MEDMARC
Treated Fairly
A ProAssurance Company

Medmarc Casualty Insurance Company
ProAssurance Specialty Insurance Company
Life Sciences
Products and Completed Operations Liability Insurance

4795 Meadow Wood Lane
Suite 335 West
Chantilly, VA 20151-2219

Phone: 703-652-1300
Fax: 703-652-1389
Email: apps@medmarc.com

Renewal 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.**
- **If there is insufficient space to answer a question, please attach additional pages.**
- **Please attach current financial information for any privately-held company.**

Broker Information

1. Company name:
2. Broker contact name:

Check box if no changes below in this section. ☐

3. License number:
   Please provide a copy of the agency license for the state in which the applicant is located.
4. Street: City: State: Zip:
5. Broker contact email:
6. Broker contact phone:
7. Billing/finance contact name:
8. Billing finance contact email:
9. Billing/finance contact phone:

Applicant/Insured Information

10. First named insured:
    Please provide the name as it should appear on the policy.
11. Street: City: State: Zip:
12. Applicant name: Title:
13. Website: Phone number:

Check box if no changes below in this section. ☐

14. Are there any changes needed to the additional named insured(s) listed on the policy?
    ☐ Yes ☐ No
    If yes, please provide additional named insured(s); percent of ownership, if any; and relationship to you.

Entity name as it should appear on the policy	*% Ownership*	*Relationship*

15. Are there any changes needed to the current Additional Insured(s) listed on the policy?
    ☐ Yes ☐ No
    If yes, please provide additional insured(s); percent of ownership, if any; and relationship to you.

Entity name as it should appear on the policy	*% Ownership*	*Relationship*

16. List companies or assets acquired (A) or sold (S) in the last year.

Entity	*A/S*	*Date Acquired/Sold*	*Description*

Projected Revenue Information

	U.S./Canada revenue ($)	*Foreign revenue ($)*
Proprietary medical device manufacturing		
Proprietary pharmaceutical/biologic manufacturing		
Contract manufacturing		
Specification development		
Distribution		
Importing for distribution		
Equipment rental		
Installation/repair/servicing		
Research and development		

Product Information

17. Have you made any changes to your product(s) or operation(s) since last year?
(E.g., New or discontinued products; products under development; new business partners, such as contract manufacturers, critical suppliers, or contract research organizations.) ***Check box if no changes.*** ☐

Regulatory History

18. Have any of your products been removed or recalled from the market in the last year?
☐ Yes ☐ No

If yes, please complete the table below.

Recall Date	*Class*	*Product*	*Reason*	*Closed?*
				☐ Yes ☐ No
				☐ Yes ☐ No

19. Have you received an FDA Warning Letter in the last year?
☐ Yes ☐ No

If yes, please attach copies of the Warning Letter and your response to FDA.

20. Has FDA visited your facilities in the last year?
☐ Yes ☐ No

If you received an FDA Form 483 during this time period, please attach copies of the 483 and your response to FDA.

21. Have you performed a GMP or similar self-audit, or has one been performed for you by a third party, in the last year?
☐ Yes ☐ No

If yes, please provide a copy of the audit report.

22. In the last year, have you reported or issued any of the following? *Check all that apply.*

☐ MDRs or adverse event reports ☐ Public health notification or field/safety alerts ☐ Dear Doctor/Healthcare Practitioner letters

23. Have any clinical trials been placed on hold by you, FDA, or another authority in the last year?

☐ Yes ☐ No

If yes, please attach explanation(s) for the hold(s).

24. In the last year, have you had any Serious Adverse Events[1] that have not yet been reported to us?

☐ Yes ☐ No

If yes, please attach descriptions of the unreported SAEs.

Continue to the next page.

[1] **Serious Adverse Event** means an undesirable experience associated with your product where the outcome to the patient:

(a) is life threatening;
(b) is death;
(c) required hospitalization (initial or prolonged);
(d) is disability or permanent damage;
(e) is a congenital anomaly or birth defect;
(f) required intervention to prevent permanent impairment or damage; or
(g) required medical intervention to prevent one of the outcomes (a) through (f) above.

Human Clinical Trial Log

25. Please list clinical trials that are ongoing or anticipated during the policy term. Attach a copy of the Protocol(s) and Informed Consent Form(s) for each.

Protocol: Number & Name	Type of Trial[2]	Risk Level[3]	Product Name & Description	Trial Phase	Total Subjects Projected	Subject Enrollment for Policy Term *Past 12 mos./ Next 12 mos.*		Trial Date *Start/End*		FDA Classification for Trial Status[4]	Number of Trial Sites	Trial Locations
		☐ SR ☐ NSR ☐ Drug										☐ Foreign ☐ Domestic ☐ Both
		☐ SR ☐ NSR ☐ Drug										☐ Foreign ☐ Domestic ☐ Both
		☐ SR ☐ NSR ☐ Drug										☐ Foreign ☐ Domestic ☐ Both
Please list additional trials on a separate page.												

