

*Product-Completed Operations/Human Clinical Trial Liability only Application*

## Life Sciences Blended Liability Policy

UNDERWRITTEN BY: THE HANOVER INSURANCE COMPANY

### CLAIMS MADE NOTICE

THIS POLICY PROVIDES COVERAGE ON A CLAIMS-MADE BASIS. SUBJECT TO ITS TERMS, THIS POLICY APPLIES ONLY TO "CLAIMS" FIRST MADE AGAINST "YOU" DURING THE "POLICY PERIOD", AUTOMATIC EXTENDED REPORTING PERIOD OR ANY PURCHASED OPTIONAL EXTENDED REPORTING PERIOD THAT MAY APPLY. PLEASE READ THE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES, COVERAGE AND COVERAGE RESTRICTIONS.

### "CLAIM EXPENSE" WITHIN LIMITS

THIS CLAIMS-MADE POLICY PROVIDES FOR "CLAIM EXPENSE" PAYABLE WITHIN, AND NOT IN ADDITION TO, THE LIMITS OF INSURANCE. "CLAIM EXPENSE" WILL REDUCE AND MAY EXHAUST THE LIMIT OF INSURANCE, AND WILL BE APPLIED AGAINST THE DEDUCTIBLE. PLEASE READ THE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES, COVERAGE AND COVERAGE RESTRICTIONS.

### APPLICATION INSTRUCTIONS

Please answer all required sections of questions completely. Whenever used in this Application, the term **you** or **your(s)** or the **Applicant** shall mean the **Named Insured** and all subsidiaries, unless otherwise stated.

### GENERAL INFORMATION

#### Your Business Operations

1. Name of Applicant: \_\_\_\_\_
2. Address of Applicant: \_\_\_\_\_
3. Website Address: \_\_\_\_\_
4. Years in Business: \_\_\_\_\_
5. Have you ever operated under another name? ☐ Yes ☐ No  
If Yes, please explain: \_\_\_\_\_
6. Do you have a parent company? ☐ Yes ☐ No  
If Yes, provide name: \_\_\_\_\_
7. Please list all your subsidiaries and your percentage of ownership in each:  
\_\_\_\_\_
8. In the past 5 years, have you engaged in any mergers, acquisitions, or divestitures? ☐ Yes ☐ No  
If Yes, please provide the date and whether you acquired, retained or divested assets, liabilities or both for each transaction.  
\_\_\_\_\_
9. For each merger or acquisition, did your due diligence process include the following:
  - a. Review of prior and pending litigation? ☐ Yes ☐ No  
If Yes, please provide a brief description: \_\_\_\_\_
  - b. Evaluation of all outstanding contracts or service agreements to be included as part of the transaction? ☐ Yes ☐ No
  - c. Analysis of intellectual property rights, including any third-party interest in or liens on these rights? ☐ Yes ☐ No

## Client Insurance Information

Please provide information on your current insurance program:

Policy Period	Insurance Company	Coverage	Limits	Deductible	Retroactive Date	Premium
			\$	\$		\$

1. Is your current Products-Completed Operations Liability coverage form provided on a Claims-Made basis? ☐ Yes ☐ No
2. Have you discontinued or ceased to provide any products, services or operations in the last five years? ☐ Yes ☐ No
  - a. If Yes, please provide details: \_\_\_\_\_
  - b. And if Yes, do you provide continuing services, support or other remedies for discontinued products, services or operations? ☐ Yes ☐ No  
If Yes, please provide details: \_\_\_\_\_
3. Does your current insurance program exclude any of your clinical trials, products or services? ☐ Yes ☐ No  
If Yes, please provide details: \_\_\_\_\_

## Requested Insurance Program

Please provide information on your requested insurance program:

Coverage	Limits	Deductible	Retroactive Date(s)
Products—Completed Operations Liability	\$	\$	
Products Recall Expense	\$	\$	Non-Applicable
Human Clinical Trial Expense	\$	Non-Applicable	Non-Applicable

