MEDICAL DEVICE a statistically significant and representative sample of Products from each production lot ("Pre-Delivery Samples") for inspection by MEDICAL DEVICE, and copies of the corresponding Batch Records and quality assurance testing records. Upon receiving such a request for Pre-Delivery Samples, Supplier shall not release any Products satisfying Purchase Orders until MEDICAL DEVICE has accepted the Pre-Delivery Samples, provided, however, that MEDICAL DEVICE shall be deemed to have accepted the Pre-Delivery Samples if Supplier does not receive written notice to the contrary within forty-five (45) days of MEDICAL DEVICE's receipt of the Pre-Delivery Samples.

(c) Any dispute between MEDICAL DEVICE and Supplier relating to the conformity of the Products to the Specifications shall be resolved in accordance with the procedures set forth in Section 9.3. Any acceptance by MEDICAL DEVICE hereunder may be revoked by MEDICAL DEVICE upon later discovery of any defect in any of the Products delivered not discoverable by the quality assurance testing of Supplier.

7.2 Rejection by MEDICAL DEVICE. All claims for alleged defects or nonconformance which may be discovered by visual inspection or shortages (not attributable to the carrier) shall be reported in writing to Supplier within thirty (30) days of receipt of Products at the destination designated on MEDICAL DEVICE's Purchase Order. All claims for alleged defects which could not be discovered by visual inspection upon arrival at the designated destination shall be reported within thirty (30) days of delivery to MEDICAL DEVICE. At Supplier's request, MEDICAL DEVICE shall promptly supply either some of the Products which are allegedly defective or some other evidence of deficiency which Supplier shall specify. MEDICAL DEVICE will segregate those Products containing alleged defects and hold them for a period of at least thirty (30) days for inspection by Supplier. Supplier shall replace the Products found to be defective or short in quantity with such quantity of the Products in good salable condition to satisfy MEDICAL DEVICE's Purchase Order requirements or shall issue a credit to MEDICAL DEVICE for the prorated invoice including shipping costs incurred, whichever MEDICAL DEVICE shall elect.

ARTICLE VIII

WARRANTY

8.1 Warranty. Supplier warrants to MEDICAL DEVICE that the Products supplied to MEDICAL DEVICE pursuant to this Agreement will (i) comply in all respects with the Specifications; (ii) be free from defects in manufacturing and materials when such Products leave Supplier's possession; (iii) shall not be adulterated or misbranded under the meaning of the FDC Act; and (iv) shall be manufactured and packaged in a FDA approved manufacturing facility and shall be manufactured and packaged in a manner which complies with the Specifications and cGMP regulations and applicable FDA regulations pertaining to the Products. The foregoing warranties are in lieu of all other expressed and implied warranties, including without limitation the implied warranties of merchantability and fitness for a particular purpose. There are no oral promises, representations or warranties collateral to or affecting this Agreement.

8.2 Survival. This warranty shall survive inspection and acceptance of the Products by MEDICAL DEVICE, and shall survive any termination of this Agreement.

ARTICLE IX

ADDITIONAL OBLIGATIONS OF SUPPLIER

9.1 Quality Assurance. Supplier shall manufacture Products in accordance with cGMP's, and FDA guidelines. Supplier shall meet all compliance and cGMP Practices established by Regulatory Authorities. In addition, Supplier shall perform semi annual process simulations, annual sterilization revalidations and Product validations every three years in accordance with ISO 13408 (Media Fills).

9.2 MEDICAL DEVICE On-Site Access. Supplier shall permit MEDICAL DEVICE representatives (at MEDICAL DEVICE's expense) to be present during the manufacture of Product(s) as requested by MEDICAL DEVICE.

9.3 Quality Control Inspections. Upon reasonable notice, Supplier shall permit representatives of MEDICAL DEVICE to observe all quality control testing, and investigations, inspect all quality control documentation and reject

Products that do not conform with the Specifications based upon Supplier's or MEDICAL DEVICE's test results. In the event of any dispute between MEDICAL DEVICE and Supplier as to whether any Products conform with the Specifications, samples of the units in dispute shall be sent by MEDICAL DEVICE and Supplier to a testing laboratory mutually agreed to by MEDICAL DEVICE and Supplier, whose findings shall be binding In the terms of financial impact the ultimate release decision however, will remain with MEDICAL DEVICE on the parties except in cases of gross and manifest error. The cost of such testing shall be borne by the party whose position is not upheld by testing laboratory.

9.4 Quality Assurance Audits. MEDICAL DEVICE's authorized representatives may conduct reasonable in-depth quality assurance audits of the Facility, including analytical laboratories. Such audits shall be arranged by mutual agreement of the parties but in no event later than three (3) business days after MEDICAL DEVICE reasonably requests an audit. Such audits may include all aspects of the Facility related to the manufacture of the Products and all procedures, operations and quality control records with respect thereto. MEDICAL DEVICE's authorized representatives will be permitted by Supplier to enter the Facility during business hours to (all of the following with respect to records, procedures operations, and materials relating to the manufacture of Products for MEDICAL DEVICE):

(i) inspect manufacturing and quality control records;

(ii) observe quality control testing operations;

(iii) inspect Raw Materials, lots of Products in process, finished Products, equipment and other facilities used to manufacture, store or package the Products; and

(iv) make at MEDICAL DEVICE's expense such tests and other inspections as MEDICAL DEVICE reasonably deems necessary.

Supplier shall provide MEDICAL DEVICE with a reasonable number of copies of quality control and manufacturing records of the Products and to take random samples of the Products at any stage of manufacture or packaging at no charge to MEDICAL DEVICE; provided that MEDICAL DEVICE shall exercise best efforts to minimize any disruption to Supplier's operations in connection therewith.

9.5 Record Maintenance/Availability. Supplier shall maintain during, and deliver to MEDICAL DEVICE after, the Term, manufacturing and packaging records for each production lot, including Batch Records and records of quality

control tests. These records shall be maintained during the Term and shall not be destroyed, even after expiration or termination of this Agreement without MEDICAL DEVICE's prior written consent. Upon termination or expiration of this Agreement, or upon the cessation of Supplier's manufacture of a particular Product, MEDICAL DEVICE shall take possession of such records. These records shall be promptly provided to MEDICAL DEVICE during the Term at its request.

9.6 Inability to Perform. Supplier shall notify MEDICAL DEVICE immediately in writing whenever it has reason to believe that it may be, or may become, unable to perform any of the terms of this Agreement. If Supplier is unable to perform within 30 days, MEDICAL DEVICE may cancel any existing firm Purchase Order or portion thereof and shall have the right to have Products produced at another supplier or to manufacture Products within its own facilities without penalty.

9.7 Investigations of Returned Materials. Supplier will cooperate with MEDICAL DEVICE in the investigation of any Product returned to MEDICAL DEVICE if the initial investigation implicates, in MEDICAL DEVICE's reasonable judgment, any activity of Supplier. Such cooperation shall commence within two days of receiving notification from MEDICAL DEVICE.

9.8 Pre-Shipping Requirements. Supplier shall not deliver any Products to MEDICAL DEVICE unless and until the Products have cleared or passed Supplier's quality assurance testing and other procedures designed to ensure conformity with the Specifications. At MEDICAL DEVICE's option, Supplier shall ship Products to such warehouse, facility or other location, as MEDICAL DEVICE may designate in "quarantine" subject to Products final acceptance under Articles VII.

9.9 Product Complaints. Any Product complaint reports received by Supplier will be faxed to the MEDICAL DEVICE within two (2) business days at:

MEDICAL DEVICE XXXX Div.
XXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXX
Complaints Department
Fax:

Supplier will investigate and respond to all complaints associated with the manufacture of Product only as requested by MEDICAL DEVICE. Upon such a request, Supplier shall investigate the complaint within fourteen (14) business days and provide a written summary to MEDICAL DEVICE.

MEDICAL DEVICE will investigate all other product complaints associated with Product not related to the manufacture of the Product.

9.10 Notice From Government Authority. In the event Supplier receives any communication, memorandum or other correspondence from any government agency or authority concerning the Product(s) Supplier shall provide a copy of same to MEDICAL DEVICE within forty-eight (48) hours after receipt thereof.

9.11 Recalls. In the event Supplier believes a recall, field alert, Product withdrawal or field correction may be necessary pursuant to any Product provided under this Agreement, Supplier shall immediately notify MEDICAL DEVICE in writing. Supplier will not act to initiate a recall, field alert, Product withdrawal or field correction without the express prior written approval of MEDICAL DEVICE. In the event MEDICAL DEVICE believes a recall, field alert, Product withdrawal or field correction may be necessary pursuant to any Product provided under this Agreement, MEDICAL DEVICE shall immediately notify Supplier in writing and Supplier shall provide all necessary cooperation and assistance to MEDICAL DEVICE.

The cost of any recalls will be borne by Supplier if the recall is due to a failure of Product(s) to meet the Specifications or other manufacturing non-conformance attributable to Supplier. Supplier shall be solely responsible for reporting to the FDA all post-marketing adverse drug experiences (ADE's) as required by 21 CFR 214.80. MEDICAL DEVICE will notify Supplier concurrently, of any adverse drug reactions coming to its attention during the term of the Agreement.

ARTICLE X

TECHNOLOGY TRANSFER

MEDICAL DEVICE shall furnish Supplier with one (1) copy of all Technology , including but not limited to process sheets, raw material and process specifications, manuals, vendors lists, and other writings and any software with respect to each Product, which may be required by Supplier to manufacture and package the Product(s) according to Specifications. Supplier agrees that MEDICAL DEVICE may use all Technology, information and writings listed in the preceding sentence for the manufacture of Product(s) both during and after the Term of this Agreement.

