Clear Form

MOODY
INSURANCE WORLDWIDE

BIOTECHNOLOGY AND MEDICAL PRODUCTS INSURANCE QUESTIONNAIRE

Return completed Questionnaire to:
Moody Insurance Worldwide
20251 Century Blvd, Suite 425
Germantown, MD 20874
Phone (301) 417-0001
Toll-free (800) 966-0001
Fax (301) 417-0040
customerservice@moodyinsurance.com

GENERAL INFORMATION

Proposed First Named Insured & Other Named Insured(s):	Today's Date:
Mailing Address:	
Location Address: (if different than above)	
Telephone Number:	Web Address:
Type of Legal Entity:	
Description of Primary Operations and Any Other Operations:	

Proposed Effective Date *(mm/dd/yyyy)*	Proposed Expiration Date *(mm/dd/yyyy)*	Date Business Started:

1. Do you have a parent company? ☐ Yes ☐ No
2. Are there any other persons or organizations such as parents, subsidiaries, affiliates, or other entities related to you (including d/b/a's), for which products and completed work liability coverage is desired? ☐ Yes ☐ No
   If yes, please list and describe their relationship to you:

Note: Listing persons or organizations here does not automatically grant coverage for them under any policy issued based on this application.

ATTACHMENTS TO QUESTIONNAIRE

Include the following with the submission, if applicable:

- ☐ Summary of relevant transactions *(If any.)*
- ☐ Copies of all protocols or investigator brochures and final informed consent documents
- ☐ Copy of FDA inspection 483
- ☐ Copy of FDA warning letter(s) (*if any.*)
- ☐ Copy of FDA untitled letter(s) (*if any.*)
- ☐ Copy of service agreement (*if any.*)
- ☐ Copy of preventative maintenance procedure (*if any.*)
- ☐ Underlying policy proposal (*if coverage requested.*)
- ☐ Five year loss runs for products and completed work liability

COMPANY PROFILE

1. Please provide a description of your products:

_____

_____

_____

2. Within the past five years, have you:

   a. Changed your name? ☐ Yes ☐ No
   b. Changed your ownership structure? ☐ Yes ☐ No
   c. Purchased or acquired another organization? ☐ Yes ☐ No
   d. Merged or consolidated operations with another organization? ☐ Yes ☐ No

   If you answered yes to any of questions 2.a.- 2.d., please attach a summary of relevant transactions.

3. Annual revenue and sales profile:

   a. Projected domestic sales: $ _____
   b. Projected foreign sales: $ _____
   c. Projected units sold: _____
   d. Current domestic sales: $ _____
   e. Current foreign sales: $ _____
   f. Current units sold: $ _____

4. Projected annual revenue by revenue source (percentages):

a.	Medical devices	%	f.	Installation, service, or repair	%
b.	Contract manufacturing	%	g.	Pharmaceutical	%
c.	Distribution	%	h.	Professional Services	%
d.	Software/information services	%	i.	Other (*please describe*)	%
e.	Royalties/licensing fees	%		_____	

5. Projected annual sales by type of medical product/service (percentages):

a.	Analytical instrument	%	k.	Lasers	%
b.	Anesthesia/respiratory	%	l.	Monitoring equipment	%
c.	Cardiac/cardiovascular	%	m.	Software	%
d.	Dental instruments	%	n.	Surgical devices	%
e.	Diagnostic kits	%	o.	Therapy/rehab equipment	%
f.	Dialysis products	%	p.	Ethical/Prescriptive	%
g.	Drug delivery devices	%	q.	OTC	%
h.	Durable medical equipment	%	r.	Professional Services	%
i.	Hospital products/supplies	%	s.	Other (*please describe*)	%
j.	Imaging devices	%		_____	

6. Intended use for your products (percentages):

   a. Clinical %
   b. Ambulatory %
   c. Home %
   d. Pediatrics %
   e. Other (*please describe*) %

   _____

7. Are your products:
   a. FDA Class III ☐ Yes ☐ No
   b. OTC ☐ Yes ☐ No
   c. Single Use ☐ Yes ☐ No
8. Do any of your past, present, or planned future operations involve the manufacture, sale, handling, distribution, or disposal of implants or latex gloves? ☐ Yes ☐ No
   If yes, please describe:

9. Contracted services (percentages):

a.	Clinical trial management/protocol development	%	g.	Manufacturing	%
b.	CLIA laboratory services	%	h.	Preclinical testing	%
c.	Design engineering	%	i.	Product packaging/sterilization	%
d.	Distribution	%	j.	Regulatory submissions/filings	%
e.	Equipment maintenance/sterilization	%	k.	Repackaging	%
f.	Information/database services	%	l.	Sales	%