1. Please provide a description of your business operations:  
\_\_\_\_\_  
\_\_\_\_\_
2. Describe any new products or services, entering the market that are substantially different in scope or end use than your current products or services?  
\_\_\_\_\_  
\_\_\_\_\_
3. Do you anticipate any significant changes in the nature of your business over the next 12 months? ☐ Yes ☐ No  
If Yes, please provide details: \_\_\_\_\_

4. Please provide a breakdown of your revenue:

Sources of Revenue	Current Annual Revenues	Projected Annual Revenues
Total U.S. Revenue	\$	\$
Total Foreign Revenue	\$	\$
Total Revenue	\$	\$

5. Please provide a breakdown of your products or services by percentage of your total revenue:

Sources of Revenue	Percentage of Your Total Revenue
Pharmaceuticals	%
Medical Devices	%
Digital Health	%
Contract Research Organization and/or Research Institute	%
Other	%

6. Do you have any association, past or present, with banned products? ☐ Yes ☐ No  
If Yes, please provide details: \_\_\_\_\_
7. Have any of your products, services or operations been subject to an investigation by any U.S. or foreign government agency? ☐ Yes ☐ No  
If Yes, please provide details: \_\_\_\_\_

8. Do you utilize nanotechnology in the development, delivery or manufacturing of your products? ☐ Yes ☐ No  
If Yes, please provide details: \_\_\_\_\_
9. Are your products and services HIPAA compliant? ☐ Yes ☐ No  
If No, please provide details: \_\_\_\_\_
10. Please check the box if you have studies or products (past, present or planned) involving any of the following classes of products:
- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Addictive Substance          | <input type="checkbox"/> Known Carcinogen                | <input type="checkbox"/> Radiation-Emitting Technologies |
| <input type="checkbox"/> Birth Control or Fertility   | <input type="checkbox"/> Known Mutagen                   | <input type="checkbox"/> SSRIs or SNRIs                  |
| <input type="checkbox"/> Gene Therapy                 | <input type="checkbox"/> Known Teratogen                 | <input type="checkbox"/> Steroids                        |
| <input type="checkbox"/> Hormone Replacement Products | <input type="checkbox"/> Mercury                         | <input type="checkbox"/> Vaccines                        |
| <input type="checkbox"/> HPAPIs or HPAlis             | <input type="checkbox"/> Pediatric/Minors/Pregnant Women | <input type="checkbox"/> Weight Management               |

## History

1. In the past 5 years:
- a. Have you received any claims or suits (insured or not) claiming damages associated with your products, services or human clinical trials? ☐ Yes ☐ No  
If Yes, provide details at the end of section.
- b. Have you given notice of any claim, circumstance or potential claim to any insurer under any insurance coverage referred to above? ☐ Yes ☐ No  
If Yes, provide details at the end of section.
- c. Are you aware of any facts or circumstances associated with your products or services that could reasonably be expected to result in a claim or suit? ☐ Yes ☐ No  
If Yes, provide details at the end of section.
2. Within the past 3 years, have you had any policy canceled or non-renewed? ☐ Yes ☐ No  
If Yes, please provide details: \_\_\_\_\_
- If you answered Yes to any of the History questions, please explain each Yes answer in detail below and provide relevant documentation:

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## PRODUCTS—COMPLETED OPERATIONS LIABILITY

### A. Pharmaceuticals

(Please complete this section if you manufacturer or distribute a pharmaceutical. If you do not, please skip this section.)

