

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.
Please attach current financial information for any privately held companies.**

Broker Information

1.	Company Name:		
2.	Address:		
3.	Primary Contact Name:	Email:	Phone:

Applicant Information

4.	Named Insured: (as it should appear on the policy)	
5.	Address:	
6.	Website:	
7.	Phone Number:	

8. 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) and % of ownership:

Additional Named Insured	%

9. Are there any changes needed to the current Additional Insured(s) included on the policy? Yes No

If yes, please provide additional insured(s) and relationship to named insured):

Additional Insured	Relationship

10. Have any companies or assets been acquired (A) or sold (S) in the past year? Yes No

If yes, please provide the following information:

Entity	A/S	Date Acquired/Sold	Description

11. Contact Information

Name	Title	Email
Primary:		
SIR Billing:		
Loss Run:		
Loss Control:		
Claim:		
Finance:		

Insurance Information

12.	Policy Renewal Date:	
13.	Current Limit of Insurance:	Desired Limit (if different):
14.	Current Self Insured Retention:	Desired Limit (if different):

15. May we provide you with a CGL quote?

Yes No

16. Do you currently purchase insurance in excess of the limits you purchase through Medmarc? Yes No

If yes, please advise the total limit:

Product/Facilities Information

Projected Revenues	U.S./Canada	Other/Foreign
17. Manufacturing: Medical Devices (proprietary products)		
18. Manufacturing: Pharmaceutical/ Biologics (proprietary products)		
19. Contract Manufacturing/OEM (products sold under other labels)		
20. Distribution		
21. Installation/Repair/Service		

Product Update (please use attachment if necessary)

22. Are there any changes to your existing products or operations?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:
23. Do you have any new products:	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:

24.	Do you have products currently under development?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:
25.	Have any products been discontinued?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:
26.	Do you have any new products that you manufacture for other companies to sell under their label?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:

27. 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)

28.	Are you planning any product recalls for this year?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please elaborate:
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29.	In the past year, have you issued any:			If yes to either of these, please elaborate:
	a.	Public Health Notifications or Safety Alerts?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
	b.	Dear Doctor/ Healthcare Practitioner Letters?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
30.	Has the FDA inspected your facilities in the last year?		Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please submit a copy of Form 483 and your response if applicable.
31.	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 <input type="checkbox"/> No <input type="checkbox"/>	If yes, please attach a copy.
32.	Is there trace ability of components to production lot?		Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe tracking method employed.

33.	Is there trace ability of components to final production?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe tracking method employed.
34.	How are final products identified?	Batch <input type="checkbox"/> Lots <input type="checkbox"/> Both <input type="checkbox"/>	
35.	If engaged in R&D, do you utilize design validation (Pre-Production Q/A)?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

36. Human Clinical Trials

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 new 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								
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A - drug						
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A - drug						
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A - drug						
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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

37.	Who reviews your company's indemnification agreements with Investigators, CROs and IRBs?		
38.	Are you using a Clinical Research Organization (CRO) in any of your studies?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
39.	Have any of your IRBs received a Warning Letter or been the subject of adverse FDA action?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please explain:
40.	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 <input type="checkbox"/> No <input type="checkbox"/>	If yes, please explain:
41.	Have any trials been discontinued or suspended, whether by you, FDA or another authority, for safety reasons?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please explain:
42.	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 <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:
43.	Do any of your studies involve subjects that are children or members of a "vulnerable" ³ patient population?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please explain:
44.	Are any clinical trials being conducted at your facility?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, could the clinical trial(s) be interrupted if there was a loss at your facility? Yes <input type="checkbox"/> No <input type="checkbox"/>

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).

45.	Are you planning any foreign clinical trials in the future?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:
46.	Are you sponsoring any clinical trials that you have invited your own employees to participate in?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please describe:
47.	Are any investigator- sponsored trials (IST) using your product?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please provide a copy of study protocol and investigator agreement. Has investigator information been reported to FDA? Yes <input type="checkbox"/> No <input type="checkbox"/>
48.	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 <input type="checkbox"/> No <input type="checkbox"/>	
49.	Do you export drugs for patients in foreign markets before those drugs have received marketing approval in the U.S.?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, do you have written authorization from FDA? Yes <input type="checkbox"/> No <input type="checkbox"/>
50.	On which websites do you publish results of your clinical trial(s)?		

Claims/Incident Information

51.	Have you reported to Medmarc all occurrences which may result in a claim against you in the future? Refer to your policy, Section IV. 2, Duties in the Event of Occurrence, Claim or Suit. Failure to promptly report all occurrences could result in loss of coverage.)	Yes <input type="checkbox"/> No <input type="checkbox"/>	If no, please explain:
52.	Did you report to the FDA all reportable incidents of death, serious injury or product malfunction associated with your device(s) as now required by regulation?	Yes <input type="checkbox"/> No <input type="checkbox"/>	If no, please explain:

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

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 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

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.

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 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.