

Medical Devices & Biotechnology Products

1. Agency Code: _____ Agency: _____
 2. Phone: _____ Fax: _____ Web site: _____
 3. Producer: _____ E-Mail Address: _____
 4. Assistant: _____ E-Mail Address: _____

Application courtesy of <http://www.insurance-applications.com>

General Information:

5. Business Name (dba): _____
 6. Legal Name: _____ Years In Business: _____
 7. Mailing Address: _____ City: _____ State: _____ Zip: _____
 8. Physical Address: _____ City: _____ State: _____ Zip: _____
 9. Contact Person: _____ Phone: _____ Fax: _____
 10. Email Address: _____ Web site: _____
 11. Type of Entity: Individual Partnership Joint Venture Corporation Other: _____
 12. Effective Date: ____ / ____ / ____ Expiration Date: ____ / ____ / ____ Need By Date: ____ / ____ / ____

Description of Operations & Exposures:

13. _____

Prior Carrier Information:

Carrier	Premium	Policy Number	Effective Date
14. _____	_____	_____	____ / ____ / ____
_____	_____	_____	____ / ____ / ____
_____	_____	_____	____ / ____ / ____
_____	_____	_____	____ / ____ / ____

Claim, Loss & Incident Information:

No losses, claims or incidents

15. Date of Loss	Description of Loss	Amt of Claim or Loss*	Date Valued	Open or Closed?
____ / ____ / ____	_____	_____	____ / ____ / ____	_____
____ / ____ / ____	_____	_____	____ / ____ / ____	_____
____ / ____ / ____	_____	_____	____ / ____ / ____	_____
____ / ____ / ____	_____	_____	____ / ____ / ____	_____

* Amount of Claim or Loss to include all amounts paid or reserved, including defense and other expense.

16. Company Loss Run: Attached Has been requested and will be available prior to binding.
 Is not available Has been requested but won't be available until after binding.

Business Information:

17. Please advise year business was founded: _____
 18. Has business's ownership or management changed in the last 5 years? Yes No
 If yes, please explain: _____
 19. Please list subsidiary names and/or legally associated companies and nature of operations: _____

Business Information:

20. Please describe any mergers or acquisitions and the products acquired within the past 5 years (including a description of the products and the date acquired): _____

21. Did you assume the liability for these products? Yes No
If yes, please explain: _____

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Medical device manufacturing and sales:

22. Please provide the following information on each product category:

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			

23. Do you have any discontinued products exposures? Yes No
If yes, please describe each products discontinued, by name, function, shelflife, discontinuation date, and annual sales): _____

24. Do your products contain component parts manufactured by others? Yes No
If yes, please explain including type of component, name of supplier, etc.): _____

25. Do you import products or component parts? Yes No
If yes, please explain: _____

Medical device manufacturing and sales:

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

If yes, please describe your controls: _____

27. Do you subcontract any product testing or efficacy trials? Yes No

If yes, please describe product(s), identify subcontractor(s), etc.: _____

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28. Do others install your product? Yes No

If yes, do you: Supervise or furnish installation instructions? Yes No
 Sign-off on installation? Yes No

29. Are your products available for lease or rent? Yes No

If yes, please explain (product type(s), customer type(s), related receipts, etc.): _____

30. Do you re-label and/or distribute any products other than those you manufacture? Yes No

If yes, please explain: _____

31. Do you have products approved for sale in other parts of the world, but not in the USA? Yes No

If yes, please describe if not already captured above: _____

32. Do you hold any of your customers or suppliers harmless? Yes No

If yes, please describe (identify entity, outline contractual terms, provide related receipts or contract value, etc.): _____

Quality Assurance Program /Instructions:

33. Do you have a risk/quality management program? Yes No

If yes, please provide the name and title of person in charge: _____

34. Please attach your QSIT process.

35. Please attach your procedure for developing product instructions and warnings.

36. How long are your testing and quality control records retained? _____

37. Please describe all product guarantees and/or warranties provided: _____

38. Please describe your certifications: _____

39. Does legal counsel review your labeling, advertising and website content on an annual basis? Yes No

40. Trade Association Membership held? Yes No

If yes, please list: _____

Other Information:

41. Do any of your employees or sub-contractors provide direct patient care? Yes No

If yes, please explain: _____

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42. Do you provide any service agreements for your products? Yes No

If yes, do you have formal:

a. Documented preventative maintenance programs for all products under a service contract?

Yes No

b. Mechanisms to notify the customer prior to the service date and products to be serviced?

Yes No

c. Procedures to follow if the device requiring preventative maintenance is not available at the time of the scheduled service? Yes No

d. Do you audit your company's compliance with the service agreements? Yes No

If no, please explain: _____

43. Do you provide product training? Yes No

If yes, do you:

a. Have a documented training program for each device? Yes No

b. Document and retain the details of each training program

(i.e. name of attendee, program, trainer, objectives covered, etc.)? Yes No

44. Have you ever conducted a product recall? Yes No

45. Do you have a current product recall plan? Yes No If yes, please attach a copy.

46. Is the applicant aware of any circumstance, incidents, situations, or accidents that have occurred during the past 5 years which may result in claim being made against the applicant, his predecessors in business, or any past or present entities not already disclosed above? Yes No

If yes, please describe below or in an attachment: _____

Attachments:

- 47. Company Loss Runs
- 48. Product Recall Plan
- 49. Sample Lease / Rental Agreement
- 50. Samples of Brochures & Advertising
- 51. Copies of any MDR's involving injury or death
- 52. Copy of most recent FDA/ISO Inspection Report
- 53. Copies of any FDA Warning Letters

READ AND SIGN BELOW:

I have reviewed this application for accuracy before signing it. As a condition precedent to coverage, I hereby state that the information contained herein is true, accurate and complete and that no material facts have been omitted, misrepresented or mis-stated. I know of no other claims or lawsuits against the applicant and I know of no other events, incidents or occurrences which might reasonably lead to a claim or lawsuit against the applicant. I understand that this is an application for insurance only and that completion and submission of this application does not bind coverage with any insurer.

Signature

Date

Print Name

Title

**APPLICATIONS MUST BE FULLY COMPLETED AND SIGNED
PRIOR TO COVERAGE BEING BOUND**

Marketing Information:

Do you currently control this account? _____ Have you inspected and do you recommend this account? _____

Price and terms needed to write the account? _____

Is this a firm order at those price and terms? _____ ***Signature of Producer:*** _____