1. Please provide a breakdown of your product revenue by product type and number of units sold:

Route of Administration	Prescription	Generic	Over-the-Counter	Percentage of Revenue Sold	Number of Units Sold
Topical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	%	
Oral	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	%	
Inhalable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	%	
Injectable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	%	
Transdermal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	%	
Drug Delivery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	%	
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	%	

2. Please provide an overview of your products and their intended usages.

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3. Do you manufacture a biologic therapeutic?  
If Yes, please provide details. \_\_\_\_\_
4. Do you manufacture an Active Pharmaceutical Ingredient (API) for: ☐ Yourself ☐ Others  
If Yes, please provide details. \_\_\_\_\_
5. Do you have any past, present or planned products that do not have formal FDA approval for marketing? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
6. Please check the box where you have studies, products, or services (past, present or future) involving any of the following specific pharmaceutical products:
- |   |  |  |  |  |
|---|--|--|--|--|
| <input type="checkbox"/> Accutane                 | <input type="checkbox"/> Ephedra       | <input type="checkbox"/> Metoclopramide      | <input type="checkbox"/> Redux         | <input type="checkbox"/> Phospho soda, sodium phosphate, or any phosphor soda or sodium phosphate based agents |
| <input type="checkbox"/> Bisphosphonate           | <input type="checkbox"/> Ephedrine     | <input type="checkbox"/> Opioids             | <input type="checkbox"/> Rosiglitazone |  |
| <input type="checkbox"/> Cisapride                | <input type="checkbox"/> Flenfluramine | <input type="checkbox"/> Phentermine         | <input type="checkbox"/> Thalidomide   |  |
| <input type="checkbox"/> Dexfenturamine           | <input type="checkbox"/> Isotretinoin  | <input type="checkbox"/> Phenylpropanolamine | <input type="checkbox"/> Thimerosa     |  |
| <input type="checkbox"/> Diethylstilbestrol (DES) | <input type="checkbox"/> L-Tryptophan  | <input type="checkbox"/> Pseudoephedrine     | <input type="checkbox"/> Troglitazone  |  |
|   |  |  |  |  |
7. Do you manufacturer or distribute cosmeceuticals, nutraceuticals, vitamins or food supplements for yourself or others? ☐ Yes ☐ No  
If Yes, please answer the remaining questions in this section:
- Please describe the nature of your products. \_\_\_\_\_
  - Do any of your products make health or lifestyle claims/benefits? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
  - Have any of your products ever fit the definition of a new dietary ingredient? ☐ Yes ☐ No  
If Yes, have pre-market safety reviews been conducted per regulations? ☐ Yes ☐ No
  - Have any of your products ever had an active ingredient that would be defined as a drug by a regulatory agency? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
  - Do you sell any muscle building, weight management or sexual enhancement products? ☐ Yes ☐ No
  - Do you sell any of your products through a multi-level marketing system? ☐ Yes ☐ No

## B. Medical Device

(Please complete this section if you manufacture, assemble, distribute or provide service to components and/or finished goods related to medical devices, biotechnology products or laboratory products/technologies. If you do not, please skip this section.)

1. How would you define yourself? Please check the box(s) below which apply to.
- ☐ Medical Device ☐ Medical Device Consumables ☐ Laboratory Analytical Equipment and Technologies
- ☐ Biotechnology Products or Consumables (excludes anything administered into the body)
2. Please provide a breakdown of your revenue by revenue source:

Source of Revenue	for yourself	for others	Percentage of Total Revenue
Component manufacturer of a product	<input type="checkbox"/>	<input type="checkbox"/>	%
Contract manufacturer of a product	<input type="checkbox"/>	<input type="checkbox"/>	%
Manufacturer of a product	<input type="checkbox"/>	<input type="checkbox"/>	%
Distributor of a product	<input type="checkbox"/>	<input type="checkbox"/>	%
Installer, servicer or repairer of a product	<input type="checkbox"/>	<input type="checkbox"/>	%
Refurbisher of a product	<input type="checkbox"/>	<input type="checkbox"/>	%
Other	<input type="checkbox"/>	<input type="checkbox"/>	%

3. Please provide an overview of your products and their intended usages.
- \_\_\_\_\_

4. Are your products labeled research use only? ☐ Yes ☐ No
5. If you are a component or a contract manufacturer:
- a. Describe the Finished Good product. \_\_\_\_\_
- b. Do you provide design, engineering and prototype services? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
- c. What percentage of your work is completed to customer specifications? \_\_\_\_\_ %
- d. Do you have a formal process for approval and acceptance by your customer for any specification, material, or manufacturing process modifications? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
- e. Are you aware of any product recalls by your customers that resulted from your product or work? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
6. Please check the box where you have any past, present or planned involvement associated with any of the following:
- ☐ Aerospace or aircraft ☐ Implantable medical device
- ☐ Automotive ☐ Industrial automation
- ☐ Biologics ☐ Latex
- ☐ Defense or military ☐ Life sustaining or life supporting medical device
- ☐ Drug delivery system ☐ Physical security devices
- If you checked any of the boxes above, please provide an explanation describing your product or work below:
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

### C. Digital Health

(Please complete this section if you provide digital health products. If you do not, please skip this section.)

1. Please check all the activities below that apply to your company and the end-use environment(s) for your products.

Source of Revenue	Products Product End-Use Environment(s)				
	Clinical	Pharmacy	Laboratory	Home	Mobile
Electronic Health, Electronic Medical or Personal Health Record	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E-Prescriptions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Decision Support	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Computerized Physician Ordering Entry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drug-to-Drug Interactions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health Kiosks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HIPAA Compliance Software/Advisory/Services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medication Coding or Dispensing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medical, Health or Nutritional Content/Advisory/Services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient Archiving Capturing System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient or Clinical Communication Portal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient Management Software	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Remote Medical Education for Clinicians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Remote Patient Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unregulated FDA Mobile Applications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Do you provide standard or customizable product solutions? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_

3. Do you perform any functions, activities or provide any product or service that involves the use or disclosure of protected health information? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
4. Do you provide any hosting, archiving or cloud services of your customers' data? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
5. How do your products interface with other digital health products or medical devices?  
\_\_\_\_\_
6. If you develop or publish Electronic Health Records or Electronic Medical Records software, is your software certified by the Office of the National Coordinator for Health Information Technology? ☐ Yes ☐ No
7. Do you manufacture or distribute any medical devices (components and/or finished goods) to complement your product solution(s) identified above? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
8. Are any of your products (past, present or planned) considered an FDA regulated medical device? ☐ Yes ☐ No  
If Yes, please complete section B–Medical Device of this Application.

#### D. Contract Research

*(Please complete this section if you operate as a clinical or contract research organization and/or a research institute. If you do not, please skip this section.)*

1. How would you define yourself? Please check the box(s) below which apply.

☐ Pre-Clinical Contract Research Organization

☐ Clinical Research Organization

☐ Research Institute

2. Please check all the activities below that apply to your company:

Pre-Clinical	for yourself	for others	Clinical	for yourself	for others
Bench research	<input type="checkbox"/>	<input type="checkbox"/>	Protocol and/or consent form development	<input type="checkbox"/>	<input type="checkbox"/>
Medicinal chemistry including target discovery and validation	<input type="checkbox"/>	<input type="checkbox"/>	Clinical trial management and/or data collection	<input type="checkbox"/>	<input type="checkbox"/>
Lead optimization and validation	<input type="checkbox"/>	<input type="checkbox"/>	Regulatory support and/or statistical analysis	<input type="checkbox"/>	<input type="checkbox"/>
In-vitro screening	<input type="checkbox"/>	<input type="checkbox"/>	Pharmacovigilance	<input type="checkbox"/>	<input type="checkbox"/>
Animal studies	<input type="checkbox"/>	<input type="checkbox"/>	Medical or pathology services performed onsite	<input type="checkbox"/>	<input type="checkbox"/>
Toxicology and/or pathology	<input type="checkbox"/>	<input type="checkbox"/>	Licensing of technology, intellectual property or data to others		<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	Providing clinical instructions to others		<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	Other	<input type="checkbox"/>	<input type="checkbox"/>

3. Do you act as a sponsor or investigator for any clinical trials? ☐ Yes ☐ No  
If Yes, please explain \_\_\_\_\_
4. Do you support the development and / or commercialization of any products? ☐ Yes ☐ No  
If Yes, please explain \_\_\_\_\_
5. Do you receive royalties for patents or other intellectual property? ☐ Yes ☐ No  
If Yes, please explain \_\_\_\_\_

6. Is someone within your organization responsible for intellectual property management and transfer of technology to others, inter-institutional agreements, etc.? ☐ Yes ☐ No  
If Yes, please identify the individual by title \_\_\_\_\_
7. Do you have protocols for identifying and handling suspected research fraud? ☐ Yes ☐ No
8. If you are a research institute only:
- How are you funded? \_\_\_\_\_
  - What are your areas of research? \_\_\_\_\_

## E. Clinical Trials

(Please complete this section if you are or plan to conduct a clinical trial. If you do not, please skip this section.)

1. Please list your clinical trials, present and planned, for the next 12 months:

Product Name and Protocol Number	# of New Subjects to be Enrolled Over the Next Policy Period	Indication	Clinical Trial Phase (I, II, III or IV)	Countries Where the Trial Takes Place

Please attach an IRB approval, clinical trial protocol and informed consent document for all clinical trials scheduled to occur over the next 12 months.

2. How many clinical trials have you sponsored in the past 3 years? \_\_\_\_\_
3. What is the total number of human subjects enrolled in the last 3 years? \_\_\_\_\_
4. What is the number of expanded access or compassionate use subject participants anticipated over the next 12 months? \_\_\_\_\_
5. Have any of your clinical trials been classified as significant risk by the FDA or IRB? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
6. Have any of your clinical trials been suspended or discontinued in whole, or in part, because of safety reasons? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
7. What is the number of clinical trial "For Cause Audits" conducted by you or a regulatory agency in the past 5 years? \_\_\_\_\_  
Please provide details. \_\_\_\_\_
8. Have any clinical investigators been cited for regulatory violations? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
9. Do you ever act as both trial sponsor and clinical investigator? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
10. Do you ever provide material or product for investigator sponsored trials? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
11. Do you have formalized Clinical Trial Suspension SOPs in place? ☐ Yes ☐ No

## PRODUCTS-COMPLETED OPERATIONS-REGULATORY AND RISK MANAGEMENT

### Regulatory

1. Are you in compliance with Title 21 CFR Part 99-Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics and Devices? ☐ Yes ☐ No  
If No, provide details. \_\_\_\_\_

2. Have you had any product(s) requiring the addition of a black box or significant safety warning to an existing label or instruction manual in the past 5 years? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
3. Do you have any outstanding FDA issues? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
4. Have you been cited by any other regulatory agency (other than the FDA) for deficiencies and/or for noncompliance in the past 3 years? ☐ Yes ☐ No  
If Yes, please provide details and your responses? \_\_\_\_\_

## Risk Management

### QUALITY CONTROL ASSURANCE

1. Do you have a formal risk management or quality management program? ☐ Yes ☐ No
2. Who is responsible for overseeing the Risk Management and Quality Management program?  
\_\_\_\_\_
3. Do your quality control procedures include formalized, standard operating procedures for the following?  
Please check all that apply:

<input type="checkbox"/> Facility sanitation controls	<input type="checkbox"/> Written systems development methodology	<input type="checkbox"/> Prototype development guidelines	<input type="checkbox"/> Customer acceptance procedure
<input type="checkbox"/> Materials and/or goods subject to atmospheric changes	<input type="checkbox"/> In-process control-point tests	<input type="checkbox"/> Finished goods or batch testing	<input type="checkbox"/> Batch records/serial product history record keeping
<input type="checkbox"/> Vendor certification/ verification process	<input type="checkbox"/> cGMP testing	<input type="checkbox"/> Labeling and packaging	<input type="checkbox"/> Written quality control program
<input type="checkbox"/> Incoming inspection of raw materials or component parts	<input type="checkbox"/> Alpha testing	<input type="checkbox"/> Shelf life and/or calibration requirements	<input type="checkbox"/> Product recall program
<input type="checkbox"/> Non-conforming material	<input type="checkbox"/> Beta testing	<input type="checkbox"/> Safe distribution of goods	<input type="checkbox"/> 3rd Party Contract manufacturing

4. Do you audit your risk management programs and standard operating procedures? ☐ Yes ☐ No
5. Do you have any sterilized products? ☐ Yes ☐ No  
If Yes:  
a. Do you use a 3rd party sterilizer? ☐ Yes ☐ No  
b. Do you sterilize the product on your premise? ☐ Yes ☐ No  
If you responded yes to either question above, please provide details:  
\_\_\_\_\_

6. Do you utilize a 3rd party vendor to package, label, warehouse or distribute your products? ☐ Yes ☐ No  
If Yes, please provide details. \_\_\_\_\_
7. How long do you retain testing and quality control records? \_\_\_\_\_
8. Are you in compliance with all applicable cGMP, GCP, GLP and QS guidelines? ☐ Yes ☐ No
9. Do you comply with any of the following industry standards?  
Please check all that apply:  
☐ ANSI ☐ FDA ☐ ISO 13485 ☐ REMS ☐ Other: \_\_\_\_\_  
☐ CE Mark ☐ ISO 9000 ☐ ISO 14971 ☐ UL / CSA / EU ☐ Other: \_\_\_\_\_
10. Do you audit your suppliers? ☐ Yes ☐ No

### SALES AND MARKETING

1. How do you sell your products and/or services? \_\_\_\_\_
2. Describe the guarantees or warranties provided with your products or services. \_\_\_\_\_



3. Do you provide service agreements for your products? ☐ Yes ☐ No
- If Yes:
- a. Do you audit your company's compliance with service agreements? ☐ Yes ☐ No
- b. Do you have a written preventative maintenance program for products under a service agreement? ☐ Yes ☐ No
4. Are any of your employees or subcontractors present during medical procedures? ☐ Yes ☐ No
- If Yes:
- a. Do you have a formal policy prohibiting physical patient contact by an employee or subcontractor? ☐ Yes ☐ No
- b. Do you provide training to your employees and subcontractors regarding appropriate communication and conduct during medical procedures? ☐ Yes ☐ No
5. Do you have a formal and documented training program for sales personnel? ☐ Yes ☐ No
6. Do you have a formal and documented training program for installation, service and repair employees? ☐ Yes ☐ No
7. Do you employ or hire by contract, acting Medical Professionals? ☐ Yes ☐ No
- If Yes, please provide details. \_\_\_\_\_
8. Are your marketing, sales, regulatory, product development and post-market surveillance employees (or subcontractors) receiving formalized and documented training in regulatory requirements and product liability? ☐ Yes ☐ No
9. Do you have legal counsel review your labels and warnings, instructions for use, and advertising materials on at least an annual basis? ☐ Yes ☐ No
10. Do you obtain written customer acceptance at pre-defined milestones or project stages? ☐ Yes ☐ No
11. Do you obtain written final acceptance or other sign-off agreements from all customers upon delivery or completion of your products or service? ☐ Yes ☐ No
12. Do you have a formalized customer complaint resolution policy and procedure? ☐ Yes ☐ No
13. Do you provide documented technical training to your customers in the use of your products or services? ☐ Yes ☐ No
- If Yes, please provide details. \_\_\_\_\_

#### POST-MARKET SAFETY SURVEILLANCE AND COMPLAINT HANDLING

1. How do you track and trace your products? \_\_\_\_\_
- If batch produced, what is the average size? \_\_\_\_\_
2. What, if any, is the shelf-life expectancy of your product? \_\_\_\_\_
3. Do you have a formal products recall program? ☐ Yes ☐ No
- If Yes:
- a. Do you conduct test recalls? ☐ Yes ☐ No
- b. Do any of your products become part of another company's product? ☐ Yes ☐ No
- c. Are any products repackaged by any other companies? ☐ Yes ☐ No
- If Yes, please provide details. \_\_\_\_\_
4. Do you have a post-implementation product or service evaluation or review procedure in place? ☐ Yes ☐ No
5. Do you have a formal policy for documenting and responding to customer complaints or requests for changes or repairs? ☐ Yes ☐ No
- If Yes:
- a. Who is responsible for fielding customer complaints? \_\_\_\_\_
- b. Do you have an escalation process in place to resolve customer complaints? ☐ Yes ☐ No
- c. Do you have a formal Corrective and Preventative Action Program (CAPA)? ☐ Yes ☐ No
6. Do you monitor and manage off-label use of your products? ☐ Yes ☐ No

7. Please describe any actions you would take if you became aware of off-label use of your products.

In addition, would any of the following actions apply?

Healthcare Professional/Dear Doctor Letter ☐ Yes ☐ No

Additional studies ☐ Yes ☐ No

Expanded product monitoring ☐ Yes ☐ No

8. Do you allow off-label information dissemination? ☐ Yes ☐ No

If Yes, under what conditions? \_\_\_\_\_

#### CONTRACT RISK TRANSFER

1. Do you have formal policies and procedures in place to obtain risk transfer documentation? ☐ Yes ☐ No

Please check all that apply:

Contract Risk Transfer Documentation	Suppliers	Vendors	Contract Mfg.	Subs or Independent Contractors	Sterilizers	Distributors	OEMs	Customers
Certificates of insurance issued annually	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Insured Status on Products / Completed Operations Liability Policy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hold Harmless language (in your favor or mutually beneficial)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indemnification language (in your favor or mutually beneficial)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Contract	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Purchase Orders / Invoice (Incl. Terms & Conditions)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Master Service Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Distribution Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Do you provide contractual hold harmless or indemnification to other entities? ☐ Yes ☐ No

If Yes, please provide details: \_\_\_\_\_

#### VII. DECLARATION AND SIGNATURE

The undersigned, acting on behalf of all Applicants, declare that the statements set forth in this Application are true and correct and that thorough efforts were made to obtain requested information from each and every Applicant proposed for this insurance to facilitate the proper and accurate completion of this Application.

The undersigned agree that the information provided in this Application and any material submitted herewith are the representations of all the Applicants and are the basis for issuance of the insurance policy provided by us. Any material submitted with the Application shall be maintained on file (either electronically or paper) with us.

It is further agreed that:

- If any of the Applicants discover or become aware of any significant change in the condition of the Applicant Organization between the date of this Application and the policy inception date, which would render the Application inaccurate or incomplete, notice of such change will be reported in writing to us immediately;
- Any policy issued, will be in reliance upon the truthfulness of the information provided in this Application; provided, however, with respect to such information, no knowledge or information possessed by any Applicant shall be imputed to any other Applicants. If any person or persons knew as of the policy inception date that such information contained in the Application(s) were untrue, inaccurate or incomplete, then coverage may be denied or canceled with respect to that person or persons if such information was material to issuance of the policy. However, if the Chairperson of the Board of Directors, President, Chief Executive Officer, or Executive Director of

the Applicant knew as of the policy inception date that such information contained in the Application(s) were untrue, inaccurate or incomplete, then coverage may be denied or canceled with respect to that person or persons and the Applicant Organization if such information was material to issuance of the policy;

- Statements in the Application, facts pertaining to or knowledge possessed by the individual signing the Application shall be imputed to the Applicant; and
- The signing of this Application does not bind the undersigned to purchase insurance

This Application must be signed by a representative of the Applicant acting as the authorized representative of the person(s) and entity(ies) proposed for this insurance.

Date

Signature/Title

(Chief Executive Officer, President, Chief Financial Officer, Managing Partner or Owner)

Produced By: Agent: \_\_\_\_\_ Agency: \_\_\_\_\_

Agent Signature: \_\_\_\_\_

Agency Taxpayer ID or SS No.: \_\_\_\_\_ Agent License No.: \_\_\_\_\_

Address (Street, City, State, Zip): \_\_\_\_\_

#### VIII. FRAUD WARNINGS

**Notice to Colorado Residents:** It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance, and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policy holder or claimant for the purpose of defrauding or attempting to defraud the policy holder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

**Notice to District of Columbia Residents:** Warning: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant. **Notice to Florida Residents:** Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony of the third degree.

**Notice to Hawaii Residents:** For your protection, Hawaii law requires you to be informed that presenting a fraudulent claim for payment of a loss or benefit is a crime punishable by fines or imprisonment, or both.

**Notice to Kentucky Residents:** Any person who knowingly and with intent to defraud an insurance company or other person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime.

**Notice to Arkansas, Louisiana & West Virginia Residents:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**Notice to Maryland Residents:** Any person who knowingly and willfully presents a false or fraudulent claim for payment of a loss or benefit or knowingly and willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**Notice to Maine, Virginia, Tennessee & Washington Residents:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**Notice to Michigan and Minnesota Residents:** Any person who knowingly and with intent to defraud an insurance company or another person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent act, which is a crime and subjects the person to criminal and civil penalties.

**Notice to Missouri & Arizona Residents:** Claim Expenses are Inside the Policy Limits. All claim expenses shall first be subtracted from the limit of liability, with the remainder, if any, being the amount available to pay for damages.

**Notice to Pennsylvania Residents:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

**Notice to New Mexico Residents:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties.

**Notice to Ohio Residents:** Any person who, with intent to defraud or knowing that he is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

**Notice to Oklahoma & Idaho Residents:** Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes any claim for the proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony.

**Notice to New Jersey Residents:** Any person who knowingly includes any false or misleading information on an application for an insurance policy or files a statement of claim containing any false or misleading information is subject to criminal and civil penalties.

**Notice to Oregon Residents:** Any person who knowingly and with intent to defraud or solicit another to defraud any insurance company: (1) by submitting an application, or (2) by filing a claim containing a false statement as to any material fact, may be violating state law.

**Notice to Vermont Residents:** Any person who knowingly presents a false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

**NOTE:** This product is not available in Massachusetts.

**GENERAL FRAUD NOTICE:**

Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly provides false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

***ATTENTION APPLICANTS IN THE FOLLOWING JURISDICTIONS***

**ALABAMA, ARKANSAS, DISTRICT OF COLUMBIA, LOUISIANA, MARYLAND, NEW MEXICO, RHODE ISLAND AND WEST VIRGINIA:**

Any person who knowingly (or willfully in MD) presents a false or fraudulent claim for payment of a loss or benefit or knowingly (or willfully in MD) presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**CALIFORNIA:** For your protection, California law requires the following to appear on this form. Any person who knowingly presents false or fraudulent information to obtain or amend insurance coverage or to make a claim for payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

**COLORADO:** It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

**FLORIDA AND OKLAHOMA:** Any person who knowingly and with intent to injure, defraud or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony (of the third degree in FL).

**KANSAS:** Any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written, electronic, electronic impulse, facsimile, magnetic, oral, or telephonic communication or statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act.

**KENTUCKY, OHIO AND PENNSYLVANIA:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

**MAINE, TENNESSEE, VIRGINIA, AND WASHINGTON:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties (may)\* include imprisonment, fines and denial of insurance benefits. \*Applies in ME Only.

**NEW HAMPSHIRE AND NEW JERSEY:** Any person who includes any false or misleading information to the best of her/his knowledge on an application for an insurance policy is subject to criminal and civil penalties.

**OREGON:** Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

**PUERTO RICO:** Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances [be] present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.

**VERMONT FRAUD NOTICE:** Any person who knowingly presents a false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

**NEW YORK:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to civil penalties not to exceed five thousand dollars and the stated value of the claim for each such violation.