ARTICLE XI

PACKAGING

All artwork, advertising and packaging information used by Supplier for Product shall be provided to Supplier by MEDICAL DEVICE or approved by MEDICAL DEVICE in writing prior to release of the first shipment of a Product. Such artwork, advertising and packaging information is and shall remain the exclusive property of MEDICAL DEVICE. Such artwork, advertising and packaging information or any reproduction thereof may not be used by Supplier following the termination of this Agreement, or during the Term of this agreement in any manner other than solely for purposes of performing hereunder and Supplier shall indemnify, defend and hold MEDICAL DEVICE harmless in the event it is in breach of this provision.

ARTICLE XII

CONFIDENTIALITY

Supplier agrees to keep confidential and not, without the prior written consent of MEDICAL DEVICE, to publish, disclose to any third party or use (except for purposes of performance under this Agreement) (a) any business information or plans of MEDICAL DEVICE, (b) the Technology supplied by MEDICAL DEVICE to Supplier in connection with this Agreement, and (c) any documentation and materials specifically developed or prepared by Supplier in performance of its duties under this Agreement and based on Technology supplied by MEDICAL DEVICE. The obligations of this paragraph do not pertain to information which is or becomes generally known to the public through no fault of Supplier. At termination of this Agreement, all such information shall be returned to MEDICAL DEVICE.

ARTICLE XIII

INDEPENDENCE OF THE PARTIES

Supplier and MEDICAL DEVICE shall at all times act as independent parties without the right or authority to bind the other with respect to any agreement, representation or warranty made with or to any third party. Except as otherwise stated herein, supplier and MEDICAL DEVICE each shall be responsible for all costs, expenses, taxes and liabilities arising from the conduct of its own business, as well as from the activities of its officers, directors, agents or employees, and each shall hold harmless and indemnify the other from any such obligations.

ARTICLE XIV

TERMINATION

14.1 Termination. Except as otherwise stated herein, this Agreement may be terminated upon the happening of one or more of the following events:

(a) By either party (i) in the case of a material breach by the other party of any one or more of the terms of this Agreement which is not remedied within thirty (30) days after receipt of written notice of the breach by the terminating party, or if such breach cannot reasonably be cured with such thirty (30) day period, if the breaching party has failed to commence such cure within such period and diligently prosecute such cure to completion within a reasonable time thereafter; and (ii) in the case of a pattern of persistent material breach, regardless of whether such persistent breaches are remedied within thirty (30) days after receipt of written notice of the breach.

(b) Immediately by either party in the event that the other party attempts to assign this Agreement without the written consent of the other party, except that MEDICAL DEVICE may assign this Agreement to a subsidiary or affiliate of MEDICAL DEVICE without the consent of Supplier. Notice of such assignment to a subsidiary or affiliate of MEDICAL DEVICE shall be provided to Supplier.

(c) Immediately by either party if the other party files a petition in bankruptcy or a petition in bankruptcy is filed against the other party which is not vacated within sixty (60) days or other party becomes insolvent or makes an assignment for the benefit of creditors or any arrangement pursuant to any bankruptcy law.

(d) By MEDICAL DEVICE for any or no reason, with or without cause upon the giving of not less than sixty (60) days prior written notice. Notwithstanding MEDICAL DEVICE's termination of the Agreement pursuant to this section 14.1(d), it shall be responsible for payment and take delivery of any Product under a firm Purchase Order in effect as of the date of notice of termination, provided all terms and conditions of this Agreement shall apply to such Product.

14.2 Rights upon Termination.

(a) Upon termination, MEDICAL DEVICE shall purchase from Supplier all inventories of Products, subject to the terms of this Agreement. Unless otherwise directed by MEDICAL DEVICE, Supplier shall complete all work in process on Purchase Orders received prior to termination . Supplier and MEDICAL DEVICE shall confer and cooperate with one another so that, insofar as is reasonably practicable, and consistent with the requirements of MEDICAL DEVICE, the quantity of Raw Materials remaining on the termination date are minimized. MEDICAL DEVICE shall remove such inventories of Products and all artwork, advertising and packaging and other MEDICAL DEVICE property from the Facility at its own cost and expense within thirty (30) day following termination.

(b) Upon termination, MEDICAL DEVICE shall remove all Equipment owned by MEDICAL DEVICE as identified in Schedule 13.2(b) located at the Facility at its own cost and expense within sixty (60) days following termination. In the event that any capital equipment is jointly owned by MEDICAL DEVICE and Supplier, Supplier shall have first option to purchase MEDICAL DEVICE's share of ownership for a cost equal to MEDICAL DEVICE's portion of the Book Value of the equipment. If supplier makes no offer of ownership, then Supplier will sell its share to MEDICAL DEVICE at a cost equal to Supplier's portion of the Book Value of the equipment. Supplier and MEDICAL DEVICE shall mutually agree prior to purchase of any such equipment on the depreciation schedules to be used by MEDICAL DEVICE and Supplier.

ARTICLE XV

FORCE MAJEURE

Neither party shall be liable for delay or failure in the performance of any of its obligations under this Agreement if and to the extent such delay or failure is due to circumstances beyond the reasonable control of such party, including but not limited to fires, floods, explosions, accidents, acts of God, war, riot, strike, lockout or other concerted acts of workers, acts of government and shortages of materials; provided, however, that the party claiming that "force majeure" has affected its performance shall give notice to the other party within ten (10) days of becoming aware of the occurrence of force majeure, giving full particulars of the cause or event and the date of first occurrence thereof. The party claiming force majeure shall use its best efforts to eliminate or prevent the cause so as to continue performing its obligations under this Agreement.

ARTICLE XVI

INDEMNITY AND INSURANCE

16.1 Indemnification of MEDICAL DEVICE. From and after the date hereof, Supplier shall indemnify, defend and hold harmless MEDICAL DEVICE from and against any and all damages, losses, obligations, deficiencies, liabilities, costs, expenses, penalties, claims and encumbrances, including, without limitation, attorneys' fees and disbursements, resulting from and arising out of (a) any breach of warranty hereunder or material nonfulfillment or nonperformance by Supplier of any agreement, covenant or obligation of Supplier under this Agreement; or (b) bodily injury arising in connection with or resulting from the manufacture of Product or from a manufacturing defect in any Product manufactured by Supplier other than in accordance with the Specifications, including the cost of defending such claims.

16.2 Indemnification of Supplier. MEDICAL DEVICE agrees to indemnify, defend, and hold harmless Supplier from and against any and all claims, causes, actions or liability arising from MEDICAL DEVICE's acts or omissions which may be brought by any party, relative to the formulation use, sale, distribution,

advertising and/or marketing of the Products, provided such claims, causes, actions or liability are not the result of Supplier's failure to manufacture Products in accordance with this Agreement.

16.3 Notice. As a prerequisite for indemnification hereunder as soon as the party claiming indemnification has actual notice of the matter for which indemnification is sought, it shall give prompt notice of such matter to the party claimed to be responsible for indemnification with the right to conduct any investigation reasonably necessary and to control the defense, appeal and settlement of the matter with the cooperation of the other party, its employees and agents as may be reasonably requested to be provided at its expense.

16.4 Survival. The indemnification contained herein shall survive inspection and acceptance of the Products by MEDICAL DEVICE, and shall survive any termination of this Agreement

ARTICLE XVII

RIGHTS AND LICENSES

17.1 Technology License. MEDICAL DEVICE hereby grants to the Supplier a non-exclusive and non-transferable right and license to use the Technology solely for the manufacture of the Products to be supplied to MEDICAL DEVICE in accordance with the terms of this Agreement.

17.2 No Ownership. Supplier expressly acknowledges and agrees that, other than the rights and licenses granted under this Agreement, it has no right or claim to any other rights to use the Technology or manufacture the Products or to any modification, alteration or improvement to the Technology or Product made by Supplier.

17.3 Termination of License. Upon the expiration or termination of this Agreement, the supplier's right to use the Technology shall terminate and the Supplier shall immediately upon such termination cease using the Technology, and return all copies of Technology, including any software, to MEDICAL DEVICE.

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ARTICLE XVIII

NOTICES

Any notice, request, instruction or other communication required or permitted to be given under this agreement shall be in writing and shall be given by sending such notice properly addressed to the other party's address shown below (or any other address as either party may indicate in Schedule 1.7 or by notice in writing to the other from time to time) by prepaid registered or certified mail, return receipt requested. All such notices shall be deemed given when received:

If to Supplier: _____
_____
_____
Attn: President

If to MEDICAL DEVICE: MEDICAL DEVICE XXXXXX Div.
XXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX
Attn: Contract Administrator

With a copy to: MEDICAL DEVICE Incorporated
One MEDICAL DEVICE Place
Attn: General Counsel

ARTICLE XIX

MISCELLANEOUS

19.1 No Assignment. Except as otherwise provided herein, neither party may assign this Agreement without the prior written consent of the other party hereto, which shall not be unreasonably withheld, provided MEDICAL DEVICE may assign the agreement to a wholly owned subsidiary or affiliate of MEDICAL DEVICE without Supplier's consent. Notice of such assignment to a wholly owned subsidiary or affiliate of MEDICAL DEVICE shall be provided to Supplier.

19.2 Enforceability. The parties hereto agree that this Agreement shall be legally binding upon them and their respective legal representatives, successors and permitted assigns.

19.3 Entire Agreement. This Agreement contains the entire understanding of the parties relating to the subject matter hereof, and supersedes all prior discussions and agreements between them with respect to the specific subject matter herein contained, and, except as set forth herein, neither party shall be bound by any definition, condition, warranty, or representation other than as expressly stated in this Agreement or as subsequently set forth in any instrument in writing signed by an authorized officer of the party to be charged.

