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
Toll free: 1-800-356-6886
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.**

I. PRODUCTS COMPLETED OPERATIONS RENEWAL

Broker Information		
1. Brokerage name:		
2. License number: *Please provide a copy of the agency license for the state in which the applicant is located.*		
3. Street:	City:	State: Zip:
4. Broker contact name:		
5. Broker contact email:	6. Broker contact phone:	

Applicant/Insured Information		
7. First named insured: *Please provide the name as it should appear on the policy.*		
8. Street:	City:	State: Zip:
9. Applicant contact name:	Title:	
10. Website:	Phone number:	

11. Are there any changes needed to the current additional named insured(s) listed on the policy?

☐ Yes ☐ No

If yes, please provide additional named insured(s), percent of ownership, and relationship to you.

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

12. 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*

13. List companies or assets acquired (A) or sold (S) within the last year.

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

Current Insurance Information

14. Desired limits, if different from current limit:

15. Desired self-insured retention or deductible, if different from current:

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

If yes, please provide the coverage information requested below.

Carrier	*Limit*	*Coverage*	*Claims Made Retro Date*

17. May we provide you with quotes for other lines of coverage?

☐ Excess Liability ☐ Standard Lines*

**If you are interested in standard lines of coverage (CGL, Auto, Property, Workers' Compensation, Umbrella) available through our partner, Pharmacists Mutual, please submit an ACORD application with this application.*

Projected Revenue Information

	U.S./Canada revenue ($)	*Foreign revenue ($)*
Proprietary medical device manufacturing		
Proprietary pharmaceutical/biologic manufacturing		
Contract manufacturing		
Contract services for others (e.g., packaging, repackaging, sterilization, regulatory)		
Specification development		
Distribution		
Importing for distribution		
Equipment rental		
Installation/maintenance/repair/servicing		
Research and development		
Consulting/design services		
Other		

If other, please describe.

Product Information

18. Have there been any changes to your existing products or operations since last year?

☐ Yes ☐ No

If yes, please describe.

19. Do you have products under development or in clinical testing that you expect to introduce during the policy term?

☐ Yes ☐ No

If yes, please describe.

20. Have any products been discontinued in the last year?

☐ Yes ☐ No

If yes, please list discontinued products and the reason(s) for discontinuation.

Product	*Reason*

21. Do you manufacture any new products for others to sell under their labels?
☐ Yes ☐ No

22. Do you sell any new products manufactured by others under your label?
☐ Yes ☐ No

Regulatory History

23. Have there been any changes to your FDA registration in the past year (e.g. no longer registered, different or additional designations, etc.)?
☐ Yes ☐ No

If yes, please describe.

24. 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

25. 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.

26. 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.

27. 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.

28. Do any of your products require a "black box warning," REMS, or other significant safety warning?
☐ Yes ☐ No

If yes, please attach any "black box warning," REMS materials, or other significant safety warning not previously supplied to us.

29. 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

30. In the last year, have you had any Serious Adverse Events[1] that have not been reported to us or a previous insurer?
☐ Yes ☐ No

If yes, please attach descriptions of the unreported SAEs.

[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 History	
Check box if no changes below in this section. ☐	
31. Are you using a contract research organization (CRO) in any of your studies? ☐ Yes ☐ No	
32. Do you use HHS-registered institutional review boards (IRBs)? ☐ Yes ☐ No	*If no, please explain.*
33. Do you use indemnification agreements with investigators, IRBs, and CROs? ☐ Yes ☐ No	*If no, please explain.*
34. Have any of your IRBs, investigators, or clinical sites received a Warning Letter or been the subject of an adverse FDA action? ☐ Yes ☐ No	*If yes, please explain.*
35. Have you or your investigator ever been cited, debarred, fined, or suspended? ☐ Yes ☐ No	*If yes, please explain.*
36. Have any trials been discontinued or suspended for safety reasons, whether by you, FDA, or another authority? ☐ Yes ☐ No	*If yes, please explain.*
37. Have any subjects had a serious adverse event (life-threatening, death, hospitalization, disability or permanent damage, congenital anomaly or birth defect, or required intervention to prevent one of these outcomes)? ☐ Yes ☐ No	*If yes, please explain.*
38. Do any of your trials involve subjects who are members of a "vulnerable"[2] patient population? ☐ Yes ☐ No	*If yes, please explain.*
39. Are you planning any foreign clinical trials during the policy term? ☐ Yes ☐ No	*If yes, please explain.*
40. Are you sponsoring any clinical trials in which you have invited your own employees to participate? ☐ Yes ☐ No	*If yes, please explain.*
41. Are any investigator-sponsored trials using your product? ☐ Yes ☐ No	*If yes, please explain.*
42. 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	*If yes, please explain.*
43. Do you export drugs for patients in foreign markets before those drugs have received marketing approval in the U.S.? ☐ Yes ☐ No	*If yes, please explain.*

[2] "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).

Human Clinical Trial Sponsorship and Funding

Check box if no changes below in this section. ☐

44. Is the named insured the trial sponsor?

☐ Yes ☐ No

If no, please explain.

45. How are your clinical trials funded?

Source	*Amount*

Continue to the next page.

Human Clinical Trial Log

46. 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[3]	Risk Level[4]	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[5]	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 attach a list of any additional clinical trials.												

[3] 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

[4] 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)**.

[5] 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

Claim/Incident Information
47. List any unreported incident(s) and/or circumstance(s) which may result in a claim against you under the coverage requested in this application.

