

Medical Device Manufacturing and Sales

1. Please provide the following information on **each product "category"** (i.e., scalpels, catheters, stents, etc.):

Domestic Sales:	Product Category:	Product Category:	Product Category:
Current Year:			
Projected Sales:			
Units Sold:			
FDA approved Class I,II,III:			
% Sales to:			
Hospitals/MD's:			
Patients/Home:			
Distributors/ Wholesalers:			
International Sales:	Product Category:	Product Category:	Product Category:
Current Year:			
Projected Sales:			
Units Sold:			
FDA approved Class I,II,III:			
% Sales to:			
Hospitals/MD's:			
Patients/Home:			
Distributors/ Wholesalers:			

2. Have you ever discontinued any products? Yes No

If yes, please provide the date and reason for discontinuation: _____

3. Do your products contain component parts manufactured by others? Yes No

If yes, please explain: _____

4. Do you import products or component parts? Yes No

If yes, please explain: _____

5. Do you subcontract any of your manufacturing (including sterilization) process to others? Yes No

If yes, please describe your controls: _____

Medical Device Manufacturing and Sales (continued)

- 6. Do others install your product? ...
If yes, do you:
- Supervise or furnish installation instructions?
- Sign-off on installation?
7. Are your products available for lease or rent?
If yes, please explain:
8. Do you distribute any products other than what you manufacturer?
If yes, please explain:

Quality Assurance Program/Instructions

- 1. Do you have a risk/quality management program?
If yes, please provide the name and title of person:
2. Please describe (or attach) your QSIT (Quality System Inspectional Technique) process:
3. Please describe (or attach) the procedure for developing product instructions and warnings:
4. How long are your testing and quality control records retained?
5. Please describe the guarantees and/or warranties provided:
6. Please describe your certifications:
7. Does legal counsel review your advertising materials and website content on an annual basis?.....

Other Information

1. Do you use any **external suppliers and/or contract manufacturers**? Yes No
If yes, what limits and terms do you require in their certificates of insurance? _____

2. Do any of your employees or sub-contractors **provide direct patient care**?..... Yes No
If yes, please explain: _____

3. Do you provide any **service agreements** for your products? Yes No
If yes, do you have a formal:
 - Documented preventative maintenance program for all products under a service contract? (*i.e., device id number, date of service, service provided, problems, service provider, etc.*) Yes No
 - Mechanism to notify the customer prior to the service date and products to be serviced? Yes No
 - Procedure to follow if the device requiring preventative maintenance is not available at the time of the scheduled service (*please attach*)?..... Yes No
 - Do you audit your company's compliance with the service agreements? Yes No*If no, please explain:* _____

 - Please attach a copy of your service agreement.

4. Do you provide **product training**? Yes No
If yes, do you:
 - Have a documented training program for each device? Yes No
 - Document and retain the details of each training program (*i.e., Name of attendee, program, trainer, objectives covered, etc.*)?..... Yes No

5. Do you have a **product recall plan**? (*please attach*) Yes No

Future Business Plans

1. Please describe any new product plans (*If your new product involves a clinical trial, please complete a St. Paul Clinical Trials Application.*) Yes No

This application is not a representation that coverage does or does not exist for a particular claim or loss, or type of claim or loss, under any insurance policy issued by The St. Paul. Whether coverage exists or does not exist for a particular claim or loss under such policy depends on the facts and circumstances involved in the claim or loss and all applicable policy wording.

The undersigned is an authorized representative of the prospective Named Insured and certifies that reasonable inquiry has been made to obtain the answers to these questions. He or she certifies that the answers are true, correct and complete to the best of his/her knowledge and belief.

Signing this application shall not constitute a binder or obligate The St. Paul to provide Medical Product Protection, but it is agreed that this application shall be the basis upon which a Policy may be issued.

Fraud Warning Notice: If a state fraud warning notice applies, please attach form #55306 to this application.

FLORIDA REQUIREMENT: Producer's License No.

Applicant's Signature	Title	Date
Agent/Broker Signature	City	Date