19.4 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the United States and the State of New York as applied by the courts therein, without reference to its provisions regarding conflicts of laws.

IN WITNESS WHEREOF, the parties hereto have read and executed this Agreement and have set their hands and seals hereto as of the day and year first above written.

MEDICAL DEVICE INCORPORATED

By: _____

Title: _____

Date: _____

SUPPLIER

By: _____

Title: _____

Date: _____

(remainder left intentionally blank)

Schedule 1.7

FORM OF DESCRIPTION OF PRODUCTS/SPECIFICATIONS AND PRICES

Product Name:

Product Price:

Specifications (See Attached)

Facility of Manufacture:

Product Specific Modifications to Supply Agreement (if any)

Notices to MEDICAL DEVICE regarding this Product shall be sent to:

Equipment for Product (if any) and any obligations/restirctions related thereto:

Additional terms:

Schedule 3.5

FORM OF CERTIFICATE OF ANALYSIS

Schedule 4.4

Capital Equipment

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement"), dated as of _____, 20XX, by and between _____ ("Supplier") and Medical Devices Incorporated ("MEDICAL DEVICES").

WITNESSETH

WHEREAS, MEDICAL DEVICES does currently or desires in the future to market, distribute and sell certain products under trademarks owned by MEDICAL DEVICES; and

WHEREAS, MEDICAL DEVICES desires to engage Supplier as a source of supply for the product(s) (as more particularly defined herein below), and Supplier desires to manufacture and supply such products to MEDICAL DEVICES, subject to and in accordance with the terms of this Agreement; and

WHEREAS, this Agreement may be used for supply of product to MEDICAL DEVICES and its wholly owned subsidiaries.

NOW, THEREFORE, in consideration of the foregoing premises, the respective representations, warranties, covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

ARTICLE I

DEFINITIONS

Unless otherwise defined in this Agreement, all capitalized terms used herein shall have the following meanings:

1.1 Batch Records. "Batch Records" shall mean batch records developed by the Supplier in the course of manufacturing separate lots of the Products.

1.2 cGMP. "cGMP" means the current good manufacturing practice regulations promulgated by FDA pursuant to the FDC Act. For Products that are drugs, the relevant regulations shall include 21 CFR 211. For Products that are medical devices, the relevant regulations shall include 21 CFR 820.

1.3 Facility. "Facility" shall mean the Supplier's facility located at _____.

1.4 Equipment. "Equipment" shall mean any equipment or machinery purchased by Supplier or provided by MEDICAL DEVICES to Supplier specifically for the purpose of manufacturing Product. Equipment shall be installed, qualified and verified by Supplier at Supplier's Facility, subject to MEDICAL DEVICES's prior written approval.

1.5 FDA. "FDA" means the Food and Drug Administration of the United States of America and/or any other governmental or regulatory agencies as may regulate or control the sale of drugs in the Territory.

1.6 FDC Act. "FDC Act" means the Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated pursuant thereto.

1.7 Product(s). "Product(s)" shall mean those finished product(s) described on a schedule 1.7, a form of which is attached hereto and any and all mutually agreed additions or deletions which MEDICAL DEVICES may make with respect thereto during the term of this Agreement. It is anticipated that multiple Products may be sourced from Supplier pursuant to this Agreement, meaning that multiple schedules 1.7 may exist.

1.8 Raw Materials. "Raw Materials" shall mean all raw materials, supplies components and packaging necessary to manufacture the Products in accordance with the Specifications.

1.9 Specifications. "Specifications" as it relates to each Product shall refer to the Raw Materials, manufacturing, labeling, packaging, quality assurance testing, and other specifications for each Product, and any and all improvements, modifications, additions and deletions which MEDICAL DEVICES may make with respect thereto during the term of this Agreement. Such improvements, modifications, additions and deletions to the Specifications shall only be effective when approved by MEDICAL DEVICES in writing. The Specifications for each particular product shall be set forth in the relevant schedule 1.7.

1.10 Technology. "Technology" shall mean the technical knowledge, Specifications and any other know-how owned by MEDICAL DEVICES relating to the manufacture of the Products, including any confidential and proprietary information which MEDICAL DEVICES owns or controls pertaining to the manufacture of the Products.

ARTICLE II

TERM

2.1 Term. The term of this Agreement shall commence on the date hereof and shall continue for a term of five (5) years unless extended or terminated in accordance with the terms of this Agreement (the "Term").

2.2 Option Years. MEDICAL DEVICES shall have the right to extend this Agreement for additional periods of one (1) year each (the "Renewal Year(s)") by delivery of written notice to Supplier at least thirty (30) days prior to the end of the Term or any Renewal Year. Each Renewal Year shall be subject to the terms and conditions hereof unless otherwise agreed in writing by the parties. For purposes of this Agreement "Term" shall refer collectively to the Term under Section 2.1 hereof and the Renewal Year(s) under section 2.2 hereof.

ARTICLE III

SUPPLY OF PRODUCTS

3.1 Supply. During the Term, Supplier shall manufacture and supply to MEDICAL DEVICES Product, as and when ordered by MEDICAL DEVICES, in accordance with the ordering, manufacturing, delivery, payment and other provisions hereof. This is not a requirements contract and Supplier is not awarded any exclusive right to manufacture any one or more Product.

3.2 Resources. During the Term, Supplier agrees to devote sufficient organizational, financial and personnel resources necessary to perform its obligations under this Agreement, including maintaining capacity to manufacture and deliver to MEDICAL DEVICES Products as described at Section 3.1 hereof.

3.3 Adherence to Specifications. During the Term, Supplier shall manufacture the Products in strict accordance with the Specifications and cGMPs. In the event MEDICAL DEVICES desires to make changes that are required by the FDA or other regulatory body that affects or impacts manufacturing, testing or the supply of Product, MEDICAL DEVICES shall provide written notice to Supplier prior to making any such change and shall consult with Supplier regarding such change,

and Supplier shall make any such change. During the term of this Agreement, if MEDICAL DEVICES desires to amend or make changes to any applicable regulatory filings or any other changes that are not required by the FDA that affects or impacts the manufacturing, testing or supply of Product, MEDICAL DEVICES shall provide written notice to Supplier of such proposed change and shall consult and obtain Supplier's written approval regarding such change. Supplier's approval shall not be unreasonably withheld, and MEDICAL DEVICES shall pay to Supplier such increased out-of-pocket costs to manufacture Product(s).

3.4.1 Raw Materials. Supplier shall be responsible for securing, inspecting and releasing adequate Raw Materials based upon MEDICAL DEVICES's requirements as contained in purchase orders submitted by MEDICAL DEVICES. MEDICAL DEVICES shall provide Raw Material specifications and may recommend suppliers. In certain instances, MEDICAL DEVICES may insist on a specific supplier to be used for Raw Material. In such an event, the suppliers will be specified in the relevant schedule 1.7.

3.5 Testing and Inspection of Product. Supplier shall conduct all quality control and other tests required to insure that Product as manufactured meets the mutually agreed upon Specifications. The cost of all such analysis, testing and evaluation shall be borne by Supplier. Supplier shall provide MEDICAL DEVICES with a Certificate of Analysis for each lot of Product, such Certificate of Analysis being in the form as attached in Schedule 3.5.

ARTICLE IV

ORDERING AND PRICES

4.1. Ordering/Quantities. Upon execution of this Agreement, MEDICAL DEVICES shall submit to Supplier a forecast listing MEDICAL DEVICES's requirements for Products for the subsequent twelve (12) months, on a rolling basis, with the first three (3) months constituting a firm Purchase Order ("Purchase Order") and the remaining nine (9) months a non-binding forecast of MEDICAL DEVICES's projected requirements for Products. Each month thereafter MEDICAL DEVICES will submit subsequent rolling forecasts constituting a firm Purchase Order for the next three (3) months and non-binding forecasts for the subsequent nine (9) months. Order quantities should approximate full batch sizes understanding there may be yield gain/loss incurred during the manufacturing process.

4.2. Excess Quantities. Notwithstanding anything contained herein to the contrary, MEDICAL DEVICES may submit a Purchase Order for quantities in excess of the quantities specified in MEDICAL DEVICES's firm portion of the forecast, and Supplier shall accept and satisfy such orders subject to Supplier's production capacity.

4.3 Prices. The prices for Product(s) sold to MEDICAL DEVICES shall be as set forth in each Schedule 1.7 (the "Prices"). Prices shall remain fixed during the Term, provided Prices may be modified based on changes in Supplier's cost to manufacture Product.Supplier shall supply MEDICAL DEVICES with not less than ninety (90) days prior written notice of any such prices change accompanied by written documentation of such change, such change to be effective for any Purchase Order submitted after the date the price change becomes effective.. Any price changes must be mutually agreed to by the parties.

4.4 Payment Terms. MEDICAL DEVICES shall pay for each order within forty-five (45) days of receipt of Supplier's invoice. The parties shall consider moving to electronic settlement of invoices provided appropriate capability exists.

ARTICLE V

DELIVERY

5.1 Shipment/Delivery Requirements. All Product(s) shall be properly packed, marked and shipped in accordance with Specifications and instructions for shipping and packaging included in the MEDICAL DEVICES Purchase Order in a format previously agreed upon by the parties. Shipments shall be routed by Supplier in accordance with the Purchase Order. Unless otherwise agreed in writing by the parties, each firm order of the Products shall be delivered to MEDICAL DEVICES's specified receiving dock by the date provided in each purchase order. Supplier, because of unforeseen transportation issues may deliver Product within three (3) days prior to the Purchase Order date and one (1) day later than Purchase Order date. MEDICAL DEVICES may deduct two (2%) percent of the invoice price for each ten (10) days delay of Product beyond the date specified in each Purchase Order.

