Medmarc Casualty Insurance Company
Noetic Specialty Insurance Company

Medmarc Insurance Group
Medical Technology-Life Sciences
Products and Completed Operations Liability Insurance

14280 Park Meadow Drive, Suite 300, Chantilly, VA 20151-2219 | Phone: 703.652.1300 or 800.356.6886 | Fax: 703.652.1389

New Business Application

This application is for a Claims Made Policy

Please answer all questions completely, using attachments if necessary.
Do not leave any space blank, please indicate "n/a" if a question is not applicable.
Please attach current financial information for any privately held companies.

Broker Information			
1.	**Company Name:**		
2.	**Address:**		
3.	**Primary Contact Name:**	**Email:**	**Phone:**
4.	**License #:** Please provide copy of agency license (must be for state applicant is located in).		

Applicant Information		
5.	**Named Insured:** (as it should appear on the policy)	
6.	**Desired Effective Date:**	
7.	**Parent Company (If Any):**	
8.	**Address:**	
9.	**Date Established:**	
10.	**Website:**	
11.	**Phone Number:**	

12. Named Insured is: ☐ Individual ☐ Partnership ☐ Corporation ☐ Joint Venture ☐ Other (Describe)

13. Additional Named Insured(s) (including % of ownership):

Additional Named Insured	%

14. Description of Operations:

15. Companies or assets acquired (A) or sold (S) within last 5 years:

Entity	A/S	Date Acquired/Sold	Description

16. Additional Insured(s): Please explain the relationship to named insured.

Additional Insured	Relationship

17. Are you a member of an industry trade group? Yes ☐ No ☐

If yes: ☐ AdvaMed ☐ MDMA ☐ Other

18. Applicant Contact Information			
Name		**Title**	**Email**
Primary:			
SIR Billing:			
Loss Run:			
Loss Control:			
Claim:			
Finance:			

Current Insurance Information		
19.	**Current Insurance Company:**	
20.	**Current Type of Insurance (Occurrence or Claims Made):**	
21.	**Policy Renewal Date:**	
22.	**Current Limit of Insurance:**	
	Desired Limit (if different):	
23.	**Current Self Insured Retention:**	
	Desired Self Insured Retention (if different):	
24.	**Current retroactive date (if claims made):** (if more than one, please outline current retroactive date schedule)	

25. Does your firm currently carry excess liability coverage? Yes ☐ No ☐

If yes:

Limit	Coverage	Claims Made Retro Date

26. May we provide you with a CGL quote? Yes ☐ No ☐

If yes, please complete both The Hartford supplemental application along with an ACORD application.
(We have an alliance with The Hartford for supporting CGL that wraps around our products coverage. Having your CGL wrap around coverage with The Hartford may avoid coverage gaps that could occur if coverage is placed with another carrier.)

27. Projected Revenue Information		
Revenues	**U.S./Canada**	**Other/Foreign**
Manufacturing: Medical Devices (proprietary products)		
Manufacturing: Pharmaceutical/ Biologics (proprietary products)		
Contract Manufacturing/OEM (products sold under other labels)		
Distribution		
Equipment Rental		
Installation/Repair/Service		
Research and Development		

Prior 3 Year Revenue Information		
Year	**U.S./Canada**	**Other/Foreign**

Product Information		
List and Describe		**(Please use attachments if necessary)**
28.	**Your products and any brochures, warning labels, etc.**	
29.	**Products currently under development and expected to be introduced in the next 12 months (including FDA status)**	
30.	**Products that have been discontinued in the last 3 years.**	
31.	**Products that you manufacture for other companies to sell under their label.**	

32.	**Products that are manufactured by other companies for sale under your label.**	
	Do you require certificates of insurance from those manufacturers?	Yes ☐ No ☐
	List your manufacturers.	
33.	**Products you make which are a component of others' final product(s)**	
34.	**Products you sell or components in your products which are imported from a foreign supplier (list foreign country)**	
35.	**Products specifically excluded from current coverage**	

36. Have any products been removed or recalled from the market in the past year? Yes ☐ No ☐

If yes, please specify the following:

Recall Date	Voluntary or Mandatory	Recall Class	Reason	Completed (Yes/No)

