CLEAR FORM

HANOVERfUSION

SUPPLEMENTAL APPLICATION

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 THEDEDUCTIBLE. PLEASE READ THE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES, COVERAGE AND COVERAGE RESTRICTIONS.

APPLICATION INSTRUCTIONS

Please answer all required sections of questions completely. The following sections are required for all applicants: General Information, Products-Completed Operations Liability, and Products-Completed Operations—Regulatory and Risk Management. Select the additional coverage options you would like to apply for by completing all the required questions for each coverage.

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.

I. GENERAL INFORMATION

A. 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 you do 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
10. Have you filed for bankruptcy in the past 7 years? ☐Yes ☐No
11. Are you in compliance with all applicable regulatory guidelines? ☐Yes ☐No
12. Please list any industry trade association memberships:

_____

B. APPLICANT 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: _____

C. REQUESTED INSURANCE PROGRAM

Please provide information on your requested insurance program:

COVERAGE	Limits	Deductible	Retroactive Date(s)
Products-Completed Operations Liability	$	$	
Errors & Omissions	$	$	
Information Security	$	$	
Privacy and Personal Injury	$	$	
Media and Content	$	$	
Data Breach Expense	$	$	
Products Recall Expense	$	$	
Human Clinical Trial Expense	$		

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		Projected Annual Revenues
Pharmaceuticals / Biologics		%
Dietary Supplement		%
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 organizations 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

   a. If No, please provide details: _____

   b. Are any products discontinued for safety reasons? ☐Yes ☐No

10. Do you import any products or ingredients? ☐Yes ☐No

    If Yes, what products/ingredients and what countries? _____

11. Please check the box if you have studies or products (past, present, or planned) involving any of the following classes of products:

☐	Addictive Substance/Opioids	☐	Radiation Emitting Technologies
☐	Birth Control or Fertility	☐	SSRIs or SNRIs
☐	Gene Therapy Known	☐	Steroids
☐	Hormone Replacement Products	☐	Vaccines
☐	HPAPIs or HPAIs	☐	Weight Management
☐	Cannabis	☐	Generic Pharmaceuticals
☐	Known Carcinogen	☐	Mesh
☐	Known Mutagen	☐	Knee Replacement and components
☐	Teratogen	☐	Hip Replacement and components
☐	Mercury	☐	Shoulder replacement and components
☐	Pediatric/Minors/Pregnant Women	☐	Generative Artificial Intelligence
☐	Metal on metal implants		

D. HISTORY

1. Within the past 5 years:
   a. Have you received any allegation(s), claims or suits (insured or not) claiming defect of any kind and/or damages associated with your products, services or human clinical trials? ☐Yes ☐No
   b. Have you given notice of any claim, circumstance or potential claim to any insurer under any insurance coverage referred to above? ☐Yes ☐No
   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
   d. Have you experienced or has your system or website been used in any type of security incident or attack (e.g. viruses, denial of service attacks, etc.)? ☐Yes ☐No
2. Within the past 3 years:
   a. Have you had contract disputes alleging non-performance of your products or services? ☐Yes ☐No
   b. Have your customers withheld payment due to contract dispute? ☐Yes ☐No
   c. Have you sued any of your customers for non-payment? ☐Yes ☐No
   d. Have you discovered or been accused of any type of privacy violation? ☐Yes ☐No
3. Within the past 3 years, have you had any policy canceled or non-renewed? ☐Yes ☐No

If you answered Yes to any of the History questions above, please explain each Yes answer in detail below and provide relevant documentation:

II. PRODUCTS COMPLETED OPERATIONS LIABILITY

A. PHARMACEUTICALS/BIOLOGICS

(Please complete this section if you manufacture 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				%	
Oral				%	
Inhalable				%	
Injectable				%	
Transdermal				%	
Drug Delivery				%	
Other				%	

2. Please provide an overview of your products and intended uses:

3. Do you manufacture a biologic therapeutic? ☐Yes ☐No

   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 Food and Drug Administration (FDA) approval for marketing? ☐Yes ☐No