5.2 Alternate Delivery Point. At the request and expense of MEDICAL DEVICES, Supplier shall ship any of the Products ordered by MEDICAL DEVICES by such carrier or carriers as MEDICAL DEVICES may designate to such warehouse, facility or other location, as MEDICAL DEVICES may designate. Such shipping instructions as provided by MEDICAL DEVICES to Supplier shall be reasonable. If Supplier fails to comply with the shipping

instructions as specified by MEDICAL DEVICES resulting in excess transfer and/or storage charges, such excess charges shall be the responsibility of Supplier.

5.3 Terms. Shipping terms shall be F.O.B. Supplier's shipping dock, freight collect.

ARTICLE VI

INSURANCE: RISK OF LOSS

6.1 During the term of this agreement Supplier shall, at its sole cost and expense, procure and maintain:

(a) Commercial General Liability insurance including coverage for products/completed operations with annual limits of liability in an amount not less than $1,000,000 per occurrence; $1,000,000 general aggregate; and $3,000,000 products/completed operations aggregate, or their equivalent in non-US locations. This insurance shall also name Medical Devices Incorporated and its subsidiaries as an additional insured. This insurance shall be primary and any insurance maintained by MEDICAL DEVICES shall be considered excess over Supplier's insurance.

(b) Workers' Compensation insurance in accordance with statutory requirements including Employer's Liability with limits in an amount not less than $1,000,000 each accident/disease, or its equivalent in non-US locations. The policy shall include a waiver of subrogation in favor of MEDICAL DEVICES.

6.2. During the term of this agreement MEDICAL DEVICES shall procure and maintain Global Transit insurance including warehouse to warehouse coverage for all property in transit in which MEDICAL DEVICES has an insurable interest, with limits of $4,000,000 per shipment, or its equivalent in non-US locations. Further, Supplier shall not procure this coverage for shipments to MEDICAL DEVICES nor charge MEDICAL DEVICES for such coverage, but will be responsible for notifying MEDICAL DEVICES no less than 72 hours in advance of any single shipment which will exceed the $4,000,000 limit, so MEDICAL DEVICES may place the necessary additional insurance coverage.

6.3. During the term of this agreement Supplier shall notify MEDICAL DEVICES in writing within 24 hours of a major business interruption and/or

natural catastrophe that may prevent or delay the delivery of goods to MEDICAL DEVICES.

6.4. All insurance policies required hereunder shall be endorsed to provide MEDICAL DEVICES with no less than 30 days prior written notice in the event of cancellation, non-renewal or material changes. The insurance company(s) providing these policies shall have a current A.M. Best rating of A- or better, and shall be licensed to do business in the applicable jurisdiction. A certificate of insurance evidencing such insurance coverage will be provided to MEDICAL DEVICES upon execution of this agreement and no less than 14 days prior to renewal of said insurance policies. The certificate of insurance shall indicate that the above 30 day notice provision applies.

6.5 Risk of Loss. Unless otherwise agreed by the parties hereto all risk of loss or damage to the Products from any cause whatsoever shall be borne by Seller until delivery of the Products to, and acceptance by, MEDICAL DEVICES or MEDICAL DEVICES's carrier at the F.O.B. Shipping Point.

ARTICLE VII

ACCEPTANCE AND CLAIMS

7.1 Inspection/MEDICAL DEVICES Quality Control Tests.

(a) All of the Products shall be received subject to MEDICAL DEVICES's inspection and may be rejected if found not to conform to the Specifications or otherwise fail to be as warranted hereunder. Within thirty (30) days of delivery to MEDICAL DEVICES, MEDICAL DEVICES may undertake its own quality control tests to ensure that the Products delivered have been manufactured by Supplier in accordance with the terms of this Agreement. MEDICAL DEVICES shall be deemed to have accepted each order delivered if supplier does not receive written notice to the contrary within the same thirty (30) day period. Such acceptance is subject to revocation upon later discovery of any latent defect in any of the Products delivered.

(b) Subject to MEDICAL DEVICES's written request, prior to releasing Products satisfying Purchase Orders hereunder, Supplier shall deliver to MEDICAL DEVICES a statistically significant and representative sample of Products from each production lot ("Pre-Delivery Samples") for inspection by MEDICAL DEVICES, and copies of the corresponding

Batch Records and quality assurance testing records. Upon receiving such a request for Pre-Delivery Samples, Supplier shall not release any Products satisfying Purchase Orders until MEDICAL DEVICES has accepted the Pre-Delivery Samples, provided, however, that MEDICAL DEVICES shall be deemed to have accepted the Pre-Delivery Samples if Supplier does not receive written notice to the contrary within forty-five (45) days of MEDICAL DEVICES's receipt of the Pre-Delivery Samples.

(c) Any dispute between MEDICAL DEVICES and Supplier relating to the conformity of the Products to the Specifications shall be resolved in accordance with the procedures set forth in Section 9.3. Any acceptance by MEDICAL DEVICES hereunder may be revoked by MEDICAL DEVICES upon later discovery of any defect in any of the Products delivered not discoverable by the quality assurance testing of Supplier.

7.2 Rejection by MEDICAL DEVICES. All claims for alleged defects or nonconformance which may be discovered by visual inspection or shortages (not attributable to the carrier) shall be reported in writing to Supplier within thirty (30) days of receipt of Products at the destination designated on MEDICAL DEVICES's Purchase Order. All claims for alleged defects which could not be discovered by visual inspection upon arrival at the designated destination shall be reported within thirty (30) days of delivery to MEDICAL DEVICES. At Supplier's request, MEDICAL DEVICES shall promptly supply either some of the Products which are allegedly defective or some other evidence of deficiency which Supplier shall specify. MEDICAL DEVICES will segregate those Products containing alleged defects and hold them for a period of at least thirty (30) days for inspection by Supplier. Supplier shall replace the Products found to be defective or short in quantity with such quantity of the Products in good salable condition to satisfy MEDICAL DEVICES's Purchase Order requirements or shall issue a credit to MEDICAL DEVICES for the prorated invoice including shipping costs incurred, whichever MEDICAL DEVICES shall elect.

ARTICLE VIII

WARRANTY

8.1 Warranty. Supplier warrants to MEDICAL DEVICES that the Products supplied to MEDICAL DEVICES pursuant to this Agreement will (i) comply in all respects with the Specifications; (ii) be free from defects in manufacturing and materials when such Products leave Supplier's possession; (iii) shall not be adulterated or misbranded under the meaning of the FDC Act; and (iv) shall be

manufactured and packaged in a FDA approved manufacturing facility and shall be manufactured and packaged in a manner which complies with the Specifications and cGMP regulations and applicable FDA regulations pertaining to the Products. The foregoing warranties are in lieu of all other expressed and implied warranties, including without limitation the implied warranties of merchantability and fitness for a particular purpose. There are no oral promises, representations or warranties collateral to or affecting this Agreement.

8.2 Survival. This warranty shall survive inspection and acceptance of the Products by MEDICAL DEVICES, and shall survive any termination of this Agreement.

ARTICLE IX

ADDITIONAL OBLIGATIONS OF SUPPLIER

9.1 Quality Assurance. Supplier shall manufacture Products in accordance with cGMP's, and FDA guidelines. Supplier shall meet all compliance and cGMP Practices established by Regulatory Authorities. In addition, Supplier shall perform semi annual process simulations, annual sterilization revalidations and Product validations every three years in accordance with ISO 13408 (Media Fills).

9.2 MEDICAL DEVICES On-Site Access. Supplier shall permit MEDICAL DEVICES representatives (at MEDICAL DEVICES's expense) to be present during the manufacture of Product(s) as requested by MEDICAL DEVICES.

9.3 Quality Control Inspections. Upon reasonable notice, Supplier shall permit representatives of MEDICAL DEVICES to observe all quality control testing, and investigations, inspect all quality control documentation and reject Products that do not conform with the Specifications based upon Supplier's or MEDICAL DEVICES's test results. In the event of any dispute between MEDICAL DEVICES and Supplier as to whether any Products conform with the Specifications, samples of the units in dispute shall be sent by MEDICAL DEVICES and Supplier to a testing laboratory mutually agreed to by MEDICAL DEVICES and Supplier, whose findings shall be binding In the terms of financial impact the ultimate release decision however, will remain with MEDICAL DEVICES on the parties except in cases of gross and manifest error. The cost of such testing shall be borne by the party whose position is not upheld by testing laboratory.

9.4 Quality Assurance Audits. MEDICAL DEVICES's authorized representatives may conduct reasonable in-depth quality assurance audits of the Facility, including analytical laboratories. Such audits shall be arranged by mutual agreement of the parties but in no event later than three (3) business days

after MEDICAL DEVICES reasonably requests an audit. Such audits may include all aspects of the Facility related to the manufacture of the Products and all procedures, operations and quality control records with respect thereto. MEDICAL DEVICES's authorized representatives will be permitted by Supplier to enter the Facility during business hours to (all of the following with respect to records, procedures operations, and materials relating to the manufacture of Products for MEDICAL DEVICES):

(i) inspect manufacturing and quality control records;

(ii) observe quality control testing operations;

(iii) inspect Raw Materials, lots of Products in process, finished Products, equipment and other facilities used to manufacture, store or package the Products; and

(iv) make at MEDICAL DEVICES's expense such tests and other inspections as MEDICAL DEVICES reasonably deems necessary.

Supplier shall provide MEDICAL DEVICES with a reasonable number of copies of quality control and manufacturing records of the Products and to take random samples of the Products at any stage of manufacture or packaging at no charge to MEDICAL DEVICES; provided that MEDICAL DEVICES shall exercise best efforts to minimize any disruption to Supplier's operations in connection therewith.