PRODUCT INFORMATION

1. Do you have any new products that are expected to be introduced or marketed in the coming year? ☐ Yes ☐ No
   If yes, please list:
2. How are your products sold?
3. Do you require certificates of insurance and hold harmless/ indemnifications from your vendors? ☐ Yes ☐ No
4. Have you ever discontinued any product? ☐ Yes ☐ No
   If yes, please provide the date of discontinuation and the reason(s) for discontinuation:
5. Do your products contain parts manufactured by others? ☐ Yes ☐ No
   If yes, please explain:
6. Do you require certificates of insurance and hold harmless/ indemnifications from your suppliers? ☐ Yes ☐ No
7. Do you import products or component parts? ☐ Yes ☐ No
   If yes, please describe:
8. Do you manufacture products sold under other's labels? ☐ Yes ☐ No
   If yes, please describe:

9. Do you have any products sold as components for other's products? ☐ Yes ☐ No
   If yes, please describe your controls:

10. Do you have products manufactured outside the US? ☐ Yes ☐ No
    If yes, please describe:

11. Do others install your products? ☐ Yes ☐ No
    If yes:
    a. Do you supervise or furnish installation instructions? ☐ Yes ☐ No
    b. Do you sign off on installation? ☐ Yes ☐ No
12. Are your products available for lease or rent? ☐ Yes ☐ No
    If yes, please explain:

13. Do you distribute any products manufactured by others? ☐ Yes ☐ No
    If yes, please explain:

14. Do you produce any biologic products including virus, serum, toxin, antitoxin, vaccine, blood, blood derivative or component, allergenic product, etc.? ☐ Yes ☐ No
    If yes, describe:

15. Do your products contain any of the following: phentermine, fenfluramine, dexfenfluramine, phenylpropanolamine hydrochloride (PPA), isotretinoin (accutane), ephedrine or derivative, diethylstilbestrol? ☐ Yes ☐ No
16. Do any products fall into the following categories: antidepressants/SSRI, ADD/ADHD, birth control, hormone therapy, pain management, weight gain, weight loss, pediatric? ☐ Yes ☐ No

CLINICAL TRIALS

1. Please provide the following information regarding your clinical trials projected to take place in the next twelve months. Also, please attach copies of all protocols or investigator brochures and final informed consent documents for all trials that will take place in the next twelve months.

Product/ protocol no.	*No. of new participants in next 12 months*	*Indication*	*Trial phase*	*Countries where the trial will take place*

2. If you have completed clinical trials previously or are currently conducting a trial:
   a. How many human clinical trials have you sponsored in the last three years? ☐ Yes ☐ No
   b. What is the total number of participants in those trials? _____
   c. Have any of your clinical trials been suspended or discontinued? ☐ Yes ☐ No
      If yes, please provide details:
      _____
      _____
   d. Do you ever act as both the trial sponsor and clinical investigator? ☐ Yes ☐ No

REGULATORY AND SAFETY SURVEILLANCE

1. In the past five years, have there been any MAUDEs or AERs filed? ☐ Yes ☐ No
   If yes, please provide details of each MAUDE or AER:
   _____
   _____
2. Have you had any product recalls in the past five years? ☐ Yes ☐ No
   If *yes, please provide the details, recall class, and status of each recall*:
   _____
   _____
3. What was the date of your most recent FDA inspection and its results? _____
   Please provide a copy of the 483 and your response(s).
4. Have you received any warning letters as a result of an FDA inspection? ☐ Yes ☐ No
   If yes, please provide a copy of each letter and your written response.
5. How many untitled letters have you received from the FDA in the last three years? _____
   If you have received any such letters, please provide a copy of each letter and your written response.
6. Do you maintain copies of vigilance reports? ☐ Yes ☐ No
   If yes, please provide the details and nature of each:
   _____
   _____
7. Have you had any product discontinued for safety reasons? ☐ Yes ☐ No
   If yes, please provide the details:
   _____
   _____
8. Do you monitor off-label use of your products?. ☐ Yes ☐ No
9. Have you found instances of off-label use of your products? ☐ Yes ☐ No
   If yes, please list such instances and your position regarding such off-label use:
   _____
   _____
10. 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

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

If yes, provide the name and title of the person responsible for such program:

12. Are you in compliance with all applicable GMP, GCP, GLP and QS guidelines? ☐ Yes ☐ No
13. Are all risk management programs and SOPs audited at least annually? ☐ Yes ☐ No
14. Do you have a formalized client complaint resolution policy and procedure? ☐ Yes ☐ No
15. Are your marketing/sales, safety surveillance, product development, and regulatory teams receiving and documenting regular training in product liability and regulatory requirements? ☐ Yes ☐ No
16. What percentage of your regulatory, safety, and sales staff have less than five years of experience?_____%
17. How long are your testing and quality control records retained? _____
18. Please describe the guarantees or warranties provided with your products or services:
19. Does legal counsel review your labels and warnings, advertising materials, and website content on at least an annual basis? ☐ Yes ☐ No
20. Do you have a product recall plan? ☐ Yes ☐ No

SERVICES INFORMATION

1. Are any of your employees or subcontractors present during procedures or providing direct patient care? ☐ Yes ☐ No
   If yes, please explain:
2. Do you ever provide technical assistance, either in person or via other means, during a patient procedure? ☐ Yes ☐ No
3. Do you ever provide any service agreements for your products? ☐ Yes ☐ No
   If yes, please attach a copy of your service agreement and answer the following:
   a. Do you have a written preventative maintenance program for all products under a service agreement (i.e., device id number, date of service, service provided, problems, service provider, etc.)? ☐ Yes ☐ No
   b. Do you have a formal mechanism to notify the customer prior to the service date and products to be serviced? ☐ Yes ☐ No
   c. Do you have a written procedure to follow if the device requiring preventative maintenance is not available at the time of the scheduled service? ☐ Yes ☐ No
      If yes, please attach a copy of your procedure.
   d. Do you audit your company's compliance with the service agreements? ☐ Yes ☐ No
4. Do you provide service on other's products? ☐ Yes ☐ No
   If yes, are you trained by the OEM? ☐ Yes ☐ No
5. Do you contract out your service work? ☐ Yes ☐ No
   If yes:
   a. Do you require certificates of insurance? ☐ Yes ☐ No
   b. Do you train the service staff? ☐ Yes ☐ No

6. Do you provide product training?..... ☐ Yes ☐ No

If yes:

a. Do you have a documented training program for each device? ..... ☐ Yes ☐ No

b. Do you document and retain the details of each training program (i.e., names of attendees, program, trainer, objectives covered, etc.)? ..... ☐ Yes ☐ No

INSURANCE INFORMATION

1. Please provide the following information for any products and completed work liability coverage that you have had over the past five years:

Policy Period			
Insurance Carrier(s)			
Policy Number(s)			
Premium			
Limits (Primary & Excess)			
Deductible/SIR			
Retroactive Date			

2. Within the past five years, has your products and completed work liability coverage (or similar coverage) been declined, cancelled, or non-renewed? (Missouri applicants-do not answer this question)..... ☐ Yes ☐ No

If yes, please provide details:

_____

_____

3. Please provide your desired limits of coverage, deductible/ self-insured retention, effective date, and retroactive date for your primary products and completed work liability insurance:

a. Each event limit: $ _____

b. Total limit: $ _____

c. Deductible/SIR (each event): $ _____

d. Effective date: _____

e. Retroactive date: _____

4. Are you seeking excess products and completed work liability insurance from us?..... ☐ Yes ☐ No

If yes, please provide your underlying policy proposal for the terms and conditions in addition to an Excess Coverage Placement Questionnaire you can receive from our underwriter.

COMPLAINTS, CLAIMS OR SUITS

1. Please list the information below regarding your loss record for products and completed work liability for the last five years. Also, please attach five years of detailed loss runs for products and completed work liability for you and your executive officers, directors, employees, parents, subsidiaries, or affiliated organizations.

	Name of Insurer(s)	*Number of Losses*	*Total Amount of Losses Paid and Reserved*
This Year			$
One Year Ago			$
Two Years Ago			$
Three Years Ago			$
Four Years Ago			$

2. Do you have any knowledge of:

   a. Any actual or threatened claim or legal proceeding against you, or against any of your executive officers, directors, employees, parents, subsidiaries, or affiliated organizations, arising out of your products or your completed work that has not been reported to your current insurer(s)?..... ☐ Yes ☐ No

   If yes, please provide the details of the actual or threatened claim or legal proceeding, including how you responded and whether it has been resolved or is ongoing:

   _____

   _____

   _____

   b. Any facts or circumstances that might reasonably be expected to give rise to a claim or legal proceeding against you, or against any of your executive officers, directors, employees, parents, subsidiaries, or affiliated organizations, arising out of your products or your completed work?..... ☐ Yes ☐ No

   If yes, please explain these facts and circumstances:

   _____

   _____

   _____

QUESTIONNAIRE COMPLETED BY

Name of Person Completing Form:	Title:	Date Completed:
Contact Phone:	Contact Email:	Contact Fax:

ADDITIONAL INFORMATION

This area may be used to provide additional information to any question. Reference section name and question number.