II. Optional Coverage: Manufacturers' Errors and Omissions[6]

If you wish to renew or purchase Manufacturers' Errors and Omissions coverage, please complete this section. If this coverage is not desired, please skip to page 11 to complete the application.

This application is for:	☐ New Business	☐ Renewal

Current Errors & Omissions Insurance Information		
For New Business, please complete the entire section. **For Renewal, please review questions 51 and 52 and complete if applicable.**		
48. Current insurance company:		
49. Current type of insurance:	☐ Occurrence	☐ Claims Made
50. Policy renewal date:		
51. Current limit of insurance: *Provide desired limits, if different from current limit.*		
52. Current self-insured retention or deductible: *Provide desired self-insured retention or deductible, if different from current.*		
53. Current retroactive date (if claims made): *If more than one, please attach current schedule of retroactive dates.*		

Product or Service Information	
Check box if no changes below in this section. ☐	
54. What is the acceptable downtime for your product/service according to your average customer's needs?	☐ No downtime is acceptable ☐ 1 day or less ☐ 2 days or less ☐ 3 days or less
55. What is the worst negative consequence that could happen to your customers' operations if your products/services were to fail or stop working?	
56. Are any of your products sold as components for others' finished products?	☐ Yes ☐ No

[6] Manufacturers' Errors and Omissions is a Claims Made and Reported policy, available on ProAssurance Specialty (non-admitted) only.

Check box if no changes below in this section. ☐

57. Who are your five largest customers?	*Size of Contract*	*Duration of Contract*

58. Are your products used in:
    a. Clinical trials ☐ Yes ☐ No
    b. Research/laboratory settings ☐ Yes ☐ No
    c. Hospitals/medical facilities ☐ Yes ☐ No

Quality Control, Training, and Support

Check box if no changes below in this section. ☐

59. What certifications do you maintain in the U.S. or in other markets?	☐ ISO 13485 ☐ ISO 9001 ☐ CE Mark ☐ Underwriters Laboratory (UL) ☐ Other:
60. What professional organization memberships does your company maintain?	

61. Do you have a written procedure for initiating, conducting, and/or complying with product recalls?
    ☐ Yes ☐ No

62. Do you have a records retention policy for the products you manufacture, sell, or service?
    ☐ Yes ☐ No

63. Do you have a documented training plan for employees, contractors, distributors and/or end users of your products?
    ☐ Yes ☐ No ☐ N/A

64. Do you install, customize, or service your products?
    ☐ Yes ☐ No

65. Do others install, customize or service your products? ☐ Yes ☐ No
    a. If yes, do you provide formal training? ☐ Yes ☐ No
    b. Written instructions? ☐ Yes ☐ No
    c. Sign off on the final product? ☐ Yes ☐ No
    d. Require liability insurance for those installing or servicing your products? ☐ Yes ☐ No

66. Do you have contingency plans to service a customer who experiences a critical failure of your product or service?
    ☐ Yes ☐ No
    If yes, please provide a copy of the contingency plan.

67. Do you provide service and repair of products other than your own?
    ☐ Yes ☐ No
    a. If yes, what percentage of total service revenue generated by this work? _____%

Suppliers

Check box if no changes below in this section. ☐

68. What percentage of your component parts are supplied by outside vendors?	_____%	Please list vendors:
69. What percentage of your component parts are supplied by foreign-based companies?	_____%	Please list countries:

70. Do you ever agree to hold harmless any suppliers for claims arising out of their products?

☐ Yes ☐ No

If yes, please explain.

71. Do you require Certificates of Insurance from your suppliers?

☐ Yes ☐ No

If yes, what limits of liability do you require? *Amount: $*_____

Contracts

Check box if no changes below in this section. ☐

72. Does your legal counsel review and approve all contracts, advertising, and promotional materials and brochures?

☐ Yes ☐ No

73. Do you require your customers to sign written agreements that outline the specification of products and services you will provide?

☐ Yes ☐ No

If yes, please provide a sample contract.

74. Do all of your contracts include the following clauses?		
a. Force majeure	☐ Yes	☐ No
b. Disclaimer of warranties	☐ Yes	☐ No
c. Limitation of liabilities	☐ Yes	☐ No
i. *If yes, in what amount?*	$_____	
d. Exclusion for consequential damages	☐ Yes	☐ No
e. Customer acceptance of interim changes and final product	☐ Yes	☐ No
f. Hold harmless provision	☐ Yes	☐ No
g. Indemnification clause	☐ Yes	☐ No
h. Payment terms	☐ Yes	☐ No

Continue to the next page.

Historical Information	
Check box if no changes below in this section. ☐	
If you answer "Yes" to any of the questions in this section, please list all occurrences and include the following information: (1) date of incident; (2) description of issue; (3) remediation made; and (4) any associated financial settlement/judgment and the amount. *Please attach an additional sheet if more space is needed.* 75. In the last year:	
a. Have any of your customers had a financial loss because of a problem related to your product or service? ☐ Yes ☐ No	*If yes, please describe.*
b. Have you had any repeated verbal or written complaints from your customers that were not easily remedied? ☐ Yes ☐ No	*If yes, please describe.*
c. Have there been any problems with below standard performance of your products or services, whether or not a complaint was made? ☐ Yes ☐ No	*If yes, please describe.*
d. Have you had a customer stop payment or request a refund because of a product or service problem in the last three years? ☐ Yes ☐ No	*If yes, please describe:*
e. Have you had a customer bring suit or threaten to bring suit because of a problem with your product or service? ☐ Yes ☐ No	*If yes, please describe:*

Continue to the next page.

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