   If Yes, what limits of liability: _____

6. Please check the box where you have studies, products, or services (past, present or future) involving any of the following specific pharmaceutical products:

☐	Accutane	☐	Fenfluramine	☐	Pioglitazone
☐	Acetaminophen	☐	Gadolinium	☐	Proton Pump Inhibitors
☐	Anabolic steroids	☐	Gamma-hydroxybutyrate (GHB), Gamma Butyrate (GBL), 1,4 Butanediol (BD)	☐	Pseudoephedrine
☐	Androstenedione	☐	Hormone Replacement Products	☐	Redux
☐	Aristochochic acid	☐	Isotretinoin	☐	Rosiglitazone
☐	Benzodiazepines	☐	Kratom	☐	Selective Serotonin Reuptake Inhibitors (SSRI)
☐	Birth control products	☐	Mercury	☐	Statins
☐	Bismacine	☐	Metoclopramide	☐	Talc
☐	Bisphosphonate	☐	Opioids	☐	Testosterone
☐	Cannabis	☐	Phenibut	☐	Thalidomide
☐	Cisapride	☐	Phentermine	☐	Thimerosal
☐	Cox-2-inhibitors	☐	Phenylpropanolamine (PPA)	☐	Troglitazone
☐	Di-(2-ethylhexyl) Phthalate (DEHP)	☐	Phospho soda, sodium phosphate, o any phosphor soda or sodium phosphate based agents	☐	Usnea and usnic acid

☐	Diethylstilbestrol (DES)				

B. DIETARY SUPPLEMENTS

Do you manufacture or distribute cosmeceuticals, nutraceuticals, vitamins or food supplements for yourself or others? ☐Yes ☐No

If Yes, please answer the remaining questions in this section:

a. Please describe the nature of your products: _____

b. Do any of your products make health or lifestyle claims/benefits? ☐Yes ☐No

If Yes, please provide details: _____

c. 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

d. Have any of your products every had an active ingredient that would be defined. as a drug by a regulatory agency? ☐Yes ☐No

If Yes, please provide details: _____

e. Do you sell any muscle building, weight management, Cannabis/CBD, energy drinks or sexual enhancement products? ☐Yes ☐No

If Yes, please provide details: _____

f. Do you sell any of your products through a multi-level marketing system? ☐Yes ☐No

g. Are you compliant with the most current regulatory requirements related to manufacturing and adverse event reporting? ☐Yes ☐No

h. Please check the box where you have studies, products, or services (past, present or future) involving any of the following specific dietary supplements:

☐	1,3 Dimethyl amylamine (DMAA)	☐	Colloidal silver	☐	Kratom
☐	1,3 Dimethyl butylamine (DMBA)	☐	Di-(2-ethylhexyl) Phthalate (DEHP)	☐	Lobelia
☐	1,4 Dimethyl pentylamine (DMHA)	☐	Ephedra	☐	Magnolia
☐	Anabolic steroids	☐	Ephedrine	☐	Phenibut
☐	Androstenedione	☐	Fenfluramine	☐	Piper Methysticum (Kava)
☐	Aristochochic acid	☐	Gamma-hydroxybutyrate (GHB), Gamma Butyrate (GBL), 1,4 Butanediol (BD)	☐	Proton Pump Inhibitors
☐	Bitter orange	☐	Germander	☐	Testosterone
☐	β-Methylphenethylamine (BMPEA)	☐	Hormone Replacement Products	☐	Usnea and usnic acid
☐	Chaparrel	☐	Jin Bu huan	☐	Yohimbe

C. 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 all the boxes(es) below that apply:

☐ 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	%	%	%
Contract manufacturer of a product	%	%	%
Manufacturer of a product	%	%	%
Distributor of a product	%	%	%
Installer, service or repairer of a product	%	%	%
Refurbisher of a product	%	%	%
Other:	%	%	%

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 below 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:

_____

_____

_____

_____

_____

_____

D. DIGITAL HEALTH

(Please complete this section if you provide digital 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:

PRODUCTS	PRODUCT END USE ENVIRONMENT(S)				
	Clinical	Pharmacy	Laboratory	Home	Mobile
Electronic, Health, Electronic Medical or Personal Health Record	☐	☐	☐	☐	☐
E-Prescriptions	☐	☐	☐	☐	☐
Clinical Decision Support	☐	☐	☐	☐	☐
Computerized Physician Ordering Entry	☐	☐	☐	☐	☐
Drug to Drug Interactions	☐	☐	☐	☐	☐
Health Kiosk	☐	☐	☐	☐	☐
HIPAA Compliance Software/Advisory/Services	☐	☐	☐	☐	☐
Medication Coding or Dispensing	☐	☐	☐	☐	☐
Medical, Health or Nutritional Content/Advisory/Services	☐	☐	☐	☐	☐
Patient Archiving Capturing System	☐	☐	☐	☐	☐
Patient or Clinical Communication Portal	☐	☐	☐	☐	☐
Patient Management Software	☐	☐	☐	☐	☐
Remote Medical Education for Clinicians	☐	☐	☐	☐	☐
Remote Patient Monitoring	☐	☐	☐	☐	☐
Unregulated FDA Mobile Applications	☐	☐	☐	☐	☐
Other:	☐	☐	☐	☐	☐

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 services?

   _____

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 compliment your product solution(s) identified above? ☐Yes ☐No

   If Yes, please provide details: _____

8. Are any of your products (past, present or planned) considered a FDA regulated medical device? ☐Yes ☐No

   If Yes, please provide details: _____

E. CONTRACT RESEARCH

(Please complete this section if you operated 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(es) that 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	☐	☐	Protocol and/or consent form development	☐	☐
Medicinal chemistry including target discovery and validation	☐	☐	Clinical trial management and/or data collection	☐	☐
Lead optimization and validation	☐	☐	Regulatory support and/or statistical analysis	☐	☐
In vitro screening	☐	☐	Pharmacovigilance	☐	☐
Animal studies	☐	☐	Medical or pathology services performed onsite	☐	☐
Toxicology and/or pathology	☐	☐	Licensing of technology, intellectual property or data to others	☐	☐
Other:	☐	☐	Providing clinical instructions to others	☐	☐
Other:	☐	☐	Other:	☐	☐

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:

   a. How are you funded? _____

   b. What are your areas of research? _____

9. Do you currently purchase specific professional liability coverage? ☐Yes ☐No

   If Yes, please explain terms and limits of insurance: _____

F. 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 & 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 last 3 years? _____
3. What is the total number of human subjects enrolled in the last 3 years? _____
4. What is the total 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 last 5 years? ☐Yes ☐No
   If Yes, 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 Standard Operating Procedure (SOPs) in place? ☐Yes ☐No
12. Do you provide Clinical Investigators, CROs or Sites with compensation other than charges for specific services rendered (e.g., enrollment bonuses, equity interest)? ☐Yes ☐No
13. What is the maximum compensation you have offered trial participants? _____

III. PRODUCTS COMPLETED OPERATIONS – REGULATORY AND RISK MANAGEMENT

A. REGULATORY

1. Are you in compliance with Title 21 CFR Part 99 – Dissemination of Information on Unapproved/New Uses for Marked Drugs, Biologics and Devices? ☐Yes ☐No

   If No, please provide details: _____

2. Have you had any product(s) requiring the additional of a black box or significant safety warning to an existing label or instruction manual in the last 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 last 3 years? ☐Yes ☐No

   If Yes, please provide details: _____

5. Do you have any products approved for use by minors? ☐Yes ☐No

B. 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 Assurance Program? _____
3. Do your quality control procedures include formalized, standard operating procedures for the following? Check all that apply:

☐	Facility sanitation controls	☐	Written systems development methodology	☐	Prototype development guidelines	☐	Customer acceptance procedure
☐	Materials and/or goods subject to atmospheric changes	☐	In-process control point tests	☐	Finished goods or batch testing	☐	Batch records/serial product history record keeping
☐	Vendor certification/ verification process	☐	cGMP testing	☐	Labeling and packaging	☐	Written quality control program
☐	Incoming inspection of raw materials or component parts	☐	Alpha testing	☐	Shelf like and/or calibration requirements	☐	Product recall program
☐	Non-conforming material	☐	Beta testing	☐	Safe distribution of goods	☐	Third 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 third 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 third 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 I	☐	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 subtractor? ☐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 your products? _____

   If batched produced, what is the average size? _

2. What, if any, is the shelf-life expectancy of your product? _____
3. Do you have a formal product recall program? ☐Yes ☐No

   If Yes:

   a. Do conduct test recalls? ☐Yes ☐No
   b. Do any of your products become part of another company's product? ☐Yes ☐No
   c. Are any of your 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? ☐Yes ☐No
   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
☐	Additional studies
☐	Expanded product monitoring

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	☐	☐	☐	☐	☐	☐	☐	☐
Additional Insured Status on Products / Completed Operations Liability Policy	☐	☐	☐	☐	☐	☐	☐	☐
Hold Harmless language (in your favor or mutually beneficial)	☐	☐	☐	☐	☐	☐	☐	☐
Indemnification language (in your favor or mutually beneficial)	☐	☐	☐	☐	☐	☐	☐	☐
Contract	☐	☐	☐	☐	☐	☐	☐	☐
Purchase Orders / Invoice (Incl. Terms & Conditions)	☐	☐	☐	☐	☐	☐	☐	☐
Master Service Agreement	☐	☐	☐	☐	☐	☐	☐	☐
Distribution Agreement	☐	☐	☐	☐	☐	☐	☐	☐

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

   If Yes, please provide details: _____

IV. ADDITIONAL COVERAGE OPTIONS

A. ERRORS AND OMISSIONS

(Please complete this section if you are applying for Errors & Omissions coverage.)

Contract Information and Contract Risk Management

1. Do you require a written contract, with your customers, for your products or services? ☐Yes ☐No

   If No, please explain: _____

   If Yes, please provide a breakdown of your contract activities below:

TYPE OF CONTRACT		What Percentage is Standard/Non-Deviating	What Percentage is Customized To Meet Customer Requirements
☐	Formal Contract	%	%
☐	Licensing Agreement	%	%
☐	Purchase Order	%	%
☐	Other	%	%

2. Do your standard contracts, licensing agreements or purchase orders contain the following provisions? Check all that apply:

☐	Statement of Work	☐	Exclusive Remedy	☐	Performance Milestones/Schedule of Deliverables
☐	Limitation of Liability	☐	Integration Clause	☐	Customer Maintenance Provision
☐	Limitation of Consequential Damages	☐	Force Majeure	☐	Hold Harmless/Indemnification Agreement
☐	Disclaimer of Warranties	☐	Arbitration Clause	☐	Conditions of customer acceptance of product or service

3. Have your standard contracts, licensing agreements or purchase orders undergone legal review? ☐Yes ☐No

   If No, please explain: _____

4. Are all deviations from your standard contracts, licensing agreements, purchase orders or customer supplied contracts reviewed by your legal counsel? ☐Yes ☐No

   If No, please give examples of deviations that do not require legal review and sign-off:

   _____

5. Who can approve any variation in your standard contracts, licensing agreements or purchase orders provisions?

   _____

6. Do you ever negotiate contracts, licensing agreements or purchase orders with customers that include a provision for liquidated damages? ☐Yes ☐No

   If Yes, please explain: _____

7. Do you ever negotiate standard contracts, licensing agreements or purchase orders with Customers in which you accept liability for consequential damages? ☐Yes ☐No

   If Yes, please explain: _____

8. Do your sales and marketing personnel receive training regarding the acceptable provisions within your customer contracts, licensing agreements or purchase orders? ☐Yes ☐No