37.	**Are you planning any product recalls for this year?**	Yes ☐ No ☐	**If yes, please elaborate:**
38.	**Do you have a written plan for product recalls?**	Yes ☐ No ☐	

39.	Have you received any warning letters in the past 12 months?	Yes ☐ No ☐	If yes, please provide a copy.
40.	Has the FDA inspected your facilities in the past year?	Yes ☐ No ☐	If yes, please submit a copy of Form 483 and your response.
41.	Have you performed a GMP (Good Manufacturing Practice) or similar self-audit, or has one been performed by a third party within the past 12 months?	Yes ☐ No ☐	If yes, please attach a copy.
42.	Do you have a loss control/ risk management program in place?	Yes ☐ No ☐	If yes, please provide the name, title and phone number of person in charge of this program (if different from Loss Control / Product Safety contact):
43.	Do you advertise your product directly to consumers/patients?	Yes ☐ No ☐	If yes, please advise what media type(s) you use (i.e. magazines, TV, internet, etc.):
44.	Do you have a record retention policy for production records?	Yes ☐ No ☐	If yes, for how many years do you retain records?
45.	Do you have any products that required the addition of a "black box warning" or other significant safety warning to labels or instructions in the last 2 years?	Yes ☐ No ☐	If yes, please list:
46.	In the past year, have you issued any:		If yes to either of these, please elaborate:
	a. Public Health Notification(s) or Safety Alerts?	Yes ☐ No ☐	
	b. Dear Doctor/ Healthcare Practitioner Letters?	Yes ☐ No ☐	

47.	**Is there trace ability of components to production lot?**	Yes ☐ No ☐	**If yes, please describe tracking method employed.**
48.	**Is there trace ability of components to final production?**	Yes ☐ No ☐	**If yes, please describe tracking method employed.**
49.	**How are final products identified?**	Batch ☐ Lots ☐ Both ☐	
50.	**If engaged in R&D, do you utilize design validation (Pre-Production Q/A)?**	Yes ☐ No ☐	

51. Human Clinical Trials Information

Please list ongoing and anticipated for the next 12 months and attach a copy of the Protocol(s) and Informed Consent Form(s) for all trials.

Protocol Number & Name	Type of Trial[1]	Significant Study	Trial Phase	Total Subjects Projected	Subject Enrollment Past Year / Current Year	Trial Date: Commence / Completion	FDA Classification for Trial Status[2]	Trial Location
Product Name & Description								
		☐ Yes ☐ No ☐ N/A - drug						
		☐ Yes ☐ No ☐ N/A - drug						
		☐ Yes ☐ No ☐ N/A - drug						
		☐ Yes ☐ No ☐ N/A - drug						

[1] Type of Trial

- **Treatment** trial – test experimental treatments, new combination of drugs, or new approaches to surgery or radiation therapy
- **Prevention** trial – look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
- **Diagnostic** trial – conducted to find better test or procedures for diagnosing a particular disease or condition
- **Screening** trial – test the best way to detect certain diseases or health conditions
- **Quality of Life** trial (or Supportive Care trial) explore ways to improve comfort and the quality of life for individuals with a chronic illness
- **Registry** trial – observational studies in which the events that happen to test subjects with a specific disease or condition are recorded without pre-defined treatment

[2] FDA classifications for trial status

- **Pending** – not yet recruiting
- **Ongoing** – recruiting and enrollment completed; study proceeding according to or ahead of schedule
- **Delayed** – study behind schedule
- **Withdrawn** – study halted prematurely, prior to enrollment of first participant
- **Suspended** – recruiting or enrolling participants has halted prematurely but potentially will resume
- **Terminated –** study halted prematurely and will not resume; participants are no longer being examined or treated.
- **Completed –** study has concluded normally; participants are no longer being examined or treated

52.	**Number of trials in the last 3 years:**			
53.	**Number of enrolled human subjects in the last 3 years:**			
54.	**Are all institutional review boards (IRBs) registered with the Department of Health and Human Services (HHS)?**	Yes ☐ No ☐		
55.	**Who reviews your company's indemnification agreements with Investigators, CROs and IRBs?**			
56.	**Are you using a Clinical Research Organization (CRO) in any of your studies?**	Yes ☐ No ☐		
57.	**Have any of your IRBs received a Warning Letter or been the subject of adverse FDA action?**	Yes ☐ No ☐	**If yes, please explain:**	
58.	**Have you or your investigator ever been cited, debarred, fined or suspended by the Office for Human Research Protections (OHRP) for violations of federal law, including research rules?**	Yes ☐ No ☐	**If yes, please explain:**	
59.	**Have any trials been discontinued or suspended, whether by you, FDA or another authority, for safety reasons?**	Yes ☐ No ☐	**If yes, please explain:**	
60.	**Have any subjects had a serious adverse event (such as hospitalization, danger to life, death, congenital anomaly, malignancy) while participating in one of your clinical trials?**	Yes ☐ No ☐	**If yes, please describe:**	
61.	**Do any of your studies involve subjects that are children or members of a "vulnerable"[3] patient population?**	Yes ☐ No ☐	**If yes, please explain:**	
62.	**Are any clinical trials being conducted at your facility?**	Yes ☐ No ☐	**If yes, could the clinical trial(s) be interrupted if there was a loss at your facility?**	Yes ☐ No ☐

[3] "Vulnerable" patients include children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, as defined by 21 CFR 56.111(3).

63.	**Are you planning any foreign clinical trials in the future?**	Yes ☐ No ☐	**If yes, please describe:**	
64.	**Are you sponsoring any clinical trials that you have invited your own employees to participate in?**	Yes ☐ No ☐	**If yes, please describe:**	
65.	**Are any investigator- sponsored trials (IST) using your product?**	Yes ☐ No ☐	**If yes, please provide a copy of study protocol and investigator agreement. Has investigator information been reported to FDA?**	Yes ☐ No ☐
66.	**Are any of your investigational (i.e. unapproved) drugs or devices accessible to seriously ill test subjects who are not candidates for clinical trials?**	Yes ☐ No ☐		
67.	**Do you export drugs for patients in foreign markets before those drugs have received marketing approval in the U.S.?**	Yes ☐ No ☐	**If yes, do you have written authorization from FDA?**	Yes ☐ No ☐
68.	**On which websites do you publish results of your clinical trial(s)?**			

Claim Incident Information

69. Has any insurance company canceled or refused to renew your insurance? Yes ☐ No ☐

If yes, please explain:

70. Loss History for the last 5 years. Please attach previous carrier loss runs. Check here if none. ☐

Policy Period	Carrier	# of Claims	$ Amount Paid	$ Amount in Reserves

71. List any incident(s) and/or circumstance(s) which may result in a claim against you under the coverage requested in this application:

Insurance Fraud Warning

For your protection, the following warning is required by various state laws: any person who knowingly and with the intent to injure, defraud, or deceive any insurance company or other person, files a statement of claim or an application containing any false, incomplete or misleading information is guilty of a crime and may be subject to criminal and civil penalties which may include imprisonment, fines, and denial of insurance.

State Specific Fraud Warning Statements

ARKANSAS / DISTRICT OF COLUMBIA / LOUISIANA / RHODE ISLAND / WEST VIRGINIA

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.

CALIFORNIA

For your protection California law requires the following to appear on this form:

Any person who knowingly presents false or fraudulent claim for the 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 policyholders or claimant with regard to settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

FLORIDA

Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim containing any false, incomplete, or misleading information is guilty of a felony of the third degree.

KENTUCKY

Any person who knowingly and with intent to defraud any 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.

MAINE / TENNESSEE / VIRGINIA / 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, or denial of insurance benefits.

MARYLAND

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

NEW JERSEY

Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

NEW MEXICO

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.

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 shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.

OHIO

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.

OKLAHOMA

WARNING: 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.

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.

The undersigned authorized officer of the applicant warrants that the statements herein are true, and acknowledges that this company is relying on the accuracy of such information in determining eligibility and qualification for insurance.

Completing and signing this application does not bind coverage. Coverage will not be bound, nor will a policy be issued until the applicant signifies acceptance of the company's premium quotation.

Signature:		**Date:**	

Print Name:	
Title/Position:	
Email:	

Please return your signed application using one of the following:
Fax: (703) 652-1389
Email: Apps@medmarc.com
Mailing Address: 14280 Park Meadow, Suite 300, Chantilly, VA 20151

WE ARE UNABLE TO BIND COVERAGE WITHOUT A PROPERLY SIGNED AND DATED APPLICATION.