9.5 Record Maintenance/Availability. Supplier shall maintain during, and deliver to MEDICAL DEVICES after, the Term, manufacturing and packaging records for each production lot, including Batch Records and records of quality control tests. These records shall be maintained during the Term and shall not be destroyed, even after expiration or termination of this Agreement without MEDICAL DEVICES's prior written consent. Upon termination or expiration of this Agreement, or upon the cessation of Supplier's manufacture of a particular Product, MEDICAL DEVICES shall take possession of such records. These records shall be promptly provided to MEDICAL DEVICES during the Term at its request.

9.6 Inability to Perform. Supplier shall notify MEDICAL DEVICES immediately in writing whenever it has reason to believe that it may be, or may become, unable to perform any of the terms of this Agreement. If Supplier is unable to perform within 30 days, MEDICAL DEVICES may cancel any existing firm Purchase Order or portion thereof and shall have the right to have Products produced at another supplier or to manufacture Products within its own facilities without penalty.

9.7 Investigations of Returned Materials. Supplier will cooperate with MEDICAL DEVICES in the investigation of any Product returned to MEDICAL DEVICES if the initial investigation implicates, in MEDICAL DEVICES's reasonable judgment, any activity of Supplier. Such cooperation shall commence within two days of receiving notification from MEDICAL DEVICES.

9.8 Pre-Shipping Requirements. Supplier shall not deliver any Products to MEDICAL DEVICES unless and until the Products have cleared or passed Supplier's quality assurance testing and other procedures designed to ensure conformity with the Specifications. At MEDICAL DEVICES's option, Supplier shall ship Products to such warehouse, facility or other location, as MEDICAL DEVICES may designate in "quarantine" subject to Products final acceptance under Articles VII.

9.9 Product Complaints. Any Product complaint reports received by Supplier will be faxed to the MEDICAL DEVICES within two (2) business days at:

Medical Devices, Inc.
Complaints Department
Fax:

Supplier will investigate and respond to all complaints associated with the manufacture of Product only as requested by MEDICAL DEVICES. Upon such a request, Supplier shall investigate the complaint within fourteen (14) business days and provide a written summary to MEDICAL DEVICES.

MEDICAL DEVICES will investigate all other product complaints associated with Product not related to the manufacture of the Product.

9.10 Notice From Government Authority. In the event Supplier receives any communication, memorandum or other correspondence from any government agency or authority concerning the Product(s) Supplier shall provide a copy of same to MEDICAL DEVICES within forty-eight (48) hours after receipt thereof.

9.11 Recalls. In the event Supplier believes a recall, field alert, Product withdrawal or field correction may be necessary pursuant to any Product provided under this Agreement, Supplier shall immediately notify MEDICAL DEVICES in writing. Supplier will not act to initiate a recall, field alert, Product withdrawal or field correction without the express prior written approval of MEDICAL DEVICES. In the event MEDICAL DEVICES believes a recall, field alert, Product withdrawal or field correction may be necessary pursuant to any Product provided under this Agreement, MEDICAL DEVICES shall immediately notify Supplier in writing and Supplier shall provide all necessary cooperation and assistance to MEDICAL DEVICES.

The cost of any recalls will be borne by Supplier if the recall is due to a failure of Product(s) to meet the Specifications or other manufacturing non-conformance attributable to Supplier. Supplier shall be solely responsible for reporting to the FDA all post-marketing adverse drug experiences (ADE's) as required by 21 CFR 214.80. MEDICAL DEVICES will notify Supplier concurrently, of any adverse drug reactions coming to its attention during the term of the Agreement.

ARTICLE X

TECHNOLOGY TRANSFER

MEDICAL DEVICES shall furnish Supplier with one (1) copy of all Technology , including but not limited to process sheets, raw material and process specifications, manuals, vendors lists, and other writings and any software with respect to each Product, which may be required by Supplier to manufacture and package the Product(s) according to Specifications. Supplier agrees that MEDICAL DEVICES may use all Technology, information and writings listed in the preceding sentence for the manufacture of Product(s) both during and after the Term of this Agreement.

ARTICLE XI

PACKAGING

All artwork, advertising and packaging information used by Supplier for Product shall be provided to Supplier by MEDICAL DEVICES or approved by MEDICAL DEVICES in writing prior to release of the first shipment of a Product. Such artwork, advertising and packaging information is and shall remain the exclusive property of MEDICAL DEVICES. Such artwork, advertising and packaging information or any reproduction thereof may not be used by Supplier following the termination of this Agreement, or during the Term of this agreement in any manner other than solely for purposes of performing hereunder and Supplier shall indemnify, defend and hold MEDICAL DEVICES harmless in the event it is in breach of this provision.

ARTICLE XII

CONFIDENTIALITY

Supplier agrees to keep confidential and not, without the prior written consent of MEDICAL DEVICES, to publish, disclose to any third party or use (except for purposes of performance under this Agreement) (a) any business information or plans of MEDICAL DEVICES, (b) the Technology supplied by MEDICAL DEVICES to Supplier in connection with this Agreement, and (c) any documentation and materials specifically developed or prepared by Supplier in performance of its duties under this Agreement and based on Technology supplied by MEDICAL DEVICES. The obligations of this paragraph do not pertain to information which is or becomes generally known to the public through no fault of Supplier. At termination of this Agreement, all such information shall be returned to MEDICAL DEVICES.

ARTICLE XIII

INDEPENDENCE OF THE PARTIES

Supplier and MEDICAL DEVICES shall at all times act as independent parties without the right or authority to bind the other with respect to any agreement, representation or warranty made with or to any third party. Except as otherwise stated herein, supplier and MEDICAL DEVICES each shall be responsible for all costs, expenses, taxes and liabilities arising from the conduct of its own business, as well as from the activities of its officers, directors, agents or employees, and each shall hold harmless and indemnify the other from any such obligations.

ARTICLE XIV

TERMINATION

14.1 Termination. Except as otherwise stated herein, this Agreement may be terminated upon the happening of one or more of the following events:

(a) By either party (i) in the case of a material breach by the other party of any one or more of the terms of this Agreement which is not remedied within thirty (30) days after receipt of written notice of the breach by the terminating party, or if such breach cannot reasonably be cured with such thirty (30) day period, if the breaching party has failed to commence such cure within such period and diligently prosecute such cure to completion within a reasonable time thereafter; and (ii) in the case of a pattern of persistent material breach, regardless of whether such persistent breaches are remedied within thirty (30) days after receipt of written notice of the breach.

(b) Immediately by either party in the event that the other party attempts to assign this Agreement without the written consent of the other party, except that MEDICAL DEVICES may assign this Agreement to a subsidiary or affiliate of MEDICAL DEVICES without the consent of Supplier. Notice of such assignment to a subsidiary or affiliate of MEDICAL DEVICES shall be provided to Supplier.

(c) Immediately by either party if the other party files a petition in bankruptcy or a petition in bankruptcy is filed against the other party which is not vacated within sixty (60) days or other party becomes insolvent or makes an assignment for the benefit of creditors or any arrangement pursuant to any bankruptcy law.

(d) By MEDICAL DEVICES for any or no reason, with or without cause upon the giving of not less than sixty (60) days prior written notice. Notwithstanding MEDICAL DEVICES's termination of the Agreement pursuant to this section 14.1(d), it shall be responsible for payment and take delivery of any Product under a firm Purchase Order in effect as of the date of notice of termination, provided all terms and conditions of this Agreement shall apply to such Product.

14.2 Rights upon Termination.

(a) Upon termination, MEDICAL DEVICES shall purchase from Supplier all inventories of Products, subject to the terms of this Agreement. Unless otherwise directed by MEDICAL DEVICES, Supplier shall complete all work in process on Purchase Orders received prior to termination . Supplier and MEDICAL DEVICES shall confer and cooperate with one another so that, insofar as is reasonably practicable, and consistent with the requirements of MEDICAL DEVICES, the quantity of Raw Materials remaining on the termination date are minimized. MEDICAL DEVICES shall remove such inventories of Products and all artwork, advertising and packaging and other MEDICAL DEVICES property from the Facility at its own cost and expense within thirty (30) day following termination.

(b) Upon termination, MEDICAL DEVICES shall remove all Equipment owned by MEDICAL DEVICES as identified in Schedule 13.2(b) located at the Facility at its own cost and expense within sixty (60) days following termination. In the event that any capital equipment is jointly owned by MEDICAL DEVICES and Supplier, Supplier shall have first option to purchase MEDICAL DEVICES's share of ownership for a cost equal to MEDICAL DEVICES's portion of the Book Value of the equipment. If supplier makes no offer of ownership, then Supplier will sell its share to MEDICAL DEVICES at a cost equal to Supplier's portion of the Book Value of the equipment. Supplier and MEDICAL DEVICES shall mutually agree prior to purchase of any such equipment on the depreciation schedules to be used by MEDICAL DEVICES and Supplier.

ARTICLE XV

FORCE MAJEURE

Neither party shall be liable for delay or failure in the performance of any of its obligations under this Agreement if and to the extent such delay or failure is due to circumstances beyond the reasonable control of such party, including but not limited to fires, floods, explosions, accidents, acts of God, war, riot, strike, lockout or other concerted acts of workers, acts of government and shortages of materials; provided, however, that the party claiming that "force majeure" has affected its performance shall give notice to the other party within ten (10) days of becoming aware of the occurrence of force majeure, giving full particulars of the cause or event and the date of first occurrence thereof. The party claiming force majeure shall use its best efforts to eliminate or prevent the cause so as to continue performing its obligations under this Agreement.