9. Do you require subcontractors or independent contractors to carry Errors and Omissions insurance? ☐Yes ☐No

   If Yes, what is the minimum policy limit required? $_____

10. Do you notify customers of known problems with your products or services? ☐Yes ☐No

    If Yes, please describe: _____

11. Do you offer 24-hour product and service customer support? ☐Yes ☐No

12. Do you have a process to evaluate the financial condition of your customers and suppliers? ☐Yes ☐No

13. What is your average contract size and duration? _____

14. Describe your three largest customer contracts, purchase orders, licensing agreements or projects:

CUSTOMER NAME	Product or Service Provided	Size of Contract, Purchase Order, Licensing Agreement or Project	Length of Contract

B. INFORMATION SECURITY & PRIVACY AND PERSONAL INJURY

(Please complete this section if you are applying for Information Security & Privacy and Personal Injury coverage.)

Organization - Cybersecurity

1. Indicate the type and number of unique records collected/maintained by you or others on your behalf. Check all that apply:

TYPE OF INFORMATION		Number of Records									
☐	Biometric information	☐	<50K	☐	50K-500K	☐	500K-1M	☐	1M-3M	☐	>3M
☐	Financial account numbers	☐	<50K	☐	50K-500K	☐	500K-1M	☐	1M-3M	☐	>3M
☐	Other personally identifying information (i.e., social security numbers, passport numbers)	☐	<50K	☐	50K-500K	☐	500K-1M	☐	1M-3M	☐	>3M
☐	Protected Health Information	☐	<50K	☐	50K-500K	☐	500K-1M	☐	1M-3M	☐	>3M
☐	Credit card numbers	☐	<50K	☐	50K-500K	☐	500K-1M	☐	1M-3M	☐	>3M
☐	Other information not described above (i.e., name, address, telephone numbers, etc.	☐	<50K	☐	50K-500K	☐	500K-1M	☐	1M-3M	☐	>3M

2. You have (check all that apply):

a.	A regularly tested and updated Written Information Security Plan	☐
b.	A regularly tested and updated Written Incident Response Plan	☐
	Are the WISP and/or the IRP tested at least annually?	☐Yes ☐No
c.	A designated Chief Information Security Officer (or equivalent)?	☐

3. Back-ups – You make (*select one*):

a.	Regular, full and incremental backups of critical data and computer systems	☐
b.	Occasional and full back-ups of critical data and computer systems	☐
c.	No back-ups of critical data and computer systems	☐
If either 2.a. or 2.b. has been selected, is one copy stored online?		☐Yes ☐No
If either 2.a. or 2.b. has been selected, is one copy stored off-site or *offline*?		☐Yes ☐No
If either 2.a. or 2.b. has been selected, how quickly could systems be operational?		
☐ Within 24 hours ☐ Within 25-48 hours ☐ Within 49-130 hours ☐ Greater than 130 hours		

4. Are devices connected to your network cataloged and mapped on a regular basis? ☐Yes ☐No
5. Are local administration rights disabled for regular employees on their devices (i.e., laptops/desktops)? ☐Yes ☐No
6. Is Multifactor Authentication (MFA) deployed and enforced on:
   ☐ All administration accounts? ☐ Remote access? ☐ All email accounts?
7. Have legacy email protocols (such as IMAP, POP3, and SMTP) been disabled? ☐Yes ☐No

   Is there any end of life (EOL) or end of support (EOS) software on your network? ☐*Yes* ☐*No*
   (EOL/EOS software is where developers stop providing updates and patches)

   If Yes, is it segregated? ☐Yes ☐No
8. Do you have an internal Security Operations Center (SOC) or utilize a third party for SOC or Managed Detection and Response (MDR) services? ☐Yes ☐No

If Yes, indicate “internal” or the name of the service provider:

Provider: _____ ☐ 24x7 Provider ☐ Working hours only provider

9. How often are network penetration tests conducted on your network (tests can be performed by you or a third party on your behalf)?

☐ Never/Occasionally ☐ Annually ☐ Semi-annually ☐ Quarterly ☐ Monthly or more often

10. Patching and Updates – You have (*select one*):

a.	Automatic updates enabled with patch management verification procedure	☐
b.	Automatic updates enabled	☐
c.	Manual updates	☐

11. Firewalls – You have (*select one*):

a.	Hardware and software firewalls deployed	☐
b.	Hardware firewall deployed	☐
c.	No firewalls deployed	☐

12. Endpoint Detections & Response (EDR) and Intrusion Detection Software – You have (*select one*):

a.	EDR and Intrusion detection software installed or activated on all Computer Systems	☐
b.	EDR solution installed or activated on all endpoints	☐
c.	No EDR solution or intrusion detection software installed or activated	☐

13. Network Security – When working remotely, your employees (*select one*):

a.	Access a segmented network via Virtual Private Network	☐
b.	Access the network via Virtual Private Network	☐
c.	Do not access a Virtual Private Network	☐

14. Email Security – You have (*select one*):

a.	Web and email (DKIM, DMARC, SPF) filtering enabled	☐
b.	Web or email (DKIM, DMARC, SPF) filtering enabled	☐
c.	Neither Web nor email filtering enabled	☐

15. Encryption – Your encryption is (*select one*):

a.	Deployed for Data at rest, in transit and on mobile devices		☐
b.	Deployed for Data at rest		☐
c.	Not deployed – Please Explain:		☐

16. Accountability – When accessing computer systems & information, employees and third parties are issued (*select one*):

a.	Separate and unique accounts with strong passwords (i.e., NIST, MS, etc.). Access is restricted to that needed to perform their duties (i.e., separate administration accounts)	☐
b.	Separate and unique accounts with strong passwords (i.e., NIST, MS, etc.)	☐
c.	Separate and unique accounts with no password construction requirements	☐

17. Information Security Training – You have the following employee training program to safeguard personal information (*select one*):

a.	Formal and documented *annual* employee training program	☐
b.	Formal but undocumented employee training program	☐
c.	No employee training program	☐

18. Has traffic using Remote Desktop Protocol (RDP) TCP ports 3389 and Server Message Block (SMB) TCP ports 445, 139, and 149 been blocked? ☐Yes ☐No

19. Please provide the name of the product and/or service deployed for the following security solution categories:

SECURITY SOLUTIONS	Provider/Product
Endpoint Protection Platform (EPP)	
Application Isolation and Containment	
Endpoint Detection and Response (EDR)	
Network Detection and Response (NDR)	
Security Information and Event Management (SIEM)	
Privileged Access Management (PAM) / Identify & Access Management (IAM)	

20. Do use vendors for any of the following:
    a. Customer Service? ☐Yes ☐No
    b. Webhosting/data center operations? ☐Yes ☐No
    c. Data Processing? ☐Yes ☐No
    d. Other – Please describe: _____

21. If user information is collected on your website, do users have the option to opt in or opt out of the allowing the collections or use of their information? ☐Yes ☐No

22. Does your company adhere to the requirements and guidance set forth with FDA and any other regulatory standards to assure cybersecurity exposures are adequately controlled in the design, productions and post-production of any medical devices manufactured or distributed by your company? ☐Yes ☐No

Product or Service Cybersecurity

1. Do you have a comprehensive cybersecurity plan in place which identifies the vulnerabilities and/or threat sources which may permit the unauthorized access, modification, misuse, or denial of use; or the unauthorized use of information that is stored, accessed or transferred from your product or service to an external recipient and may impact patient safety? ☐Yes ☐No

   If Yes, does it include?

   (Check all that apply)

☐	Monitoring cybersecurity information sources for emerging vulnerabilities and risk
☐	Protocols for vulnerability intake and handling
☐	Defined process to detect and assess both the presence and impact of a vulnerability or threat
☐	Defined acceptable performance with respect to protecting, responding, and recovering from a cybersecurity risk
☐	A vulnerability disclosure policy and practice
☐	Deploying mitigations that address cybersecurity risk early and prior to exploitation

2. Do you incorporate the following into your product or service Risk Management protocols? (Check all that apply)

☐	Defined process for assessing the exploitability of a cybersecurity vulnerability
☐	Defined process to evaluate cybersecurity risk versus essential clinical performance of your product or service
☐	Defined process to determine whether or not the exploitation of an identified vulnerability can be categorized as an acceptable or unacceptable risk
☐	Defined process to communicate threats
☐	Defined process for assessing the severity impact to patient health of a cybersecurity vulnerability
☐	Defined requirements necessary to achieve device safety and effectiveness
☐	Defined process to systematically conduct risk evaluations and determine whether a cybersecurity vulnerability affecting your product or service presents an acceptable or unacceptable risk
☐	Protocols to establish, document, and maintain throughout the lifecycle of the product or service, an ongoing process for identifying hazards associated with cybersecurity

3. Do you incorporate the following into your product or services' cybersecurity remediation protocols? (Check all that apply)

☐	Ensure the version for acquired software is supported by the vendor
☐	Protect web applications by deploying Web Application Firewalls (WAF) and non web-based applications with specific application firewalls
☐	Ensure explicit error checking is performed and documented for all input on in-house developed software
☐	Test in-house developed and third party procured web applications for common security weaknesses prior to deployment and whenever updates are made
☐	Maintain separate environments for production and nonproduction systems
☐	Use standard hardening configuration templates for applications that rely on a database
☐	Ensure software development personnel receive training in writing secure code for their specific development environment
☐	Ensure development artifacts are not included in deployed software or accessible in production environment for in-house developed applications

4. Have you had to remediate cyber security vulnerabilities in the past 3 years? ☐Yes ☐No

   If Yes, were they successful? ☐Yes ☐No

Personal Injury Liability

1. Do you sell or share personal and/or confidential information gathered from customers or others? (This includes information gathered form your website or by other means.) ☐Yes ☐No

   If Yes, do you notify and obtain the consent of customers or others prior to disseminating this information? ☐Yes ☐No

2. Do you have a chat room, bulletin board or social media site? ☐Yes ☐No

   If Yes, please provide the following information:

   a. Who are the primary users of the chat room, bulletin board or social media site (i.e., employees, vendors, customers, etc.)?

      _____

   b. Do you monitor the chat room, bulletin board or social media site? ☐Yes ☐No

   c. How quickly do you remove content and posts when you are notified they are unacceptable or infringing? _____

C. MEDIA AND CONTENT

(Please complete this section if you are applying for Media and Content coverage.)

Intellectual Property

1. Do you provide any of the following?
   (Check all that apply)

☐	Applications/software that enables the copying or dissemination of the content of others (ie., music, art, photos, graphics, video, written works, etc.)
☐	A file swapping network
☐	Access to the file sharing activities (i.e., peer to peer)

2. Do you have intellectual property or business methods clearance procedures? ☐Yes ☐No

   If Yes, check all that apply:

☐	The acquisition of all the necessary rights, licenses, releases and consents applicable to content or services created or provided by you or third parties	☐	Legal review of all referral and affiliate program agreements
☐	Permission to use and legal review of the trademarks and/or service marks of others		Legal review of the following performed prior to release, use, dissemination of or modification to regardless of the medium **(check all that apply)**: ☐ Content ☐ Business Methods ☐ Product Technology used ☐ Websites ☐ Work Services ☐ Advertising and Marketing
☐	New hire and independent contractor agreements include signed statements that new employees and contractors will not disseminate or use any previous employer's or client's trade secrets or other intellectual property		Trademark and/or service mark searches and clearances for all your: ☐ Domain names ☐ Service names, designs or logos
☐	The contractual acquisition of all rights (including electronic rights) to work done by you by third parties, including hold harmless and indemnification clauses, which inure to your benefit pertaining to that work		Content searches and clearances perform by your: **(check all apply)** ☐ Legal counsel ☐ Professional search company ☐ Computerized database search
☐	Legal review performed with respect to laws in jurisdictions outside the U.S.	☐	Permission from owners of sites you link or frame
☐	Disclaimers on your website pertaining to content made available or disseminated	☐	Legal review of all licensing and/or cross-licensing agreements

V. 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 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 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.

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.

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 Number:_____

Address (Street, City, State, Zip):_____