[2] Type of Trial

- **Treatment** trial – tests experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy
- **Prevention** trial – looks 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 tests or procedures for diagnosing a particular disease or condition
- **Screening** trial – tests the best way to detect certain diseases or health conditions
- **Quality of Life** trial (or Supportive Care trials) – explores 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

[3] FDA defines a Significant Risk **(SR)** Device as a device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

All other devices are considered to be of Nonsignificant Risk **(NSR)**.

[4] 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 the 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

Insurance Fraud Warnings and Important Notices

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

ALABAMA

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

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 information to obtain or amend insurance coverage or to make a 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 or willfully presents a false or fraudulent claim for payment of a loss or benefit or who knowingly or 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

Fraud Warning

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.

IMPORTANT NOTICE

In the event you are applying for claims-made coverage, please note the following important information. The information provides you with important guidance in the event your purchase claims-made coverage from us.

1. This is a claims-made policy.

2. This policy is subject to its terms and conditions:

   a. applies only to any claim first made against the insured during the policy period or any applicable Extended Reporting Period; and

   b. does not apply to any claim first made against the insured after the policy period or any applicable Extended Reporting Period or reported after coverage termination.

3. This policy provides no coverage for claims arising out of Occurrences which took place prior to any Retroactive Date shown in the policy.

4. During the first several years of a claims-made relationship, claims made rates are comparatively lower than occurrence rates. The insured can expect substantial annual premium increases, independent of overall rate level increases, until the claims made relationship reaches maturity.

5. All coverage for the policy ceases upon the policy termination date, except for the sixty (60) day automatic Basic Extended Reporting Period, unless an additional Supplemental Extended Reporting Period is purchased.

6. A Supplemental Extended Reporting Period of five (5) years is available for purchase upon the payment of additional premium. Potential coverage gaps may arise upon expiration of the Extended Reporting Period. Within thirty (30) days after policy termination, we will send you written notice describing the Basic Extended Reporting Period, the availability of, and the premium for, and the importance of purchasing additional Extended Reporting Period coverage. You must send us a written notice requesting the Supplemental Extended Reporting Period endorsement within the greater time period of ninety (90) days after termination of coverage or thirty (30) days from our mailing or delivery date of the notice for the Supplemental Extended reporting Period.

7. The rates for the Supplemental Extended Reporting Period will be based upon the rates in effect at the time of coverage termination. Such rates may be subject to substantial increase over the rates currently in effect and such rates may or may not be indicative of future rate changes. Upon your written request, we will provide you with the average statewide percentage changes and the effective date of each rate revision for this particular type of insurance which we have implemented in the state of New York during the five-year period immediately preceding the effective date of the policy.

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.

OREGON

Any person who knowingly and with intent to defraud any insurance company or another 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, may be committing a fraudulent insurance act, which may be a crime and may subject the person to criminal and civil penalties.

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 set forth in this Application are true and complete, and acknowledges and understands that the Medmarc Casualty Insurance Company and its affiliated company, ProAssurance Specialty Insurance Company, are relying on the accuracy and completeness of such information in determining eligibility, qualification, and pricing for the insurance provided. The undersigned also warrants that it has not suppressed or misstated any material facts or made any misleading representations. If the information provided in this Application should change between thedate of the Application and the effective date of the policy, the undersigned warrants that he or she will immediately report such changes to the Insurer. Completing and signing this Application does not bind the undersigned to purchase this insurance, nor does it bind coverage. Coverage will not be bound, nor will a policy be issued, until the applicant signifies acceptance of the company's premium quotation.

(For Montana only, the word "warrants" in the paragraph above is replaced with "represents.")

By signing below, you consent to the receipt of electronic notices and documents (collectively, "Documents"). Documents include any notice or document required as part of an insurance transaction or that is to serve as evidence of coverage. Notwithstanding the previous information, you may request at any time to have a Document sent to you in paper form also. You may also withdraw your consent at any time. Upon information and belief, the only software/hardware requirements for you to access a Document are a valid email address and the ability to open Documents in various formats. You can request a paper copy of a Document withdraw your consent, and/or notify us of a problem opening a Document, by contacting our support team at: LSS@medmarc.com.

Authorized Signature:		**Date:**	
Print Name:			
Title:			
Email:			

If you are electronically submitting this document, apply your electronic signature to this form by checking the Electronic Signature and Acceptance box below. By doing so, you agree that your use of a key pad, mouse, or other device to check the Electronic Signature and Acceptance box constitutes your signature, acceptance, and agreement as if actually signed by you in writing and has the same force and effect as a signature affixed by hand.

☐ Electronic Signature and Acceptance - Authorized Signature

Please return your signed application using one of the following:
Fax: (703) 652-1389
Email or click Submit: apps@medmarc.com
Mailing: 4795 Meadow Wood Lane, Suite 335 West, Chantilly, VA 20151

Submit