ARTICLE XVI

INDEMNITY AND INSURANCE

16.1 Indemnification of MEDICAL DEVICES. From and after the date hereof, Supplier shall indemnify, defend and hold harmless MEDICAL DEVICES from and against any and all damages, losses, obligations, deficiencies, liabilities, costs,

expenses, penalties, claims and encumbrances, including, without limitation, attorneys' fees and disbursements, resulting from and arising out of (a) any breach of warranty hereunder or material nonfulfillment or nonperformance by Supplier of any agreement, covenant or obligation of Supplier under this Agreement; or (b) bodily injury arising in connection with or resulting from the manufacture of Product or from a manufacturing defect in any Product manufactured by Supplier other than in accordance with the Specifications, including the cost of defending such claims.

16.2 Indemnification of Supplier. MEDICAL DEVICES agrees to indemnify, defend, and hold harmless Supplier from and against any and all claims, causes, actions or liability arising from MEDICAL DEVICES's acts or omissions which may be brought by any party, relative to the formulation use, sale, distribution, advertising and/or marketing of the Products, provided such claims, causes, actions or liability are not the result of Supplier's failure to manufacture Products in accordance with this Agreement.

16.3 Notice. As a prerequisite for indemnification hereunder as soon as the party claiming indemnification has actual notice of the matter for which indemnification is sought, it shall give prompt notice of such matter to the party claimed to be responsible for indemnification with the right to conduct any investigation reasonably necessary and to control the defense, appeal and settlement of the matter with the cooperation of the other party, its employees and agents as may be reasonably requested to be provided at its expense.

16.4 Survival. The indemnification contained herein shall survive inspection and acceptance of the Products by MEDICAL DEVICES, and shall survive any termination of this Agreement

ARTICLE XVII

RIGHTS AND LICENSES

17.1 Technology License. MEDICAL DEVICES hereby grants to the Supplier a non-exclusive and non-transferable right and license to use the Technology solely for the manufacture of the Products to be supplied to MEDICAL DEVICES in accordance with the terms of this Agreement.

17.2 No Ownership. Supplier expressly acknowledges and agrees that, other than the rights and licenses granted under this Agreement, it has no right or claim to any other rights to use the Technology or manufacture the Products or to any

modification, alteration or improvement to the Technology or Product made by Supplier.

17.3 Termination of License. Upon the expiration or termination of this Agreement, the supplier's right to use the Technology shall terminate and the Supplier shall immediately upon such termination cease using the Technology, and return all copies of Technology, including any software, to MEDICAL DEVICES.

ARTICLE XVIII

NOTICES

Any notice, request, instruction or other communication required or permitted to be given under this agreement shall be in writing and shall be given by sending such notice properly addressed to the other party's address shown below (or any other address as either party may indicate in Schedule 1.7 or by notice in writing to the other from time to time) by prepaid registered or certified mail, return receipt requested. All such notices shall be deemed given when received:

If to Supplier: _____

_____

_____

Attn: President

If to MEDICAL DEVICES: Medical Devices, Inc.
Attn: Contract Administrator

With a copy to: Medical Devices Incorporated
One Medical Devices Place
Attn: General Counsel

ARTICLE XIX

MISCELLANEOUS

19.1 No Assignment. Except as otherwise provided herein, neither party may assign this Agreement without the prior written consent of the other party hereto, which shall not be unreasonably withheld, provided MEDICAL DEVICES may assign the agreement to a wholly owned subsidiary or affiliate of MEDICAL DEVICES without Supplier's consent. Notice of such assignment to a wholly owned subsidiary or affiliate of MEDICAL DEVICES shall be provided to Supplier.

19.2 Enforceability. The parties hereto agree that this Agreement shall be legally binding upon them and their respective legal representatives, successors and permitted assigns.

19.3 Entire Agreement. This Agreement contains the entire understanding of the parties relating to the subject matter hereof, and supersedes all prior discussions and agreements between them with respect to the specific subject matter herein contained, and, except as set forth herein, neither party shall be bound by any definition, condition, warranty, or representation other than as expressly stated in this Agreement or as subsequently set forth in any instrument in writing signed by an authorized officer of the party to be charged.

19.4 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the United States and the State of New York as applied by the courts therein, without reference to its provisions regarding conflicts of laws.

(remainder left intentionally blank)

IN WITNESS WHEREOF, the parties hereto have read and executed this Agreement and have set their hands and seals hereto as of the day and year first above written.

MEDICAL DEVICES INCORPORATED

By: _____

Title: _____

Date: _____

SUPPLIER

By: _____

Title: _____

Date: _____

(remainder left intentionally blank)

Schedule 1.7

FORM OF DESCRIPTION OF PRODUCTS/SPECIFICATIONS AND PRICES

Product Name:

Product Price:

Specifications (See Attached)

Facility of Manufacture:

Product Specific Modifications to Supply Agreement (if any)

Notices to MEDICAL DEVICES regarding this Product shall be sent to:

Equipment for Product (if any) and any obligations/restirctions related thereto:

Additional terms:

Schedule 3.5

FORM OF CERTIFICATE OF ANALYSIS

Schedule 4.4

Capital Equipment

1.1 RATING SUMMARY/CONTINUOUS IMPROVEMENT SHEET — PRODUCTION SUPPLIERS
CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS

SUPPLIER NAME: _____ DATE:

COMMODITY CODE: RATING THIS ASSESSMENT: _____%
RATING LAST ASSESSMENT: _____%

	1 Awareness	2 Initiation	3 Development	4 Acceptable	5 Outstandig
1.0 Total Quality Management					
1.1 Management Leadership					
1.2 External Customer Involvement & Satisfaction					
1.3 Strategic Quality Planning					
1.4 Human Resource Management					
1.5 Process Quality Management					
1.6 Information Mgmt & Analysis					
1.7 Total Quality Results					
1.8 Social Responsibility & Environmental Impact					
2.0 Quality Systems & Performance					
2.1 Quality Systems Assessment					
2.2 Parts Quality Performance (PPM)					
2.3 SPC Application					
2.4 Corrective Action (C/A) System					
2.5 Sub Tier Supplier Selection & Control					
2.6 Customer Systems Audits (Surveys)					
2.7 Internal System/Procedure Audits					
3.0 Cost					
3.1 Annual Cost Improvement Results					
3.2 RFQ Response Capability					
3.3 Cost Data Base Level Attainment					
3.4 Comprehensive Costing Capabilities					
4.0 Delivery					
4.1 Ex Works Plus In Transit Leadtime					
4.2 Just-In-Time Delivery Capabiities					
4.3 Packaging, Labeling & Shipping Capabilities					
5.0 Materials Management Activities/Processes					
5.1 Leadtime Capability/Flexibility					
5.2 Capacity Loading/Resource Availabilities					
5.3 Sub Tier Supplier Management					
6.0 Technical Support & Facilities Capabilities					
6.1 Continuous Supplier Involvement (CSI)					
6.2 Equipment Capabilities and Safety					
6.3 Present/Future Facilities Capabilities					

GRAND TOTAL SCORED

TOTAL REQUIRED POINTS
(33X4 LESS N/A'S)

CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS
1.0 TOTAL QUALITY MANAGEMENT

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
						SUPPLIER	MD
1.1 Management Leadership	▪ Awareness of the need for Quality Policy.	▪ Quality Policy is viewed as "meeting customer specifications." ▪ Quality Policy is documented.	▪ Quality Policy is service or product focused and is an executive priority. ▪ Management is aware of Quality Policy.	▪ The Senior Executives support Quality Policy for both external and internal customer satisfaction. ▪ Employees are aware of the Quality Policy statement.	▪ Employees are completely empowered to fulfill the organization's Quality Policy. ▪ The organization's Quality Policy is totally customer oriented and widely known.		
1.2 External Customer Involvement & Satisfaction	▪ Sales department is the customer contact. ▪ Awareness of need to address customer complaints. ▪ Awareness of need to measure customer satisfaction.	▪ Sr. executives meets key customers. ▪ Process in place to review customer complaints. ▪ Customer satisfaction metric development.	▪ Sr. executives meets customers, but not a structured approach. ▪ Customer satisfaction is monitored ongoing. ▪ Supplier tracks customer satisfaction metrics.	▪ Sr. executives meets customers in an organized program. ▪ A process is in place to resolve customer problems/concerns. ▪ Goals/targets set for customer satisfaction improvement.	▪ Customer communication is well integrated in ongoing operations. ▪ Customers needs & services are anticipated and continuously improved.		

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
1.3 Strategic Quality Planning	▪ Awareness of need for a strategic Total Quality Management plan and process.	▪ Total Quality Management plan is being developed.	▪ Total Quality Management plan is short term (at least 2 years).	▪ Total Quality Management plans are long term (more than 2 years) with annual milestones defined.	▪ Total Quality Management plans are completely integrated & benchmarked to world class standards.		
1.4 Human Resource Management	▪ Awareness of need for training of employees. ▪ Awareness of the need for employee satisfaction. ▪ Awareness of need for employee involvement.	▪ Training plan is available for job skills and TQM. ▪ Program for employee satisfaction is planned. ▪ Employee involvement approach is being developed.	▪ Total Quality & Skills training is provided to selected employees. ▪ Defined program for employee satisfaction measurement in place. ▪ Employee involvement is selective in company.	▪ Total Quality & Skills training is provided to all employees including Executives. ▪ Employee satisfaction is measured and improvement is actively pursued by management. ▪ Quality teams exists and are encouraged by management.	▪ Management is pursuing professional development, e.g. Certified Procurement Mgr. (CPM), Certified Quality Engineer (CQE), etc. ▪ Employee satisfaction level is monitored with improvement evident. ▪ Cross-functional employee involvement teams are functioning (on-going) with results evident.		
1.5 Process Quality Management	▪ Organizational focus is on control of product quality processes.	▪ Need is recognized to also control business/admin. processes.	▪ Data collection started on business/admin. As well as production and service processes.	▪ Data collected, statistically analyzed, tracked for major business/admin. And production/service processes.	▪ Continuous improvement & optimization of production, service and business/admin. company processes is occurring.		

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
1.6 Information Management & Analysis	▪ Awareness of need for Cost of Quality data. ▪ Awareness of the value of statistical tools for data analysis. ▪ Awareness of need to analyze problems.	▪ Cost of Quality indicators are being planned for products & service. ▪ Statistical analysis is used very little or not at all. ▪ Problem analysis done but process is informal.	▪ Product & service indicators are tracked for some products & services. ▪ Statistical analysis is performed on major processes or services	▪ All major products & service quality indicators are tracked. ▪ Performance metrics & targets are defined for all major processes and services.	▪ Internal & some external cost of quality improvement results exist. ▪ Improvement activities are tracked to defined targets.		
1.7 Total Quality Results	▪ Awareness of Internal/External Customer TQ results. ▪ Need for Total Quality measurement system is known.	▪ Internal/External Customer TQ results are known but not tracked. ▪ Some Total Quality indicators are defined.	▪ Internal/External Customer TQ results are tracked. ▪ Most Total Quality indications are defined.	▪ Internal/External Customer TQ results exhibit consistent improvement trend. ▪ Company Quality indicators are defined.	▪ Process and results management is driven throughout supply chain. ▪ Total Quality indicators, are customer oriented & Continuous Improvement aggressively pursued.		
1.8 Social Responsibility and Environmen-tal Impact	▪ Supplier is aware of need to monitor impact to society. ▪ Awareness of environmental protection responsibilities. ▪ Aware of need for Ozone depleting chemicals (ODC) control. ▪ Aware of need to control process waste. ▪ Aware of need for Waste emission controls.	▪ Occasional review of supplier impact to society. ▪ Emergency/disaster environmental plan only. Not prevention based. ▪ ODC replacement has been started by supplier. ▪ Target waste recycle opportunities identified. ▪ Regulations are understood and company is actively planning for compliance.	▪ Responsibilities assigned to monitor supplier impact to society. ▪ Environmental rules enforced on exception basis for present requirements only. ▪ All ODC chemical usage is identified and phase-out plan is being developed. ▪ Many process waste opportunities on trial basis now. ▪ Non-compliant stream technology and capital allocated.	▪ Process developed to monitor social impact to society, e.g., contributions. ▪ Enforcement of environmental rules is management driven and considers future requirements. ▪ All ODC usage has ceased now or supplier has a phase-out plan. ▪ Virtually all process waste is recycled and remainder is planned for. ▪ Waste streams comply with present omission regulations.	▪ Ongoing monitoring of social impact to society by management. ▪ Environmental protection efforts are recognized by society and are evergreen. ▪ No ODC used by supplier or sub tier suppliers now. ▪ All process waste is recycled/reclaimed. ▪ Zero plant emissions and plans anticipate future regulations.		

CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS
2.0 QULAITY SYSTEMS AND PERFORMANCE

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
						SUPPLIER	MD
2.1 Medical Devices Supplier Quality Systems (Initial certification only)	▪ Aware of need for "Approved" Survey rating. ▪ Survey results	▪ Survey rating is "Cond. Approved for time", and Action Plan is in place.	▪ Acceptable Survey score is 70% or higher for materials	▪ Acceptable survey is required for initial certification and the rating is 80% or more	▪ Survey score is 90% or higher (Production suppliers). ▪ Service supplier has 50% or more elements at Stage 5. ▪ Supplier is ISO 9001 or 9002 registered.		
2.2 Parts Quality Performance Parts per Million (PPM) (See Note for Service Suppliers performance)	▪ Supplier is aware of Problem Supplier process or is a candidate due to high PPM compared to commodity average.	▪ Last 6 months PPM exceeds commodity limit but does not qualify for Problem Supplier process. ▪ More than 6 NCMR's in last 6 months.	▪ Last 6 months PPM exceeds Certification Limit but is below commodity average. ▪ More than 4 but less than 6 NCMR's in last 6 months.	▪ Last 6 months PPM level less than or equal to Certification Limit. ▪ 4 or less NCMR's in last 6 months (problems not related). *	▪ Zero PPM in last 12 months and no supplier responsibility line fallout. ▪ No NCMR's in last 12 months and no supplier responsible Line Fallout.		
2.3 Part or Service Certification Performance	▪ Aware of responsibility to achieve Certification level of parts or service processes to plan.	▪ Certification of parts/service achieved but is driven by SQA and only after frequent replanning.	▪ Certification of parts/service is achieved to PQ plan with SQA support.	▪ Can independently achieve certification for processes (unless otherwise exempted by the Supplies Operation management). *	▪ Supplier is independently planning and achieving part/service certification for all customers products/services.		

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
2.4 Statistical Process Control (SPC) Application	▪ Aware of need to monitor & improve SPC limits. ▪ Awareness of need for control charting.	▪ SPC limits are monitored but no action is taken to improve. ▪ Control charting is done by QC Department in office, real time.	▪ SPC limits are monitored for improvement but no improvement is evident. ▪ Control charting is done by QC Inspector for the person controlling the process, real time.	▪ SPC limits are monitored and improvement is evident. ▪ Control charting is done in real time by the person controlling the process.	▪ Build to nominal is a company goal and results evident. ▪ Process operator uses direct input computer controls for monitoring variables		
2.5 Corrective Action (C/A) System	▪ Awareness of need for solving problems.	▪ C/A is only taken when reported by customers. ▪ C/A's are piece part related only.	▪ C/A is taken for all problems but not formalized system. ▪ C/A's are generally used for specific preventative actions for parts, service and admin.	▪ All problems are formally tracked and analyzed for root cause and C/A effectiveness. ▪ C/A's are generally used for generic preventative actions for parts, service & admin. ▪ Timely and robust C/A response is provided for C/A requests.	▪ All problems are tracked to close out and elevated when required. ▪ Systematic problem analysis over time is done to identify opportunities for continuous improvement. ▪ Timely and robust C/A response is provided for <u>all</u> customers C/A requests.		
2.6 Sub Tier Supplier Selection & Control	▪ Awareness of need for sub-tier supplier selection process. ▪ Supplier uses Line Fallout to judge part quality. ▪ Awareness of need for a part or service order process. ▪ The importance of a problem feedback system is known.	▪ Sub-tier suppliers are selected by lowest cost. ▪ Rec. Insp. is used selectively for some sub-tier supplier parts. ▪ Orders for parts, services and materials are verbally communicated. ▪ Problem feedback system for major problems only.	▪ Sub-tier suppliers are selected based on Quality performance/capability. ▪ Supplier relies on Rec. Insp. verification of sub-tier supplier parts. ▪ Part drawing or purchasing spec. is used to communicate requirements to sub-tier suppliers. ▪ Problem feedback to supplier for all problems (except random).	▪ Supplier uses a system to select sub-tier suppliers based on Quality, Cost, Delivery & Service. ▪ Supplier has a formal acceptance process to assure 100% acceptable parts from their sub-tier suppliers. ▪ Supplier documents quality requirements to their sub-tier suppliers. ▪ Supplier has problem feedback and tracking for all problems and supplier performance.	▪ Supplier approves sub-tier suppliers by on site assessment based on part critically. ▪ Supplier requires PQ of parts by the sub-tier supplier. ▪ Supplier uses CSI with sub-tier suppliers for critical parts/services. ▪ Supplier has a format quality measurement & rating system for their sub-tier suppliers.		

CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS
2.0 QUALITY SYSTEMS AND PERFORMANCE

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
						SUPPLIER	MD
2.7 Customer Systems Audits (Bausch 7 Lomb Surveys)	▪ Supplier is aware of need for customer audits.	▪ Supplier is willing to allow periodic audits.	▪ Supplier supports periodic survey audits.	▪ Supplier will perform periodic systems audits if requested.	▪ Results of audits are tracked & reviewed by supplier mgmt.		
2.8 Internal System/Procedure Audits	▪ Supplier is aware of need for internal systems audits (Self-assessment).	▪ Procedures are randomly reviewed for currentness and compliance. ▪ Results of audits are documented. ▪ Informal C/A follow up by supplier.	▪ Key procedures are reviewed/audited to an informal process. ▪ Results are documented & distributed to mgmt. ▪ Random follow up by mgmt. to close out C/A's.	▪ All procedures are regularly reviewed/audited to documented system. ▪ Results are documented & reviewed by mgmt. ▪ Random follow up by mgmt. to close out C/A's.	▪ All procedures are regularly reviewed/audited to documented system. ▪ Results are documented reviewed by Sr. mgmt routinely. ▪ Regular follow up mtgs. are scheduled until all deficiencies are resolved.		

CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS
3.0 COST

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
						SUPPLIER	MD
3.1 Annual Cost Performance Results	▪ Supplier has contract price over the past 2 months.	▪ Supplier has kept the price the same or shown productivity of 1% over the past 12 months.	▪ Supplier has shown productivity of 2%-4% over the past 12 months.	▪ Supplier has shown productivity of 5% over the past 12 months or has otherwise satisfied Commodity Team requirements. ** ▪ Supplier is actively and continuously pursuing cost savings ideas, both in-house and via change process with MD.	▪ Supplier has shown productivity of 5% per year over the past 24 months. ▪ Supplier has 3 to 5 year plan to capture year over year productivity.		
3.2 Request for Quotes (RFQ) response capability	▪ Supplier able to respond to detailed RFQ's.	▪ Supplier consistently responds to detailed RFQ's in ≤6 weeks.	▪ Supplier consistently responds to detailed RFQ's in ≤ 4 weeks.	▪ Supplier consistently responds to detailed RFQ's in ≤ 2 weeks. ▪ Supplier submits detailed cost breakdowns.	▪ Supplier consistently responds to detailed RFQ's in ≤ 1 week. ▪ Supplier submits detailed cost breakdowns.		
3.3 Cost Data Base Level Attainment	▪ Supplier is typically within 50 percent of MD cost estimate for materials or the service contract estimate.	▪ Supplier is typically within 20 percent of MD cost estimate for materials or service contract.	▪ Supplier is typically within 10 percent of MD cost estimate for materials or service contract.	▪ Supplier typically comes within 5 percent of MD cost estimate without negotiations. ▪ Supplier openly discusses cost information.	▪ Supplier typically comes in at or below MD cost estimate for materials or service contract. ▪ Supplier brings in new ideas that lower cost.		
3.4 Comprehensive Costing Capabilities	▪ Awareness of the need for variable rates. ▪ Awareness of the need to control material mark up and to know what the percentage covers.	▪ Hourly rates based on groups of like equipment, processes, or services. ▪ Defines the content of Material Overhead but some costs are double counted.	▪ Hourly rates set for each piece of equipment, processes, or service activity. ▪ Material Overhead is defined and not double counted.	▪ Hourly rates for each piece of equipment, process or service activity determined via direct costing method. ▪ Applies Material Overhead relaxed to the actual cost of material acquisition.	▪ Cost determined via Activity Based Costing Concept. ▪ Does not apply Material Overhead in normal cases, only in unusual cases.		

CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS
4.0 DELIVERY

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
						SUPPLIER	MD
4.1 Ex works plus intransit leadtime	▪ Aware of need for fast order response.	▪ Less than or equal to 10 weeks delivery.	▪ Less than or equal to 8 weeks delivery.	▪ Less than or equal to 7 weeks deliver (5 weeks or less for STD. Components).	▪ Less than or equal to 4 weeks delivery.		
4.2 Just-In-Time(JIT) Delivery Capabilities	▪ Awareness of step pricing and range pricing of parts. ▪ Contract considers minimum order quantities for all parts. ▪ Contract considers minimum delivery quantities for all parts.	▪ Contract considers step pricing or range pricing for some parts. ▪ Contract considers minimum order quantities for some parts. ▪ Contract considers minimum delivery quantities for some parts. ▪ Supplier has not applied set up reduction techniques.	▪ Contract contains no reference to minimum order quantities, minimum delivery quantities, step pricing or range pricing. ▪ Supplier working to reduce set-up times for JIT delivery. ▪ No delivery quantity limits applied.	▪ Contract contains no reference to minimum buys, minimum order quantities, minimum delivery quantities, step pricing or range pricing. ▪ Supplier has reduced set-up times for JIT delivery. ▪ Supplier uses MD forecasts for delivery. ▪ Supplier is working continuous flow production and adopting work cells to reduce WIP.	▪ Supplier can adjust production in increments of 1 to match orders. ▪ Supplier continuously improves set-up times. ▪ Supplier plans production using forecast and has JIT delivery when requested. ▪ Supplier has optimized work cells minimizing WIP and enabling JIT.		
4.3 Problem supplier list appearance for delivery.	▪ No appearance on list or delivery problems for last 2 months.	▪ No appearance on list or delivery problems for last 4 months.	▪ No appearance on list or delivery problems for last 6 months.	▪ No appearance on list or delivery problems for last 8 months.	▪ No appearance on list or delivery problems for last 24 months.		
4.4 Packaging, Labeling & Shipping Capabilities	▪ Supplier is aware of equipment and need for bar coding. ▪ Aware of need for Bar code label approval.	▪ Bar code capability is present but not used. ▪ Bar code label submitted for approval but not accepted or waiting for feedback.	▪ Bar coded labels being used for some MD orders but not all. ▪ Bar code label has been approved.	▪ Bar Coded labels being used for MD orders submitted.	▪ Bar coded labels totally implemented and utilized for all customers. ▪ Supplier utilizes cost effective returnable packaging that meets customer requirements (where applicable).		

Ex Works = material is ready for shipment on supplier dock

CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS
5.0 MATERIALS MANAGEMENT ACTIVITIES/PROCESSES

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
						SUPPLIER	MD
5.1 Lead-time Capability/ Flexibility	▪ Supplier is aware of the need to respond to MD increases in materials or service requirements. ▪ Supplier understands the need to notify when they will cease to provide parts assemblies or service.	▪ Supplier understands and responds to increased requirements but only with additional lead-time. ▪ Supplier provides at least 1 month notice prior to discontinuing parts, assemblies or service and will continue to provide deliveries for 3 months.	▪ Supplier can handle up to 20% increase in requirements within contract lead-time. ▪ Supplier provides at least 3 month notice prior to discontinuing parts, assemblies or service and will continue to provide deliveries for 6 months.	▪ Supplier can handle more than 20% increase in requirements within contract lead-time. ▪ Supplier provides at least 6 months notice prior to discontinuing parts, assemblies or service and will continue to provide deliveries for 12 months.	▪ Supplier can handle increased requirements of up to 50% within contract lead-time. ▪ Supplier provides at least 1 year notice prior to discontinuing parts, assemblies or service and will continue to provide deliveries for 18 months.		
5.2 Capacity Loading/ Resource Availabilities	▪ Supplier is aware of need to manage production and service planning for maximum utilization.	▪ Part/process/service capability up to 55% utilized.	▪ Plan in place to enable part/process/service capability between 70-90% utilized. ▪ Plan in place for employer cross training.	▪ Part/process/service capability is between 75-90% utilized (assuming 2 shifts/5 day week). ▪ Employees are cross-trained to allow movement to areas of increased workload as required.	▪ Part/process/service capability >90% utilized (assuming 2 shift/5 day week). ▪ Employees are "certified" on specific key equipment/services, processes and jobs. ▪ Process in place to address potential bottlenecks.		
5.3 Sub Tier Supplier Management	▪ Supplier is aware of the need to manage their Sub-tier suppliers for materials and service acquisitions.	▪ Supplier has a plan to manage and develop Sub-tier Suppliers.	▪ Sub-tier supplier base has been condensed and major suppliers identified.	▪ Sub-tier Supplier Base is condensed and providing Q,C,D benefit to the supplier with Year Over Year productivity.	▪ Sub-tier Supplier Base being managed to provide benchmark Q, C, D & S.		

CERTIFIED SUPPLIER ASSESSMENT/BUSINESS REVIEW PROCESS
6.0 TECHNICAL SUPPORT AND FACILITIES CAPABILITIES

ASSESSMENT ELEMENT	STAGE 0-1 AWARENESS	STAGE 2 INITIATION	STAGE 3 DEVELOPMENT	STAGE 4 INTERNALIZATION (ACCEPTABLE)	STAGE 5 DESIRED STATE (OUTSTANDING)	ASSESSMENT RATING	
						SUPPLIER	MD
6.1 Continuous Supplier Involvement (CSI)	▪ Supplier aware of need for their participation in CSI meetings.	▪ CSI meeting attended by Supplier sales person only.	▪ CSI meeting attended by Supplier Technical person only	▪ CSI meeting attended by a swell prepared supplier tech person and key personnel as required. ▪ Supplier actively/ effectively participates in all CSI meetings when requested.	▪ CSI meeting attended as required by Suppliers: ➢ Tool makers ➢ Marketing ➢ Matl supplier ➢ Customer rep ➢ Supplier QC rep ▪ Supplier full support resolution to all CSI concems/action items.		
6.2 Equipment Capabilities and Safety	▪ Supplier aware of need for equipment upgrade, e.g. computerized, automatic, state of art, etc. ▪ Supplier is aware of need to identify Safety risks. ▪ Supplier is aware of need for documented Safety standards. ▪ Supplier is aware of need to assign Safety responsibilities.	▪ Equipment upgrade requirements are regularly reviewed, e.g. computerized, automatic, etc. ▪ Plans in place to determine health & safety risks to employees/customers. ▪ Some documented safety rules & procedures exist. ▪ Safety responsibilities are assigned.	▪ Equipment upgrade being implemented, e.g., computerized, automatic, etc. ▪ Safety and health risks are identified. ▪ Selective monitoring of compliance to safety rules and procedures. ▪ Roles & responsibilities are defined & actively pursued.	▪ Ongoing consideration for equipment upgrade, e.g. computerized, automatic, etc. ▪ Safety and health risks are identified and communicated to personnel. ▪ There are regular safety inspections in the workplace.	▪ Continuously seeks state-of-art technology & development capability with optimum automation. ▪ Workplace has no lost time accidents in past year or since last Assessment. ▪ Safety of employees and customers is management priority.		
6.3 Present/Future Facilities Capabilities	▪ Supplier is aware of importance for a well maintained workplace. ▪ Supplier is aware of need for facilities upgrade.	▪ Maintenance is adequate but poor housekeeping ▪ Supplier has short-term plans only – 1 year.	▪ Workplace maintenance and housekeeping is minimum acceptable. ▪ Long range strategy is developed – 2 years.	▪ Workplace is clean adequately maintained and provides a quality working environment. ▪ Supplier long range facilities strategy is fully developed – 3 years.	▪ Ongoing facility inspection for maintenance, housekeeping and safety. ▪ Supplier has defined and documented long range facilities strategy with clear progress demonstrated toward strategic goals.		

Medical Device, Inc.
Supplier Selection
Supplier Based Management Team

Commodity:

Candidates:

Reviewer:

Date:

Selection:

Justification

Attachments: