

SERFF Tracking Number: MMCI-125888362 State: Arkansas  
Filing Company: Medmarc Casualty Insurance Company State Tracking Number: EFT \$50  
Company Tracking Number: MCIC-AR-111008  
TOI: 18.0 Product Liability Sub-TOI: 18.1000 Product Liab - Claims Made Only  
Product Name: Defense Outside  
Project Name/Number: /

## Filing at a Glance

Company: Medmarc Casualty Insurance Company

Product Name: Defense Outside

SERFF Tr Num: MMCI-125888362 State: Arkansas

TOI: 18.0 Product Liability

SERFF Status: Closed

State Tr Num: EFT \$50

Sub-TOI: 18.1000 Product Liab - Claims Made Only

Co Tr Num: MCIC-AR-111008

State Status: Fees verified and received

Filing Type: Form

Co Status:

Reviewer(s): Betty Montesi, Edith Roberts

Author: Nicole Calhoun

Disposition Date: 12/09/2008

Date Submitted: 11/11/2008

Disposition Status: Approved

Effective Date Requested (New): 12/11/2008

Effective Date (New):

Effective Date Requested (Renewal): 12/11/2008

Effective Date (Renewal):

State Filing Description:

## General Information

Project Name:

Status of Filing in Domicile:

Project Number:

Domicile Status Comments:

Reference Organization:

Reference Number:

Reference Title:

Advisory Org. Circular:

Filing Status Changed: 12/09/2008

State Status Changed: 12/09/2008

Deemer Date:

Corresponding Filing Tracking Number: MCIC-AR-111008

Filing Description:

Medmarc Casualty Insurance Company ("Medmarc Casualty" or the "Company") hereby submits the attached filing for use on all new and renewal business effective December 11, 2008 or upon your approval if sooner. The forms being filed are as follows:

CG 38 C 09 08, an independent products completed operations liability coverage form with defense costs outside from policy limits. This policy form replaces previously approved coverage form CG 38 C 06 96.

Form CG 38 C 09 08 will be used for the Company's existing Medical Device Technology - Life Sciences Program.

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The use of these forms does not result in an increase or decrease in rates. This filing is being made simultaneously over the next month in multiple states, including Vermont, our domicile state.

For informational purposes, please note that Medmarc Casualty Insurance Company is a specialty casualty insurance insurer and underwrites products liability for life sciences technology companies. Its parent company, Medmarc Mutual Insurance Company, was founded in 1979 by the medical device industry. Medmarc Casualty's new coverage form was developed as a part of an on-going effort to continually review and improve its insurance contract so as to accomplish its mission to serve the industry that founded the program.

## Company and Contact

### Filing Contact Information

Nicole Calhoun, ncalhoun@medmarc.com  
 14280 Park Meadow Drive (703) 652-1338 [Phone]  
 Chantilly, VA 20151

### Filing Company Information

Medmarc Casualty Insurance Company	CoCode: 22241	State of Domicile: Vermont
14280 Park Meadow Drive	Group Code:	Company Type:
Chantilly, VA 20151	Group Name:	State ID Number:
(800) 356-6886 ext. 326[Phone]	FEIN Number: 59-0615164	
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## Filing Fees

Fee Required? Yes  
 Fee Amount: \$50.00  
 Retaliatory? No  
 Fee Explanation: state form filing fee \$50 x form filing = \$50  
 Per Company: No

COMPANY	AMOUNT	DATE PROCESSED	TRANSACTION #
Medmarc Casualty Insurance Company	\$50.00	11/11/2008	23847853

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## Correspondence Summary

### Dispositions

Status	Created By	Created On	Date Submitted
Approved	Edith Roberts	12/09/2008	12/09/2008

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## Disposition

Disposition Date: 12/09/2008

Effective Date (New):

Effective Date (Renewal):

Status: Approved

Comment:

Rate data does NOT apply to filing.

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Item Type	Item Name	Item Status	Public Access
<b>Supporting Document</b>	Uniform Transmittal Document-Property & Casualty	Approved	Yes
<b>Form</b>	Commercial General Liability (Claims Made) Declaration Page	Approved	Yes
<b>Form</b>	Amendment of Coverage Territory - Exclusion of Foreign Countries	Approved	Yes
<b>Form</b>	Batch Clause	Approved	Yes
<b>Form</b>	Composite Rate	Approved	Yes
<b>Form</b>	Additional Insured - Controlling Interest	Approved	Yes
<b>Form</b>	Additional Insured - Designated Person or Organization	Approved	Yes
<b>Form</b>	Additional Insured - Primary Coverage	Approved	Yes
<b>Form</b>	Exclusion - Designated Person or Organization	Approved	Yes
<b>Form</b>	Exclusion - Aircraft Products	Approved	Yes
<b>Form</b>	Extended Discovery Period - Unlimited and Replenishment of Limits	Approved	Yes
<b>Form</b>	Extended Discovery Period - Six (6) Years and Replenishment of Limits	Approved	Yes
<b>Form</b>	Extended Discovery Period - Unlimited Duration & No Replenishment of Limits	Approved	Yes
<b>Form</b>	Discontinued Operations or Products Liability Coverage	Approved	Yes
<b>Form</b>	Multiple Self-Insured Retentions w/Combined Aggregate	Approved	Yes
<b>Form</b>	Waiver of Transfer of Rights of Recovery Against Others To Us	Approved	Yes
<b>Form</b>	Composite Rate w/Optional Maximum Premium Agreement	Approved	Yes
<b>Form</b>	Composite Rate w/Surplus Sales Waiver	Approved	Yes
<b>Form</b>	Medical Professional Services Liability	Approved	Yes
<b>Form</b>	Supplemental Extended Discovery Period Coverage Purchase	Approved	Yes
<b>Form</b>	Insuring Agreement Amendatory - Specified Foreign Clinical Trial Compensation	Approved	Yes

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 Product Name: Defense Outside  
 Project Name/Number: /

<b>Form</b>	Self-Insured Retention Per Claimant	Approved	Yes
<b>Form</b>	Personal & Advertising Injury Liability - Clinical Testing	Approved	Yes
<b>Form</b>	Limited Coverage Territory	Approved	Yes
<b>Form</b>	Limitation of Coverage to Designated Product(s) or Work	Approved	Yes
<b>Form</b>	Exclusion - Designated Product(s) or Work	Approved	Yes
<b>Form</b>	Amendment of Limits of Insurance	Approved	Yes
<b>Form</b>	Broad Named Insurance	Approved	Yes
<b>Form</b>	Schedule of Retroactive Dates	Approved	Yes
<b>Form</b>	Name Change	Approved	Yes
<b>Form</b>	Personal & Advertising Injury	Approved	Yes
<b>Form</b>	Mailing Address Change	Approved	Yes
<b>Form</b>	Clinical Investigator-Sponsored or Initiated Clinical Trials	Approved	Yes
<b>Form</b>	Specific Named Insured	Approved	Yes
<b>Form</b>	Policy Change	Approved	Yes
<b>Form</b>	Extended Discovery Period for Clinical Testing in Israel	Approved	Yes
<b>Form</b>	Amended Definition of Damages	Approved	Yes
<b>Form</b>	Coverage Change	Approved	Yes
<b>Form</b>	Notice of Claim Reporting Period	Approved	Yes
<b>Form</b>	Products Completed Operations Liability Coverage Form (Claims Made - Defense Costs Outside	Approved	Yes

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 TOI: 18.0 Product Liability Sub-TOI: 18.1000 Product Liab - Claims Made Only  
 Product Name: Defense Outside  
 Project Name/Number: /

## Form Schedule

Review Status	Form Name	Form #	Edition Date	Form Type Action	Action Specific Data	Readability	Attachment
Approved	Commercial General Liability (Claims Made) Declaration Page	312	01 08 01 08	Declaration Replaced s/Schedule	Replaced Form #:0.00 312 02 07 Previous Filing #:		312 01 08 - CGL (Claims Made) Declaration Page.pdf
Approved	Amendment of Coverage Territory - Exclusion of Foreign Countries	045	01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 045 06 96 Previous Filing #:		045 01 08 Exclusion - Foreign Coverage.pdf
Approved	Batch Clause	092	01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 092 11 96 Previous Filing #:		092 01 08 Batch Clause.pdf
Approved	Composite Rate	095	03 08 03 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 095 06 96 Previous Filing #:		095 03 08 - Composite Rate Endorsement.pdf
Approved	Additional Insured - Controlling Interest	157	03 08 03 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 157 09 96 Previous Filing #:		157 03 08 - Additional Insured - Controlling Interest.pdf
Approved	Additional Insured - Designated Person or Organization	163	01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 163 10 96 Previous Filing #:		163 01 08 - Additional Insured - Designated Person Or Organization (2).pdf
Approved	Additional Insured - Primary	168	03 08 03 08	Endorsement/Amendment Replaced	Replaced Form #:0.00 168 11 96		168 03 08 Additional

SERFF Tracking Number: MMCI-125888362 State: Arkansas  
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 Product Name: Defense Outside  
 Project Name/Number: /

Coverage	ent/Condi ons	Previous Filing #:	Insured - Primary Coverage.pdf
Approved Exclusion - Designated Person or Organization 180 01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 180 11 96 Previous Filing #:	180 01 08 - Exclusion - Designated Person Or Organization .pdf
Approved Exclusion - Aircraft Products 190 01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 190 11 96 Previous Filing #:	190 01 08 - Exclusion - Aircraft Products.pdf
Approved Extended Discovery Period - Unlimited and Replenishment of Limits 243 09 08 09 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 243 11 96 Previous Filing #:	243 09 08 - Extended Discovery Period Endorsement - Unlimited and Replenishment.pdf
Approved Extended Discovery Period - Six (6) Years and Replenishment of Limits 245 09 08 09 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 245 11 96 Previous Filing #:	245 09 08 - Extended Discovery Period - 6 Years and Replenish.pdf
Approved Extended Discovery Period - Unlimited Duration & No Replenishment of Limits 246 01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 246 11 96 Previous Filing #:	246 01 08 - Extended Discovery Period Endorsement - Unlimited- No Replenishme

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 TOI: 18.0 Product Liability Sub-TOI: 18.1000 Product Liab - Claims Made Only  
 Product Name: Defense Outside  
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Approved	Discontinued Operations or Products Liability Coverage	251 01 08 01 08	Endorsement/Amendment/Conditions	Replaced Form #:0.00 251 12 96 Previous Filing #:	251 01 08 - Discontinued Operations Products Liability Coverage.pdf
Approved	Multiple Self-Insured Retentions w/Combined Aggregate	311 03 08 03 08	Endorsement/Amendment/Conditions	Replaced Form #:0.00 311 09 99 Previous Filing #:	311 03 08 - Multiple Self-Insured Retentions With Aggregate Endorsement.pdf
Approved	Waiver of Transfer of Rights of Recovery Against Others To Us	314 03 08 03 08	Endorsement/Amendment/Conditions	Replaced Form #:0.00 314 09 99 Previous Filing #:	314 03 08 - Waiver of Rights of Recovery.pdf
Approved	Composite Rate w/Optional Maximum Premium Agreement	318 03 08 03 08	Endorsement/Amendment/Conditions	Replaced Form #:0.00 318 01 00 Previous Filing #:	318 03 08 - Composite Rate Endorsement With Maximum Premium Agreement (2).pdf
Approved	Composite Rate w/Surplus Sales Waiver	319 03 08 03 08	Endorsement/Amendment/Conditions	Replaced Form #:0.00 319 01 00 Previous Filing #:	319 03 08 Composite Rate Endorsement With Surplus Sales

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 TOI: 18.0 Product Liability Sub-TOI: 18.1000 Product Liab - Claims Made Only  
 Product Name: Defense Outside  
 Project Name/Number: /

					Waiver (2).pdf
Approved	Medical Professional Services Liability	321 01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 321 01 00 Previous Filing #:	321 01 08 - Medical Professional Services Liability Endorsement.pdf
Approved	Supplemental Extended Discovery Period Coverage Purchase	324 01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 324 01 00 Previous Filing #:	324 01 08 - Supplemental Extended Discovery Period Coverage Purchase Endorsement.pdf
Approved	Insuring Agreement Amendatory - Specified Foreign Clinical Trial Compensation	328 01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 328 01 00 Previous Filing #:	328 01 08 - No Fault Insuring Agreement Amendatory.pdf
Approved	Self-Insured Retention Per Claimant	346 01 08 01 08	Endorsement/Amendment/Conditions Replaced	Replaced Form #:0.00 346 01 02 Previous Filing #:	346 01 08 - Self-Insured Retention Per Claimant Endorsement.pdf
Approved	Personal & Advertising Injury Liability - Clinical Testing	400 01 08 01 08	Endorsement/Amendment/Conditions New	0.00	400 01 08 - Personal and Advertising Injury - Liability Testing.pdf
Approved	Limited Coverage	401 03 08 03 08	Endorsement New	0.00	401 03 08 -

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 TOI: 18.0 Product Liability Sub-TOI: 18.1000 Product Liab - Claims Made Only  
 Product Name: Defense Outside  
 Project Name/Number: /

	Territory		nt/Amendm ent/Condi ons		Limited Coverage Territory.pdf
Approved	Limitation of Coverage to Designated Product(s) or Work	402 01 08 01 08	Endorseme New nt/Amendm ent/Condi ons	0.00	402 01 08 - Limitation of Coverage to Designated Products.pdf
Approved	Exclusion - Designated Product(s) or Work	404 01 08 01 08	Endorseme New nt/Amendm ent/Condi ons	0.00	404 01 08 - Exclusion Designated Products.pdf
Approved	Amendment of Limits of Insurance	405 03 08 03 08	Endorseme New nt/Amendm ent/Condi ons	0.00	405 03 08 - Amendment of Limits of Insurance.pdf
Approved	Broad Named Insurance	407 03 08 03 08	Endorseme New nt/Amendm ent/Condi ons	0.00	407 03 08 - Broad Named Insured Endorsemen t.pdf
Approved	Schedule of Retroactive Dates	408 01 08 01 08	Endorseme New nt/Amendm ent/Condi ons	0.00	408 01 08 - Schedule of Retroactive Dates.pdf
Approved	Name Change	409 03 08 03 08	Endorseme New nt/Amendm ent/Condi ons	0.00	409 03 08 - Change of Name.pdf
Approved	Personal & Advertising Injury	411 05 08 05 08	Endorseme New nt/Amendm ent/Condi ons	0.00	411 05 08 - Personal and Advertising Injury Endorsemen t.pdf

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 Product Name: Defense Outside  
 Project Name/Number: /

Approved	Mailing Address Change	412 01 08 01 08	Endorsement/Amendment/Conditions New	0.00	412 01 08 - Change of Mailing Address Endorsement.pdf
Approved	Clinical Investigator-Sponsored or Initiated Clinical Trials	413 03 08 03 08	Endorsement/Amendment/Conditions New	0.00	413 03 08 - Clinical Investigator-Sponsored Clinical Trials.pdf
Approved	Specific Named Insured	414 03 08 03 08	Endorsement/Amendment/Conditions New	0.00	414 03 08 - Specific Named Insured Endorsement.pdf
Approved	Policy Change	415 01 08 01 08	Endorsement/Amendment/Conditions New	0.00	415 01 08 - Policy Change Endorsement.pdf
Approved	Extended Discovery Period for Clinical Testing in Israel	418 03 08 03 08	Endorsement/Amendment/Conditions New	0.00	418 03 08 - Extended Discovery Period for Clinical Testing in Israel.pdf
Approved	Amended Definition of Damages	420 05 08 05 08	Endorsement/Amendment/Conditions New	0.00	420 05 08 - Amended Damages Definition Endorsement.pdf
Approved	Coverage Change	426 09 08 09 08	Endorsement/Amendment New	0.00	426 09 08 - Coverage

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 Product Name: Defense Outside  
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		ent/Condi ons	Change Endorsemen t.pdf
Approved	Notice of Claim Reporting Period	427 10 08 10 08 Endorseme New nt/Amendm ent/Condi ons	0.00 427 10 08 - Notice of Claim Reporting Period Endorsemen t.pdf
Approved	Products Completed Operations Liability Coverage Form (Claims Made - Defense Costs Outside	CG 38 C 09 08 Policy/CoveReplaced rage Form	Replaced Form #:0.00 CG 38 C 06 96 Previous Filing #: CG 38 C 09 08 FINAL 092008.pdf





MEDICAL TECHNOLOGY - LIFE SCIENCES
Medmarc Casualty Insurance Company

THIS IS A CLAIMS-MADE POLICY
PLEASE READ THE ENTIRE FORM CAREFULLY.

PRODUCTS/COMPLETED OPERATIONS LIABILITY
DECLARATIONS

FIRST NAMED INSURED AND ADDRESS

PRODUCER'S NAME AND ADDRESS

POLICY NUMBER:

PRIOR POLICY:

POLICY PERIOD: From to at 12:01 A.M. Standard Time at your address shown above.

RETROACTIVE DATE: Coverage under this policy does not apply to "bodily injury" or "property damage" which occurs before the Retroactive Date as shown.

IN RETURN FOR THE PAYMENT OF THE PREMIUM, AND SUBJECT TO ALL THE TERMS AND CONDITIONS OF THIS POLICY, WE AGREE WITH YOU TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

1. LIMITS OF INSURANCE

POLICY PRODUCTS/COMPLETED OPERATIONS AGGREGATE LIMIT \$
EACH OCCURRENCE LIMIT \$
DEFENSE EXPENSES \$ INSIDE THE LIMITS
MEDICAL EXPENSE COVERAGE (CLINICAL TESTING ONLY) \$ EACH PERSON

2. ADVANCE POLICY PREMIUM \$

3. SELF-INSURED RETENTION AMOUNTS \$ PER OCCURRENCE
\$ AGGREGATE

4. ENDORSEMENTS ATTACHED TO THIS POLICY SEE ATTACHED

5. FOR CLASSIFICATIONS, CODES, PREMIUM BASIS, RATES AND ADVANCE PREMIUM, SEE THE ATTACHED COMPOSITE RATE ENDORSEMENT.

BY: [Signature]
Authorized Representative

DATE:

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**AMENDMENT OF COVERAGE TERRITORY - EXCLUSION OF FOREIGN COUNTRIES**

SECTION VI - Definitions, 12. is replaced by the following:

12. "**Coverage territory**" means:

The United States of America (including its territories and possessions), Puerto Rico and Canada.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**BATCH CLAUSE**

SECTION VI – Definitions, 36, the term "occurrence" with respect to "products/completed operations hazard" is amended to include the following:

All "claims" for "damages" arising from a single "lot" or "batch" of "your product" which have the same known or suspected hazard, defect, deficiency or source of contamination will be considered to be one "occurrence." Therefore, when multiple losses are considered to be one "occurrence", you must only satisfy a single "self-insured retention" amount. Likewise, our limit of liability due to "bodily injury" and "property damage" is limited to that of a single "occurrence".

Definitions:

1. With respect to "medical devices, "Lot" or "Batch" means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits, and can be distinguished by the specific date of production or by a "batch number", "lot number" or "control number".
2. With respect to "drugs",
  - a. "Batch" means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
  - b. "Lot" means a "batch", or a specific identified portion of a "batch", having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.
3. "Lot number", "control number", or "batch number" means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**COMPOSITE RATE ENDORSEMENT**

Except as stated, this endorsement is subject to all the terms and conditions of this policy:

- A. The premium shown on the Declarations page is the amount to be paid in advance of insurance becoming effective. This premium, as shown, is only an estimate of the total premium for this policy. You may, at anytime revise your estimate and adjust the premium you have placed on deposit.
- B. The advance premium will be held by us until the end of the policy period. At that time the final premium will be determined. If the earned premium exceeds the advance premium you have placed on deposit, including any mid-term changes, you will pay the excess to us. If the earned premium is less than the advance premium we will pay you. Any return premium will be subject to the terms and conditions of the minimum premium provisions. The final premium will be established no later than 180 days after the expiration of this policy.
- C. Each year, as part of the renewal process, we will review your account and make revisions as we deem appropriate. You may request that we review and re-rate your account any time. The rating basis in effect at the inception of your policy will govern that which will be used during the policy year for any changes made and reported to us, whether initiated by you or us.
- D. Your failure to cooperate is grounds for non-renewal of this policy at the completion of the current policy period.

E.	<u>Product Categories</u>	<u>Estimated Sales</u>	<u>\$2Mil Limit Rate per \$1,000 Sales</u>	<u>Excess of \$2 mil limit rate per \$1,000 sales</u>
			\$            \$	
			Developed Premium:	\$
			Minimum Term Premium:	\$
F.	Total Advance Premium			\$

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**ADDITIONAL INSURED - CONTROLLING INTEREST**

The following provision is added to Section II - Who Is an Insured, paragraph 3.

Any person(s) or organization(s) shown on the Schedule below which exercises "financial control" over you but only with respect to their liability arising out of their "financial control." "Financial control" means greater than 50 percent financial ownership or enough voting stock to control management and operations by influencing or electing its board of directors.

**SCHEDULE**

Name of Person(s) or Organization(s):

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**ADDITIONAL INSURED - DESIGNATED PERSON OR ORGANIZATION**

Section II - Who is an Insured – paragraph 3 is amended to include as an additional insured the person(s) or organization (s) shown in the Schedule, but only with respect to liability for “bodily injury” or “property damage” caused, in whole or in part, by:

1. Your acts or omissions; or
2. The acts or omissions of those acting on your behalf;

in connection with “your product” or in the performance of “your work” for the additional insured(s) designated below. There is no coverage for the additional insured for “bodily injury” or “property damage” arising out of the sole negligence of the additional insured or by those acting on behalf of the additional insured.

**SCHEDULE**

Additional Insured Person(s) or Organization(s)/Description of Work Performed:

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**ADDITIONAL INSURED - PRIMARY COVERAGE**

Section II - Who is an Insured – Part 3. is amended to include as an additional insured the person(s) or organization (s) shown in the Schedule, but only with respect to liability for “bodily injury” or “property damage” caused, in whole or in part, by:

1. Your acts or omissions; or
2. The acts or omissions of those acting on your behalf;

in connection with “your product” or in the performance of “your work” for the additional insured(s) designated below. There is no coverage for the additional insured for “bodily injury” or “property damage” arising out of the sole negligence of the additional insured or by those acting on behalf of the additional insured.

The insurance afforded to such person(s) or organization(s) is primary and shall not contribute with any other insurance which such person(s) or organization(s) have.

SCHEDULE

Additional Insured

Description of Product/Work Performed

All other terms and condition remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**EXCLUSION - DESIGNATED PERSON OR ORGANIZATION**

This insurance does not apply to any "claim" for "bodily injury" or "property damage" arising out of "your products" or "your work" and included within the "products/completed operations hazard." by any person(s) or organization(s) shown in the Schedule below:

SCHEDULE

Name of Person(s) or Organization(s):

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**EXCLUSION - AIRCRAFT PRODUCTS**

This insurance does not apply to "bodily injury" or "property damage" included in the "products/completed operations hazard" and arising out of any "aircraft products" manufactured, sold, handled or distributed by you or any other insured.

"Aircraft Products" means aircraft (including missiles or spacecraft, "launch vehicles" and any ground support or control equipment used therewith), or any article furnished by any insured and installed in aircraft or used in connection with aircraft or for spare parts for aircraft or tooling used for the manufacture thereof, including ground, handling tools and equipment and also means training aids, instructions, manuals, blueprints, engineering or other data, and/or any article in respect of which engineering or other advice and/or services and/or labor have been given or supplied by any insured relating to any aircraft or aircraft article.

"Launch Vehicle" as applied to "aircraft products" means any vehicle including parts detached on route, designed, constructed or intended to place into space any spacecraft, satellite or spaceship and shall include both manned and unmanned vehicles.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**EXTENDED DISCOVERY PERIOD ENDORSEMENT  
UNLIMITED DURATION AND REPLENISHMENT OF LIMITS**

1. Section V – Extended Discovery Periods, the last paragraph under item 2 is deleted in its entirety and revised to read as follows:

The Basic Extended Discovery Period does not reinstate or increase the limit of insurance.

2. Section V - Extended Discovery Period, paragraph 4 is deleted and replaced with the following:

4. An optional Supplemental Extended Discovery Period of unlimited duration is available, with respect to “claims” arising from “occurrences” not previously reported to us, but only by an endorsement and for an extra charge. This supplemental period starts when the Basic Extended Discovery Period, set forth in Paragraph (3) above ends.

You must give us a written request for the endorsement within ninety (90) days after the end of the policy period. The Supplemental Extended Discovery Period will not go into effect unless you pay the additional premium promptly when due.

We will determine the actual premium for the Supplemental Extended Discovery Period Endorsement in accordance with our rules and rates. In doing so, we may take into account the following:

- a. The exposures or hazards insured against; and
- b. Previous types and amounts of insurance; and
- c. Limits of Insurance available under this Coverage Part for future payment of “damages”; and
- d. Other related factors.

The additional premium will not exceed 200% of the annual premium for the Coverage Part and is fully earned when the Supplemental Extended Discovery endorsement takes effect.

This endorsement shall set forth the terms, not inconsistent with this Section, applicable to the Supplemental Extended Discovery Period, including a provision to the effect that the insurance afforded for “claims” first received during such period is excess over any valid and collectible insurance available under policies in force after the Supplemental Extended Discovery Period starts.

If the Supplemental Extended Discovery Period is in effect, we will provide a supplemental aggregate limit of insurance described below, but only for “claims” first received and recorded during the Supplemental Extended Discovery Period.

The supplemental aggregate limit of insurance will be equal to the dollar amount shown in the Declarations in effect at the end of the policy period for the “Aggregate Limit”.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**EXTENDED DISCOVERY PERIOD ENDORSEMENT  
SIX (6) YEARS AND REPLENISHMENT OF LIMITS**

1. Section V – Extended Discovery Periods, the last paragraph under item 2 is deleted in its entirety and revised to read as follows:

The Basic Extended Discovery Period does not reinstate or increase the limit of insurance.

2. The following paragraph is added to Section V – Extended Discovery Periods, paragraph 4.:

If the Supplemental Extended Discovery Period is in effect, we will provide a supplemental aggregate limit of insurance described below, but only for claims first received and recorded during the Supplemental Extended Discovery Period.

The supplemental aggregate limit of insurance will be equal to the dollar amount shown in the Declarations in effect at the end of the policy period for the “Aggregate Limit”.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**EXTENDED DISCOVERY PERIOD ENDORSEMENT –  
UNLIMITED DURATION AND NO REPLENISHMENT OF LIMITS**

Section V - Extended Discovery Period, paragraph 4 is deleted and replaced with the following:

4. An optional Supplemental Extended Discovery Period of unlimited duration is available, with respect to “claims” arising from “occurrences” not previously reported to us, but only by an endorsement and for an extra charge. This supplemental period starts when the Basic Extended Discovery Period, set forth in Paragraph (3) above ends.

You must give us a written request for the endorsement within ninety (90) days after the end of the policy period. The Supplemental Extended Discovery Period will not go into effect unless you pay the additional premium promptly when due.

We will determine the actual premium for the Supplemental Extended Discovery Period Endorsement in accordance with our rules and rates. In doing so, we may take into account the following:

- a. The exposures or hazards insured against; and
- b. Previous types and amounts of insurance; and
- c. Limits of Insurance available under this Coverage Part for future payment of “damages”; and
- d. Other related factors.

The additional premium will not exceed 200% of the annual premium for the Coverage Part and is fully earned when the Supplemental Extended Discovery endorsement takes effect.

This endorsement shall set forth the terms, not inconsistent with this Section, applicable to the Supplemental Extended Discovery Period, including a provision to the effect that the insurance afforded for “claims” first received during such period is excess over any valid and collectible insurance available under policies in force after the Supplemental Extended Discovery Period starts.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

---

**DISCONTINUED OPERATIONS OR PRODUCTS LIABILITY COVERAGE**

Coverage for "your products" or "your work" as shown in the Schedule below applies only to "bodily injury" or "property damage" included in the "products/completed operations hazard" that arises out of "your products" or "your work" described in the Schedule below that were developed, manufactured, sold, handled, distributed, disposed of or work performed or completed by you or on your behalf, prior to \_\_\_\_\_.

**SCHEDULE**

Description of products or work performed:

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**MULTIPLE SELF-INSURED RETENTIONS WITH COMBINED AGGREGATE ENDORSEMENT**

It is hereby understood and agreed that the provision entitled Self-Insured Retention on the Declarations Page shall consist of the following:

There shall be one or more of the following "self-insured retentions" applicable to "damages" and "defense expenses" because of all "bodily injury" or "property damage" caused by any one "occurrence".

1. The first "self insured retention" shall consist of a \_\_\_\_\_ per occurrence "self-insured retention" which shall be applicable to each and every "occurrence" involving \_\_\_\_\_ applicable to:
2. The second "self-insured retention" shall consist of a \_\_\_\_\_ per occurrence "self-insured retention" which shall be applicable to each and every "occurrence" involving \_\_\_\_\_ applicable to:
3. The third "self-insured retention" shall consist of a \_\_\_\_\_ per occurrence "self-insured retention" which shall be applicable to each and every "occurrence" involving \_\_\_\_\_ applicable to:
4. All of the "self-insured retentions" shall be jointly subject to a \_\_\_\_\_ combined Annual Aggregate "self-insured retention".
5. Each of the "self-insured retentions" shall be mutually exclusive and only one of them shall apply to each "occurrence".

All other terms and conditions remain the same.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE**

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**WAIVER OF TRANSFER OF RIGHTS OF RECOVERY AGAINST OTHERS TO US**

We waive any right of recovery we may have under Section IV – Conditions, paragraph 12 against the person or organization shown in the Schedule below because of payments we make for "damages" arising out of "your product" or "your work" done under a contract with that person or organization and included in the "products/completed operations hazard". This waiver applies only to the person or organization shown in the Schedule below.

**SCHEDULE**

Name of Person or Organization:

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

---

**COMPOSITE RATE ENDORSEMENT WITH MAXIMUM PREMIUM AGREEMENT**

Except as stated, this endorsement is subject to all the terms and conditions of this policy:

- A. The premium shown on the Declarations page is the amount to be paid in advance of insurance becoming effective. This premium, as shown, is only an estimate of the total premium for this policy. You may, at anytime revise your estimate and adjust the premium you have placed on deposit.
- B. The advance premium will be held by us until the end of the policy period. At that time the final premium will be determined. If the earned premium exceeds the advance premium you have placed on deposit, including any mid-term changes, you will pay the excess to us. If the earned premium is less than the advance premium we will pay you. Any return premium will be subject to the terms and conditions of the minimum premium provisions. The final premium will be established no later than 180 days after the expiration of this policy.
- C. Each year, as part of the renewal process, we will review your account and make revisions as we deem appropriate. You may request that we review and re-rate your account any time. The rating basis in effect at the inception of your policy will govern that which will be used during the policy year for any changes made, whether initiated by you or us.
- D. Your failure to cooperate is grounds for non-renewal of this policy at the completion of the current policy period.
- E.
- | <u>Product Categories</u> | <u>Estimated Sales</u> | <u>\$2 Mil Limit Rate per \$1,000 Sales</u> | <u>Excess of \$2 mil limit rate per \$1,000 sales</u> |
|---------------------------|------------------------|---|---|
|                           |                        | \$  | \$  |
|                           |                        | Developed Premium:                          | \$  |
|                           |                        | Minimum Term Premium:                       | \$  |
- F. Total Advance Premium: \$
- G. Maximum Premium Agreement  
No additional premium will be charged for sales that exceed \$

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**COMPOSITE RATE ENDORSEMENT WITH SURPLUS SALES WAIVER**

Except as stated, this endorsement is subject to all the terms and conditions of this policy:

- A. The premium shown on the Declarations page is the amount to be paid in advance of insurance becoming effective. This premium, as shown, is only an estimate of the total premium for this policy. You may, at anytime revise your estimate and adjust the premium you have placed on deposit.
- B. The advance premium will be held by us until the end of the policy period. At that time the final premium will be determined. If the earned premium exceeds the advance premium you have placed on deposit, including any mid-term changes, you will pay the excess to us. If the earned premium is less than the advance premium we will pay you. Any return premium will be subject to the terms and conditions of the minimum premium provisions. The final premium will be established no later than 180 days after the expiration of this policy.
- C. Each year, as part of the renewal process, we will review your account and make revisions as we deem appropriate. You may request that we review and re-rate your account any time. The rating basis in effect at the inception of your policy will govern that which will be used during the policy year for any changes made, whether initiated by you or us.
- D. Your failure to cooperate is grounds for non-renewal of this policy at the completion of the current policy period.

E.	<u>Product Categories</u>	<u>Estimated Sales</u>	<u>\$2 Mil Limit Rate per \$1,000 Sales</u>	<u>Excess of \$2 mil limit rate per \$1,000 sales</u>
			\$	\$
			Developed Premium:	\$
			Minimum Term Premium:	\$

F. Total Advance Premium: \$

G. Surplus Sales Waiver Agreement

No additional premium will be charged for sales that exceed \$ \_\_\_\_\_ unless and until the amount of sales becomes greater than \$ \_\_\_\_\_.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**MEDICAL PROFESSIONAL SERVICES LIABILITY ENDORSEMENT**

SCHEDULE:

<u>Description of Medical Professional Services</u>	<u>Premium Basis</u>	<u>Rate</u>	<u>Premium</u>
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A. Section II - Who is an Insured, paragraph 2 is amended to include:

Your "employees" or any other person(s) or organization(s) acting on your behalf with respect to the rendering of or failure to render "medical professional services" as described in the Schedule above.

B. Section I - Products/Completed Operations Bodily Injury and Property Damages Liability, paragraph 2.p. does not apply to the medical professional services in the Schedule above.

C. Section VI - Definitions, is amended to include the following:

"Medical Professional Services" includes all "bodily injury" caused by an "occurrence" consisting of a negligent act, error or omission in the rendering or failure to render "medical professional services" whether committed by you or by any person(s) or organization(s) acting under your direction, control or supervision or whose negligent acts, errors or omissions you are legally responsible for in connection with any , medical, dental or surgical devices, equipment or appliances, medications, drugs, biologics, blood or blood products which is manufactured, sold or distributed by you.

However, "medical professional services" does not include:

- a. Liability resulting from a criminal act by any health care provider;
- b. Any liability your employee may have as a proprietor, hospital administrator, officer, stockholder, or member of the board of directors, trustees, or governors of any:
  - (1) Hospital, nursing home or sanitarium; or
  - (2) Clinic with bed and board facility; or
  - (3) Laboratory or other business.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**SUPPLEMENTAL EXTENDED DISCOVERY PERIOD COVERAGE PURCHASE  
ENDORSEMENT**

In consideration of the \$\_\_\_\_\_ premium charged, a Supplemental Extended Discovery Period of \_\_\_\_\_ year(s) is provided as described in Section V - EXTENDED DISCOVERY PERIODS.

1. The following is added to Section IV – Conditions, paragraph 7.b.:
  - (4) The other insurance has a policy period which begins or continues after the Supplemental Extended Discovery Period begins.
2. This endorsement will not take effect unless the additional premium for it, as set forth in SECTION V, is paid when due. If that premium is paid when due, this endorsement may not be canceled.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**INSURING AGREEMENT AMENDATORY ENDORSEMENT**  
Conformance with Specified Foreign Clinical Trial Compensation Guidelines

Section I. COVERAGES, Part A, paragraph 1.a. is amended by the addition of the following:

This insurance applies to compensation to volunteer research or test subjects for any “bodily injury” or “property damage” caused by participation in industry-sponsored and approved human clinical research studies in accordance with the guidelines specified in the Schedule below and sponsored by you or any person(s) or organization(s) acting on your behalf:

**SCHEDULE**

All other terms and conditions remain unchanged.



THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

---

**PERSONAL AND ADVERTISING INJURY LIABILITY COVERAGE – CLINICAL TESTING**

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This insurance applies to "personal and advertising injury" caused by an offense arising out of or in any way related to "clinical testing" on or away from your premises when conducted by you or on your behalf, but only if the offense was committed in the "coverage territory" during the policy period.

**1. Insuring Agreement**

- a. We will pay those sums that the insured becomes legally obligated to pay as damages because of "personal injury" or "advertising injury" to which this insurance applies.
- b. This insurance applies to:
  - (1) "Personal injury" caused by an offense arising out of your business, excluding advertising, publishing, broadcasting or telecasting done by or for you; or
  - (2) "Advertising injury" caused by an offense committed in the course of advertising your goods, products or services.

**2. Definitions**

- a. "Personal and advertising injury" means injury, including consequential "bodily injury", arising out of one or more of the following offenses:
  - (1) False arrest, detention or imprisonment; or
  - (2) Malicious prosecution; or
  - (3) The wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room, dwelling or premises that a person occupies, committed by you or persons or organizations acting on your behalf; or
  - (4) Oral or written publication, in any manner, of material that slanders or libels a person or organization or disparages a person's or organization's goods, products or services; or
  - (5) Oral or written publication, in any manner, of material that violates a person's right of privacy; or
  - (6) Copying, in your "advertisement", a person's or organization's "advertising idea" or style of "advertisement"; or
  - (7) Infringement of copyright, slogan, or title of any literary or artistic work, in your "advertisement"; or
  - (8) Discrimination or humiliation that results in injury to the feelings or reputation of a natural person.
- b. "Advertisement" means the widespread public dissemination of information or images that has the purpose of inducing the sale of goods, products or services through:
  - (1) Radio; or

All other terms and condition remain unchanged.

**PERSONAL AND ADVERTISING INJURY LIABILITY COVERAGE – CLINICAL TESTING  
(CONT'D)**

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- (2) Television; or
- (3) Billboard; or
- (4) Magazine; or
- (5) Newspaper; or
- (6) Any other publication that is given widespread public distribution.

However, "advertisement" does not include:

- (1) The design, printed material, information or images contained in, on or upon the packaging or labeling of any goods or products; or
  - (2) An interactive conversation between or among persons through a computer network.
- c. "Advertising idea" means any idea for an "advertisement"

**3. Exclusions**

This insurance does not apply to:

**a. Knowing Violation Of Rights Of Another**

"Personal and advertising injury" caused by or at the direction of the insured with the knowledge that the act would violate the rights of another and would inflict "personal and advertising injury".

**b. Material Published With Knowledge Of Falsity**

"Personal and advertising injury" arising out of oral or written publication of material, if done by or at the direction of the insured with knowledge of its falsity.

**c. Material Published Prior To Retroactive Date**

"Personal and advertising injury" arising out of oral or written publication of material whose first publication took place before the "retroactive date".

**d. Criminal Acts**

"Personal and advertising injury" arising out of a criminal act committed by or at the direction of the insured.

**e. Contractual Liability**

"Personal and advertising injury" for which the insured has assumed liability in a contract or agreement. This exclusion does not apply to liability for damages that the insured would have in the absence of the contract or agreement.

**PERSONAL AND ADVERTISING INJURY LIABILITY COVERAGE – CLINICAL TESTING  
(CONT'D)**

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**f. Breach Of Contract**

"Personal and advertising injury" arising out of a breach of contract, except an implied contract to use another's advertising idea in your "advertisement".

**g. Quality Or Performance Of Goods – Failure To Conform To Statements**

"Personal and advertising injury" arising out of the failure of goods, products or services to conform with any statement of quality or performance made in your "advertisement".

**h. Wrong Description Of Prices**

"Personal and advertising injury" arising out of the wrong description of the price of goods, products or services stated in your "advertisement".

**i. Infringement Of Copyright, Patent, Trademark Or Trade Secret**

"Personal and advertising injury" arising out of the infringement of copyright, patent, trademark, trade secret or other intellectual property rights. Under this exclusion, such other intellectual property rights do not include the use of another's advertising idea in your "advertisement". However, this exclusion does not apply to infringement in your "advertisement", of copyright, trade dress or slogan.

**j. Electronic Chatrooms Or Bulletin Boards**

"Personal and advertising injury" arising out of an electronic chatroom or bulletin board the insured hosts, owns, or over which the insured exercises control.

**k. Unauthorized Use Of Another's Name Or Product**

"Personal and advertising injury" arising out of the unauthorized use of another's name or product in your e-mail address, domain name or metatag, or any other similar tactics to mislead another's potential customers.

**l. War**

"Personal and advertising injury", however caused, arising, directly or indirectly, out of:

- (1) War, including undeclared or civil war; or
- (2) Warlike action by a military force, including action in hindering or defending against an actual or expected attack, by any government, sovereign or other authority using military personnel or other agents; or
- (3) Insurrection, rebellion, revolution, usurped power, or action taken by governmental authority in hindering or defending against any of these.

**PERSONAL AND ADVERTISING INJURY LIABILITY COVERAGE – CLINICAL TESTING  
(CONT'D)**

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**m. Distribution Of Material In Violation Of Statutes**

"Personal and advertising injury" arising directly or indirectly out of any action or omission that violates or is alleged to violate:

- (1) The Telephone Consumer Protection Act (TCPA), including any amendment of or addition to such law; or
- (2) The CAN-SPAM Act of 2003, including any amendment of or addition to such law; or
- (3) Any statute, ordinance or regulation, other than the TCPA or CAN-SPAM Act of 2003, that prohibits or limits the sending, transmitting, communicating or distribution of material or information.

All other terms and condition remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

---

**LIMITED COVERAGE TERRITORY**

Non-admitted or Compulsory Insurance under Section IV - Conditions , paragraph 6 does not apply.

Paragraph 12. under Section VI - Definitions is replaced by the following:

12. "Coverage Territory" means:

- a. The United States of America (including its territories and possessions), Puerto Rico and Canada;  
or
- b. International waters or airspace, but only if the "bodily injury" or "property damage" occurs in the course of travel or transportation between any places included in a. above; or
- c. All other parts of the world if the "bodily injury" or "property damage" arises out of:
  - (1) Goods or products made or sold by you in the "coverage territory" described in a. above;  
or
  - (2) The activities of a person whose home is in the "coverage territory" described in a. above, but is away for a short time on your business.

All other terms and condition remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

---

**LIMITATION OF COVERAGE TO DESIGNATED PRODUCT(S) OR WORK(S)**

This insurance applies only to “bodily injury” or “property damage” arising out of “your product(s)” or “your work(s)” shown in the Schedule below:

**SCHEDULE**

Your product(s) or work(s) performed:

All other terms and condition remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

---

**EXCLUSION—DESIGNATED PRODUCT(S) OR WORK(S)**

This insurance does not apply to "bodily injury" or "property damage" included in the "products/completed operations hazard" and arising out of "your product(s)" or "your work(s)" shown in the Schedule below.

**SCHEDULE**

Designated Product(s) or Works(s):

All other terms and condition remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**AMENDMENT OF LIMITS OF INSURANCE**

<b>Effective Date</b>  « 1 »	<b>Policy Number</b>  « 2 »
------------------------------------	-----------------------------------

The Limits of Insurance shown in paragraph 1 of the Declarations are replaced by the Limits of Insurance shown in the Schedule below.

**SCHEDULE**

**1. LIMITS OF INSURANCE:**

POLICY PRODUCTS/COMPLETED OPERATIONS AGGREGATE LIMIT	\$	
EACH OCCURRENCE LIMIT	\$	
DEFENSE EXPENSES	\$	
MEDICAL EXPENSE COVERAGE (CLINICAL TESTING ONLY)	\$	EACH PERSON

All other terms and condition remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**BROAD NAMED INSURED ENDORSEMENT**

It is agreed that the first sentence of the second paragraph of the policy preamble is replaced with the following:

Throughout this policy the words “you” and “your” refer to:

- a. the “first named insured” shown in the Declarations, and
- b. any other person or organization qualifying as a “named insured” under this policy and the person(s) or organization(s) shown in the schedule below, and
- c. all owned or controlled business entities existing at policy inception or formed or acquired during the policy period in which a “named insured” owns an interest of more than 50 percent and is responsible for procuring insurance.

**SCHEDULE**

Name of Person(s) or Organization(s):

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**SCHEDULE OF RETROACTIVE DATES**

With respect to the “named insureds” shown in the Schedule below, the “retroactive date” shown on the Declarations is replaced by the “retroactive date(s)” indicated for these specific “named insureds”:

SCHEDULE		
Named Insured	Retroactive Date	Limit of Insurance

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**FIRST NAMED INSURED CHANGE ENDORSEMENT**

<b>Effective Date</b> « 1 »	<b>Policy Number</b> « 2 »
--------------------------------	-------------------------------

The name of the “first named insured” shown on the policy Declarations page is changed:

From:

To:

All other terms and conditions remain unchanged.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

---

**PERSONAL AND ADVERTISING INJURY LIABILITY COVERAGE – CLINICAL TESTING**

**1. Insuring Agreement**

We will pay those sums that the insured becomes legally obligated to pay as “damages” because of “personal and advertising injury” to which this insurance applies, caused by an offense:

- a. Committed in the course of “clinical testing”, when conducted by you or on your behalf, on or away from your premises; and
- b. Committed in the "coverage territory" during the policy period; and
- c. Arising out of your business.

**2. Definitions**

- a. "Personal and advertising injury" means injury, including consequential "bodily injury", caused by one or more of the following offenses:
  - (1) False arrest, detention or imprisonment; or
  - (2) Malicious prosecution; or
  - (3) The wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room, dwelling or premises that a person occupies, committed by you or persons or organizations acting on your behalf; or
  - (4) Oral or written publication, in any manner, of material that slanders or libels a person or organization or disparages a person's or organization's goods, products or services; or
  - (5) Oral or written publication, in any manner, of material that violates a person's right of privacy; or
  - (6) The misappropriation of another's advertising idea in your “advertisement”; or
  - (7) Infringing upon another's copyright, trade dress or slogan in your “advertisement”; or
  - (8) Discrimination or humiliation that results in injury to the feelings or reputation of a natural person.
- b. “Advertisement” means a notice that is broadcast or published to the general public or specific market segments about your goods, products or services for the purpose of attracting customers or supporters. For the purposes of this definition:
  - (1) Notices that are published include material placed on the Internet or on similar electronic means of communication; and
  - (2) Regarding web-sites, only that part of a website that is about your goods, products or services for the purposes of attracting customers or supporters is considered an “advertisement”.

However, “advertisement” does not include:

- (1) The display or design of printed material, information or images contained in, on or upon the packaging or labeling of any goods, products or services; or
- (2) An interactive conversation between or among persons through a computer network.

All other terms and conditions remain unchanged.

**PERSONAL AND ADVERTISING INJURY LIABILITY COVERAGE – CLINICAL TESTING  
(CONT'D)**

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**3. Exclusions**

This insurance does not apply to:

**a. Insureds in Media and Internet Type Businesses**

"Personal and advertising injury" committed by an insured whose business is:

- (1) Advertising, broadcasting, publishing or telecasting;
- (2) Designing or determining content or websites for others; or
- (3) An Internet search, access, content or service provider.

**b. Knowing Violation Of Rights Of Another**

"Personal and advertising injury" caused by or at the direction of the insured with the knowledge that the act would violate the rights of another or would result in "personal and advertising injury".

**c. Material Published With Knowledge Of Falsity**

"Personal and advertising injury" arising out of oral or written publication of material, if done by or at the direction of the insured with knowledge of its falsity.

**d. Material Published Prior To Retroactive Date**

"Personal and advertising injury" arising out of oral or written publication of material whose first publication took place before the "retroactive date".

**e. Criminal Acts**

"Personal and advertising injury" arising out of a criminal act committed by or at the direction of the insured.

**f. Contractual Liability**

"Personal and advertising injury" for which any insured is obligated to pay by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for "damages" that the insured would have in the absence of the contract or agreement.

**g. Breach Of Contract**

"Personal and advertising injury" arising out of a breach of contract, except an implied contract to use another's advertising idea in your "advertisement".

**h. Quality Or Performance Of Goods – Failure To Conform To Statements**

"Personal and advertising injury" arising out of the failure of goods, products or services to conform with any statement of quality or performance made in your "advertisement".

**i. Wrong Description Of Prices**

"Personal and advertising injury" arising out of the wrong description of the price of goods, products or services stated in your "advertisement".

**j. Electronic Chatrooms Or Bulletin Boards**

"Personal and advertising injury" arising out of an electronic chatroom or bulletin board the insured hosts, owns, or over which the insured exercises control.

**PERSONAL AND ADVERTISING INJURY LIABILITY COVERAGE – CLINICAL TESTING  
(CONT'D)**

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**k. Infringement Of Patent, Copyright, Trademark Or Theft of Trade Secret**

"Personal and advertising injury" arising out of any actual or alleged infringement of patent, copyright, trademark, trade dress, service mark, or other designation of origin or authenticity, theft of trade secret, false marking, misappropriation, or other intellectual property rights. Under this exclusion, such other intellectual property rights do not include the misappropriation of another's advertising idea in your "advertisement". However, this exclusion does not apply to infringement in your "advertisement", of copyright, trade dress or slogan.

**l. Unauthorized Use Of Another's Name Or Product**

"Personal and advertising injury" arising out of the unauthorized use of another's name or product in your e-mail address, domain name or metatag, or any other similar tactics to mislead another's potential customers.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**MAILING ADDRESS CHANGE ENDORSEMENT**

<b>First Named Insured</b>	<b>Effective Date</b>	<b>Policy Number</b>
< 3>	< 1>	< 2>

The mailing address of the “first named insured” shown on the policy Declarations page is changed:

From:

To:

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

---

**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**Clinical Investigator-Sponsored or Initiated Clinical Trials Endorsement**

1. This insurance applies to “bodily injury” or “property damage” arising out of “clinical testing” sponsored by physicians holding an investigational device exemption (“IDE”) or investigational new drug exemption (“IND”) and shown in the Schedule below, who both initiate and conduct a clinical investigation, and under whose immediate direction the investigational device, “drug” or “biologic” is being used, administered or dispensed in accordance with the study protocol and in connection with “your product”.
2. Definitions:
  - a. “Investigational New Drug Application (IND)” means a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new “drug” or “biological product” that has not been approved for marketing by the FDA.
  - b. “Investigational Device Exemption (IDE)” means an exemption allowing the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval which allows for lawful shipment for the purpose of conducting investigations of the investigational device.

SCHEDULE

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**SPECIFIC NAMED INSURED ENDORSEMENT**

It is agreed that the first sentence of the second paragraph of the policy preamble is replaced with the following:

Throughout this policy the words “you” and “your” refer to:

- a. the “first named insured” shown in the Declarations, and
- b. any other person or organization qualifying as a “named insured” under this policy and the person(s) or organization(s) shown in the schedule below.

**SCHEDULE**

Name of Person(s) or Organization(s):

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**POLICY CHANGE ENDORSEMENT**

<b>First Named Insured</b>	<b>Effective Date</b>	<b>Policy Number</b>
< 3>	< 1>	< 2>

The terms or conditions of your policy are changed as follows:

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**EXTENDED DISCOVERY PERIOD FOR CLINICAL TESTING IN ISRAEL**

Section V - Extended Discovery Periods is deleted in its entirety with respect to claims filed under the jurisdiction of the courts of the State of Israel in accordance with Israel's Ministry of Health Pharmaceutical Administration's Guidelines for Clinical Trials in Human Subjects (January 2006 or as amended) and replaced as follows:

1. We will provide an Extended Discovery Period of eighty-four (84) months, starting with the completion/discontinuation of the clinical trials shown in the Schedule below;
2. The Extended Discovery Period applies only to "claims" for "bodily injury" or "property damage" that occurred after any applicable "retroactive date" but before the end of the policy period;
3. A "claim" first made during the basic Extended Discovery Period will be deemed to have been made on the last day of the policy;
4. The Extended Discovery Period does not reinstate or increase the Limits of Insurance and does not extend the policy period.
5. No additional premium is required to effect this coverage and once in effect the Extended Discovery Period may not be cancelled.

SCHEDULE

Description of Study Protocol/Clinical Trial and Completion Date

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE**

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**AMENDED DEFINITION OF DAMAGES ENDORSEMENT**

The definition of “damages” found in Section VI – Definitions, para. 13, is deleted in its entirety and replaced with the following:

**13. “Damages”** means money:

- a.** awarded by a court or an administrative tribunal against an insured; or
- b.** the payment of which an insured is obligated to make under a binding settlement agreement.

“Damages” because of “bodily injury” includes payment for care, loss of services or death resulting at any time from the “bodily injury”.

“Damages” does not include any (1) fines, (2) penalties, (3) taxes, or (4) the return of or restitution of fees, profits or charges for services rendered.

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**COVERAGE CHANGE ENDORSEMENT**

<b>First Named Insured</b>	<b>Effective Date</b>	<b>Policy Number</b>
< 3>	< 1>	< 2>

The terms or conditions of your policy are changed as follows:

All other terms and conditions remain unchanged.

THIS ENDORSEMENT CHANGES THE COVERAGE FORM. PLEASE READ IT CAREFULLY.

This endorsement modifies insurance provided under the following:

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**PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM**

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**NOTICE OF CLAIM REPORTING PERIOD ENDORSEMENT**

A. Section IV – Conditions, Notice of Claim, paragraph 2.b(2) is replaced by the following:

(2) notify us in writing promptly.

All other terms and conditions remain unchanged.

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# Medmarc®

## MEDICAL TECHNOLOGY -- LIFE SCIENCES PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM

(DEFENSE EXPENSES ARE OUTSIDE THE POLICY LIMITS)

**THIS INSURANCE PROVIDES CLAIMS MADE COVERAGE.  
PLEASE READ THE ENTIRE POLICY CAREFULLY.**

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# MEDICAL TECHNOLOGY -- LIFE SCIENCES PRODUCTS/COMPLETED OPERATIONS LIABILITY COVERAGE FORM

(DEFENSE COSTS ARE OUTSIDE THE POLICY LIMITS)

**THIS INSURANCE PROVIDES CLAIMS MADE COVERAGE.**

**PLEASE READ THE ENTIRE POLICY CAREFULLY.**

Various provisions in this policy restrict coverage. Read the entire policy carefully to determine rights, duties and what is and is not covered.

Throughout this policy the words "you" and "your" refer to the "first named insured" shown in the Declarations, and any other person or organization qualifying as a "named insured" under this policy. The words "we", "us" and "our" refer to the Company providing this insurance.

The word "insured" means any person or organization qualifying as such under Section II - Who Is An Insured.

Other words and phrases that appear in quotation marks have special meaning. Refer to Section VI – Definitions.

## SECTION I – COVERAGES

### A. PRODUCTS/COMPLETED OPERATIONS BODILY INJURY AND PROPERTY DAMAGE LIABILITY

#### 1. Insuring Agreement

- a. We will pay those sums, in excess of the "self-insured retention", that the insured becomes legally obligated to pay as "damages" because of "bodily injury" or "property damage" included within the "products/completed operations hazard" caused by products to which this insurance applies. We will have the right and duty to defend the insured against any "suit" seeking those "damages," and to control the defense. However, we will have no duty to defend any insured against any "suit" seeking "damages" for "bodily injury" or "property damage" to which this insurance does not apply. We may, at our discretion, (1) investigate any "occurrence," (2) defend any "claim", and (3) settle any "claim" or "suit" that may result. In those instances in which we either are obligated to defend or, at our discretion, choose to defend, we will designate legal counsel to defend any "claim" or "suit" whether or not the amount of the "claim" or "suit" is unspecified or less than the "self-insured retention" shown in the Declarations.

But:

- (1) The amount we will pay for "damages" is limited as described in Section III - Limits of Insurance; and
- (2) Our right and duty to defend and control the defense applies regardless of whether or not your "self-insured retention" has been used up in payment of "judgments", "settlements" and "defense expenses"; and

- (3) Our right and duty to defend end when we have used up the applicable limit of insurance in the payment of "judgments" or "settlements" under Section 1.A – Products Completed Operations Bodily Injury and Property Damage Liability or Section 1.B – Medical Expenses-Clinical Testing; and

- (4) No other obligation or liability to pay sums or perform acts or services is covered unless explicitly provided for under Section 3.B – Defense Expenses.

- b. This insurance applies to "bodily injury" and "property damage" only if:

- (1) The "bodily injury" or "property damage" is caused by an "occurrence" that takes place in the "coverage territory"; and

- (2) The "bodily injury" or "property damage" did not occur before the "retroactive date", if any, shown in the Declarations or after the end of the policy period, provided that, all "bodily injury" and "property damage" that commences prior to the "retroactive date" and continues after the "retroactive date" will be deemed to have occurred before the "retroactive date"; and

- (3) A "claim" for "damages" because of the "bodily injury" or "property damage" is first made against any insured, in accordance with Paragraph (c) below, during the policy period or any Extended Discovery Period we provide under Section V - Extended Discovery Periods.

- c. A "claim" by a person or organization seeking "damages" will be deemed to have been made at the earlier of the following times:

- (1) When notice of such "claim" is received by any insured or by us, whichever comes first; or
- (2) When we make "settlement" in accordance with Paragraph (1.a) above.

- d. All "claims" for "damages" because of "bodily injury" to the same person, including "damages" claimed by any person or organization for care, loss of services, or death resulting at any time from the "bodily injury", will be deemed to have been made at the time the first of those "claims" is made against any insured.

- e. All "claims" for "damages" because of "property damage" causing loss to the same person or organization will be deemed to have been made at the time the first of those "claims" is made against any insured.

## 2. Exclusions

This insurance does not apply to:

### a. Expected or Intended Injury

"Bodily injury" or "property damage" expected or intended from the standpoint of any insured.

This exclusion does not apply to:

- (1) "Bodily injury" or "property damage" resulting from the use of reasonable force to protect persons or property; or
- (2) "Bodily injury" or "property damage" arising out of products manufactured or distributed by you for which all known actual and potential side effects, adverse reactions, contraindications, warnings or precautions were disclosed in clinical testing, "informed consent", product package inserts, or labeling cleared for marketing by any government health authority or regulatory body.

### b. Willful and Intentional Acts

A "claim" based upon or arising out of any dishonest, intentionally fraudulent, criminal, malicious or knowingly wrongful act or omission committed by or at the direction of any insured, including but not limited to, any violation of the laws and regulations of any government health authority or regulatory body establishing safety standards or the violation of any anti-trust law.

### c. Contractual Liability

"Damages" for which any insured is obligated to pay by reason of the assumption of liability in a contract or agreement.

This exclusion does not apply to liability for "damages":

- (1) That the insured would have in the absence of the contract or agreement; or
- (2) Assumed in a contract or agreement that is an "insured contract", provided the "bodily injury" or "property damage" occurs subsequent to the execution of the contract or agreement. Solely for the purposes of liability assumed in an "insured contract", reasonable attorney fees and necessary litigation expenses incurred by or for a party other than an insured are deemed to be "damages" because of "bodily injury" or "property damage", provided:
  - (a) Liability to such party for, or for the cost of, that party's defense has also been assumed in the same "insured contract"; and
  - (b) Such attorney fees and litigation expenses are for defense of that party against a civil or alternative dispute resolution proceeding in

which "damages" to which this insurance applies are alleged.

### d. Workers' Compensation and Similar Laws

Any obligation of any insured under a workers' compensation, disability benefits or unemployment compensation law or any similar law.

### e. Employer's Liability

"Bodily injury" to:

- (1) An "employee" of any insured arising out of and in the course of:
  - (a) Employment by any insured; or
  - (b) Performing duties related to the conduct of the insured's business; or
- (2) The spouse, child, parent, brother or sister of that "employee" as a consequence of Paragraph (1) above.

This exclusion applies whether the insured may be liable as an employer or in any other capacity and to any obligation to share "damages" with or repay someone else who must pay "damages" because of the injury.

### f. War

Damages arising, directly or indirectly, out of:

- (1) War, including undeclared or civil war; or
- (2) Warlike action by a military force, including action in hindering or defending against an actual or expected attack, by any government, sovereign or other authority using military personnel or other agents; or
- (3) Insurrection, rebellion, revolution, usurped power, or action taken by governmental authority in hindering or defending against any of these.

### g. Damage to Property

"Property damage" to:

- (1) Property you own, rent, lease or occupy, including but not limited to any costs or expenses incurred by you, or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property; or
- (2) Premises you sold, gave away or abandoned, if the "property damage" arises out of any part of those premises; or
- (3) Property loaned to you; or
- (4) Personal property in the care, custody or control of the insured.

Paragraph (2) of this exclusion does not apply if the premises are "your work" and were never occupied, rented or held for rental by you.

### h. Damage to Your Product

"Property damage" to "your product" arising out of it or any part of it.

**i. Damage to Your Work**

"Property damage" to "your work" arising out of it or any part of it and included in the "products/completed operations hazard".

This exclusion does not apply if the damaged work out of which the damage arises was performed on your behalf by a subcontractor.

**j. Damage to Impaired Property or Property Not Physically Injured**

"Property damage" to "impaired property" or property that has not been physically injured, arising out of:

- (1) A defect, deficiency, inadequacy or dangerous condition in "your product" or "your work"; or
- (2) A delay or failure by you or anyone acting on your behalf to perform a contract or agreement in accordance with its terms.

This exclusion does not apply to the loss of use of other property arising out of sudden and accidental physical injury to "your product" or "your work" after it has been put to its intended use.

**k. Return of Payment**

A demand for the return of all or any part of payments made for "your product" or "your work," or a dispute regarding fees or charges, or which result from cost guarantees or estimates of cost.

**l. Nuclear Energy**

(1) "Damages":

- (a) With respect to which an "insured" under the policy is also an insured under a nuclear energy liability policy issued by Nuclear Energy Liability Insurance Association, Mutual Atomic Energy Liability Underwriters, Nuclear Insurance Association of Canada or any of their successors, or would be an insured under any such policy but for its termination upon exhaustion of its limit of liability; or
- (b) Resulting from the "hazardous properties" of "nuclear material" and with respect to which (a) any person or organization is required to maintain financial protection pursuant to the Atomic Energy Act of 1954, or any law amendatory thereof, or (b) the "insured" is, or had this policy not been issued would be, entitled to indemnity from the United States of America, or any agency thereof, under any agreement entered into by the United States of America, or any agency thereof, with any person or organization.

(2) Under any Medical Payments coverage, to expenses incurred with respect to "bodily injury" resulting from the "hazardous properties" of "nuclear material" and arising out of the operation of a "nuclear facility" by any person or organization.

(3) "Damages" resulting from "hazardous properties" of "nuclear material", if:

- (a) The "nuclear material" (a) is at any "nuclear facility" owned by, or operated by or on behalf of, an "insured" or (b) has been discharged or dispersed therefrom; or
- (b) The "nuclear material" is contained in "spent fuel" or "waste" at any time possessed, handled, used, processed, stored, transported or disposed of, by or on behalf of an "insured"; or
- (c) The "bodily injury" or "property damage" arises out of the furnishing by an "insured" of services, materials, parts or equipment in connection with the planning, construction, maintenance, operation or use of any "nuclear facility", but if such facility is located within the United States of America, its territories or possessions or Canada, this exclusion (3) applies only to "property damage" to such "nuclear facility" and any property thereat.

(4) As used in this exclusion:

"Hazardous properties" includes radioactive, toxic or explosive properties.

"Nuclear material" means "source material", "special nuclear material" or "by-product material".

"Source material", "special nuclear material", and "by-product material" have the meanings given them in the Atomic Energy Act of 1954 or in any law amendatory thereof.

"Spent fuel" means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a "nuclear reactor".

"Waste" means any waste material (a) containing "by-product material" other than the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its "source material" content, and (b) resulting from the operation by any person or organization of any "nuclear facility" included under the first two paragraphs of the definition of "nuclear facility".

"Nuclear facility" means:

- (a) Any "nuclear reactor"; or
- (b) Any equipment or device designed or used for (1) separating the isotopes of uranium or plutonium, (2) processing or utilizing "spent fuel", or (3) handling, processing or packaging "waste"; or
- (c) Any equipment or device used for the processing, fabricating or alloying of "special nuclear material" if at any time the total amount of such material in the custody of the "insured" at the premises where such equipment or device is located consists of or contains more than 25 grams of Plutonium or uranium 233 or any combination thereof, or more than 250 grams of uranium 235; or

(d) Any structure, basin, excavation, premises or place prepared or used for the storage or disposal of "waste";

and includes the site on which any of the foregoing is located, all operations conducted on such site and all premises used for such operations.

"Nuclear reactor" means any apparatus designed or used to sustain nuclear fission in a self-supporting chain reaction or to contain a critical mass of fissionable material.

"Property damage" includes all forms of radioactive contamination of property.

This exclusion does not apply to "bodily injury" or "property damage" arising out of nuclear material or hazardous properties of "your product" or "your work," including but not limited to the manufacture, sale, distribution or servicing of radiation-emitting "medical devices", radioactive isotopes or radiopharmaceuticals cleared for marketing by any government health authority or regulatory body for a specific medical diagnostic or therapeutic indication for use.

**m. Recall of Products, Work or Impaired Property**

"Damages" claimed for any loss, cost or expense incurred by any insured for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

- (1) "Your product"; or
- (2) "Your work"; or
- (3) "Impaired property";

if such product, work, or property is withdrawn or recalled from the market or from use by or at the direction of any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition in such product, work or property.

This exclusion also applies to the costs of regaining goodwill, market share, revenue or "profit" or the costs of redesigning "your product" or "your work".

**n. Infringement of Intellectual Property Rights**

"Damages" arising out of any actual or alleged infringement of patent, copyright, trade secret, trade name, trademark, trade dress, service mark or other designation of origin or authenticity, or out of false marking or misappropriation.

**o. Electronic Data**

"Property damage" arising out of the loss of, loss of use of, damage to, corruption of, inability to access, or inability to manipulate "electronic data".

As used in this exclusion, "electronic data" means information, facts or programs stored as or on, created or used on, or transmitted to or from computer software, including systems and applications software, hard or floppy disks, CD-ROMS, tapes,

drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

**p. Professional Services Liability**

"Damages" due to the rendering of or failure to render the following services:

- (1) Medical, surgical, dental, pharmaceutical or nursing treatment, or any diagnostic test or procedure including, but not limited to:
    - (a) the furnishing or dispensing of "drugs" or medical, dental or surgical supplies, devices or appliances; or
    - (b) Administration of medication; or
    - (c) Making a medical diagnosis of a patient's condition for the purpose of instituting treatment; or
    - (d) Diagnosis based on assessment, planning, intervention and evaluation of a patient or test/trial subject; or
    - (e) Judgments regarding a patient's care and treatment; or
    - (f) Performing a surgical procedure; or
    - (g) Interpreting test results.
  - (2) Diagnostic Testing or Laboratory Services, including but not limited to:
    - (a) Medical or diagnostic testing, techniques or procedures used for the:
      1. Detection, diagnosis or treatment of any sickness, disease, condition or injury; or
      2. Evaluation of a patient's response to treatment or medication; or
    - (b) The reporting of or reliance upon the results of such medical or diagnostic testing, techniques or procedures as described above.
  - (3) Pharmacy Services
    - (a) Consulting, diagnostic, referral, or similar services including, but not limited to, performing blood tests, prescribing and administering "drugs", and managing drug therapy; or
    - (b) the prescribing of goods or products.
- q. Securities, Financial Interest and Antitrust**
- "Damages" arising out of or by reason of:
- (1) The purchase, or sale, or offer of sale, or solicitation of any security, debt, bank deposit or financial interest or instrument; or
  - (2) Any representations made at any time in relation to the price or value of any security, debt, bank deposit or financial interest or instrument; or
  - (3) Any depreciation or decline in price or value of any security, debt, bank deposit or financial interest or instrument; or
  - (4) Violation of any antitrust law.

**r. Asbestos**

“Damages” arising, in whole or in part, out of:

- (1) Inhaling, ingesting or exposure to asbestos or goods or products containing asbestos; or
- (2) The use of asbestos in constructing or manufacturing any goods, products or structures; or
- (3) The removal of asbestos from any goods, products or structures; or
- (4) The manufacture, transportation, storage, handling, distribution, sale, application, mining, consumption or disposal of asbestos or goods or products containing asbestos.

**s. Pollution**

- (1) “Bodily injury” or “property damage” which would not have occurred in whole or part but for the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of pollutants at any time.
- (2) Any loss, cost or expense arising out of any:
  - (a) Request, demand or order that any insured or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of pollutants; or
  - (b) “Claim” or “suit” by or on behalf of a governmental authority for “damages” because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or neutralizing, or in any way responding to, or assessing the effects of “pollutants”.

“Pollutants” means any solid, liquid, gaseous, or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acid, alkalis, chemicals and waste. Waste includes material to be recycled, reconditioned or reclaimed.

This exclusion does not apply where “your product” was cleared by any government health authority or regulatory body for marketing with a specific indication for medical diagnostic or therapeutic use.

- b. Subject to the Medical Expense Coverage Limit as shown on the Declarations, we will make these payments regardless of fault. These payments will not exceed the applicable limit of insurance.
- c. As used in this section, “medical expenses” means reasonable expenses for:
  - (1) First aid administered at the time of an accident; and
  - (2) Necessary medical, surgical, x-ray and dental services, including prosthetic devices; and
  - (3) Necessary ambulance, hospital, professional nursing and funeral services.

**2. Exclusions**

We will not pay “medical expenses” for “bodily injury”:

- a. To an “employee”, “volunteer worker”, or principal of any insured.
- b. To a person hired to do work for or on behalf of any insured.
- c. To a person, whether or not an “employee” of any insured, if benefits for the “bodily injury” are payable or must be provided under a workers’ compensation or disability benefits law or a similar law.
- d. To a person injured while taking part in athletics.
- e. Excluded under Products/Completed Operations Liability Coverage Part.
- f. For a deterioration of the existing state of health which would have occurred or persisted even without participation in the clinical trial.
- g. That occurred because the “test/trial subject” contravened express instructions given during the “clinical testing”.

**SECTION II – WHO IS AN INSURED**

**1. If you are designated in the Declarations as:**

- a. **An individual**  
You and your spouse are insureds, but only with respect to the conduct of a business of which you are the sole owner.
- b. **A partnership or joint venture**  
You are an insured. Your members, your partners, and their spouses are also insureds, but only with respect to the conduct of your business.
- c. **A limited liability company**  
You are an insured. Your members are also insureds, but only with respect to the conduct of your business. Your managers are insureds, but only with respect to their duties as your managers.
- d. **An organization other than a partnership, joint venture or limited liability company**  
You are an insured. Your “executive officers” and “directors” are insureds, but only with respect to their duties as your “executive officers” or “directors”. Your stockholders are also insureds, but only with respect to their liability as stockholders.

**B. MEDICAL EXPENSES - CLINICAL TESTING**

**1. Insuring Agreement**

We will pay any “medical expenses”, in excess of the “self-insured retention”, for:

- a. “Bodily injury” to any “test/trial subject” who is being treated or cared for in a medical facility arising out of “your products” in connection with “clinical testing” of which you are the “sponsor,” provided that:
  - (1) The “medical expenses” are incurred and reported to us in writing within one year from the date that the “bodily injury” is known to the insured; and
  - (2) The “test/trial subject” submits to examination, at our expense, by physicians of our choice, as often as we reasonably require.

2. Each of the following is also an **insured**:

**a. Medical Staff Members**

Any member of your medical staff, such as a physician, medical director or medical review officer, nurse, emergency medical technician or paramedic, but only with respect to his or her legal liability for providing or failing to provide any supervisory or instructional services. This definition of insured shall not be extended to the rendering of or failure to render professional services contained in Paragraph (2.p) of Section I.A - Products/Completed Operations Bodily Injury and Property Damage Liability.

**b. Employees and Volunteer Workers**

Your "employees" or "volunteer workers", other than either your "executive officers" or "directors" (if you are an organization other than a partnership, joint venture or limited liability company) or your managers (if you are a limited liability company), but only for acts within the scope of their employment by you or while performing duties related to the conduct of your business. This includes your field or sales representatives and service technicians providing technical expertise, product training and sales support to existing and prospective customers within or outside of health care facilities, in connection with the sale, loan, lease or delivery of "your product".

However, no "employee" or "volunteer worker" is insured for:

(1) "Bodily injury":

- (a) To you, to your partners or members (if you are a partnership or joint venture), to your members (if you are a limited liability company), to your "executive officers" or "directors" if you are an organization other than a partnership, joint venture or limited liability company, or to a co-"employee" while in the course of his or her employment or as he or she is performing duties related to the conduct of your business, or to your "volunteer workers" while performing duties related to the conduct of your business; or
- (b) To the spouse, child, parent, brother or sister of any person described in Paragraph (a) above; or
- (c) For which there is any obligation to share "damages" with or repay someone else who must pay "damages" because of the injury described in Paragraphs (a) or (b) above.

3. Each of the following is also an **insured**:

However, no such person or organization is an insured with respect to any liability arising out of the sole negligence of such person or organization.

**a. Vendors**

Any person(s) or organization(s) acting as your vendor, but only with respect to "bodily injury" or "property damage" arising out of "your products" which are distributed or sold in the regular course of

the vendor's business, subject to the following additional exclusions:

The insurance afforded to the vendor does not apply to "bodily injury" or "property damage" arising out of:

- (1) The assumption of liability in a contract or agreement. This exclusion does not apply to liability for "damages" that the vendor would have in the absence of the contract or agreement; or
- (2) Any express warranty unauthorized by you; or
- (3) Any biological, physical or chemical change in the product made intentionally by the vendor; or
- (4) Repackaging, unless unpacked solely for the purpose of inspection, demonstration, testing, dispensing of products in the required amount or dosage, or the substitution of parts under instructions from the manufacturer, and then repackaged in the original container. This exclusion does not apply to repackaging of "drugs" by a licensed pharmacist or to the transfilling of oxygen; or
- (5) Any failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the products; or
- (6) Demonstration, installation, servicing or repair operations, except such operations performed in connection with the sale of "your product," provided any demonstration is within the scope of the vendor's duties and authority; or
- (7) Products which, after distribution or sale by you, have been labeled or relabeled--other than identification labels--or used as a container, part or ingredient of any other thing or substance by or for the vendor, except for the dispensing of products in the required amount of dosage; or
- (8) the sole negligence of the vendor for its own acts or omissions or those of its "employees" or anyone else acting on its behalf.

This insurance does not apply to any insured person or organization, from whom you have acquired such products, or any ingredient, part or container, entering into, accompanying or containing such products.

**b. Real Estate Managers**

Any person (other than your "employee") or any organization while acting as your real estate manager.

**c. Temporary Custodians of Your Property**

Any person or organization having proper temporary custody of your property if you die, but only:

- (1) With respect to liability arising out of the maintenance or use of that property; and
- (2) Until your legal representative has been appointed.

**d. Legal Representative If You Die**

Your legal representative if you die, but only with respect to duties as such. That representative will have all your rights and duties under this Coverage Part.

**e. Scientific Advisory Boards or Data Safety Monitoring Committees**

Your "Scientific Advisory Board" or "Data Safety Monitoring Committee" and each member thereof, but only with respect to "bodily injury" or "property damage" arising out of activities performed on your behalf.

**f. Contract or Clinical Research Organizations**

Any "contract or clinical research organization" and each member thereof, conducting "clinical testing," on your behalf, of products manufactured or distributed by you, but only if "clinical testing" follows your testing protocols.

**g. Clinical Research Coordinators, Monitors or Investigators**

Any person or organization conducting "clinical testing" on your behalf, of products designed, developed, manufactured, sold, handled, supplied or distributed by you but only if "clinical testing" follows your testing protocols.

**h. Institutional Review Boards or Medical Ethics Committees**

Any "institutional review board" or "medical ethics committee" and each member thereof, but only with respect to "bodily injury" and "property damage" for "clinical testing" performed on your behalf.

**i. Grantors of Licenses**

Any grantor of a license to you, where required in writing provided the "bodily injury" or "property damage" occurs subsequent to the execution of the contract or agreement, for as long as the licensing agreement between the parties exists.

**j. Independent Engineers or Consultants**

Any engineer or consultant, but only with respect to liability for "bodily injury" or "property damage" caused, in whole or in part, by your acts or omissions or the acts or omissions of those acting on your behalf, in the performance of your ongoing operations performed by you or on your behalf.

With respect to the insurance afforded this additional insured, the following additional exclusion applies:

This insurance does not apply to "bodily injury" or "property damage" arising out of the rendering of or failure to render any professional services by or for you, including:

- (1) The preparing, approving or failing to prepare or approve designs, drawings, specifications, estimates, opinions, plans, reports, surveys, field orders or change orders; or
- (2) Supervisory, inspection, engineering, testing or consulting activities; or

- (3) An error, omission, defect or deficiency in any test performed, or an evaluation, a consultation or advice given by or on behalf of any insured; or
- (4) The reporting or reliance upon any such test, evaluation, consultation or advice; or
- (5) An error, omission, defect or deficiency in experimental data or the insured's interpretation of that data.

**k. Authorized Representative**

Any "authorized representative" appointed or designated by you in writing, who is located within Europe, to act as your liaison with the local competent authorities in accordance with the European Union's Medical Device Directive.

**l. Product Registries**

Any "product registry" engaged or contracted by you to provide post market safety and effectiveness surveillance services for "your products" after they have been cleared or approved for marketing.

**4. Newly Acquired or Formed Organization**

Any organization you newly acquire or form, other than a partnership, joint venture or limited liability company, and over which you maintain financial interest of more than 50% of the voting stock, will qualify as a "named insured" if there is no other similar insurance available to that organization. However:

- a. Coverage under this provision is afforded only until the 90th day after you acquire or form the organization or the end of the policy period, whichever is earlier; and
- b. Coverage does not apply to "bodily injury" or "property damage" that occurred before you acquired or formed the organization, unless otherwise agreed to in writing by us.

No person or organization is an insured with respect to the conduct of any current or past partnership, joint venture or limited liability company that is not shown as a "named insured" in the Declarations.

**SECTION III – LIMITS OF INSURANCE**

**A. LIMITS OF INSURANCE**

1. The Limits of Insurance shown in the Declarations fix the most we will pay regardless of the number of:
  - a. Insureds; or
  - b. "Claims" made or "suits" brought; or
  - c. Persons or organizations making "claims" or bringing "suits".
2. The "Aggregate Limit" is the most we will pay.
3. Subject to Paragraph (2) above, the Each Occurrence Limit is the most we will pay for "damages" because of all "bodily injury" and "property damage" arising out of any one "occurrence".
4. If two or more policies issued to you by us or another insurance company within the Medmarc Insurance Group apply to "bodily injury" or "property damage" caused by the same "occurrence," or to medical expenses for "bodily

injury” to any “test/trial subject” arising out of the same “clinical testing,” then our total liability shall not exceed the highest applicable Each Occurrence Limit and the Medical Payment limit stated in the Declarations of any applicable policy issue to you by an insurance company within the Medmarc Insurance Group.

5. The Limits of Insurance for each of the coverages provided by this policy will apply excess of the “self-insured retention”.
- a. The “self-insured retention”:
    - (1) Will apply only to “occurrences” covered under this policy; and
    - (2) Will apply separately to each “occurrence”; and
    - (3) Will include all amounts under Section III.B – Defense Expenses.
  - b. Your bankruptcy, insolvency or inability to pay the “self-insured retention” will not increase our obligations under this policy.
  - c. In the event there is any other insurance, whether or not collectible, applicable to any “claim” made under this policy, the insured will be responsible for the full “self-insured retention” before the Limits of Insurance under this policy apply.

The Limits of Insurance for each of the coverages provided by this policy apply regardless if the policy period is more than or less than twelve (12) months, starting with the beginning of the policy period shown in the Declarations. If the policy period is extended by endorsement after the initial issuance of the policy, then the additional period will be deemed part of the last preceding period for purposes of determining the Limits of Insurance.

## **B. DEFENSE EXPENSES**

- 1. We will pay, with respect to any “occurrence” or “claim” that we investigate, defend or settle, or any "suit" against an insured that we defend, “defense expenses”. These payments will contribute to the exhaustion of the stated “self-insured retention” amounts but will not reduce the limits of insurance.
- 2. If we defend an insured against a "suit" and an indemnitee of the insured is also named as a party to the "suit", we will defend that indemnitee if all of the following conditions are met:
  - a. The "suit" against the indemnitee seeks “damages” for which the insured has assumed the liability of the indemnitee in a contract or agreement that is an "insured contract"; and
  - b. This insurance applies to such liability assumed by the insured; and
  - c. The obligation to defend, or the cost of the defense of, that indemnitee, has also been assumed by the insured in the same "insured contract"; and
  - d. The allegations in the "suit" and the information we know about the "occurrence" are such that no conflict appears to exist between the interests of the insured and the interests of the indemnitee; and

- e. The indemnitee and the insured ask us to conduct and control the defense of that indemnitee against such "suit" and agree that we can assign the same counsel to defend the insured and the indemnitee; and
  - f. The indemnitee:
    - (1) Agrees in writing to:
      - (a) Cooperate with us in the investigation, “settlement” or defense of the "suit"; and
      - (b) Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the "suit"; and
      - (c) Notify any other insurer whose coverage is available to the indemnitee; and
      - (d) Cooperate with us with respect to coordinating other applicable insurance available to the indemnitee; and
    - (2) Provides us with written authorization to:
      - (a) Obtain records and other information related to the “suit”; and
      - (b) Conduct and control the defense of the indemnitee in such “suit”.
  - g. So long as the above conditions are met, attorneys’ fees incurred by us in the defense of that indemnitee, necessary litigation expenses incurred by us and necessary litigation expenses incurred by the indemnitee at our request will be paid as “defense expenses”. Such payments will be deemed to be “damages” for “bodily injury” and “property damage” and will contribute to the exhaustion of the “self-insured retention” amounts.
  - h. Our obligation to defend an insured’s indemnitee ends when we have used up the applicable limit of insurance in the payment of “judgments,” “settlements,” or any combination thereof; or the conditions set forth above, or the terms of the agreement described herein are no longer met.
- 3. In the event you are entitled by law to select independent counsel to defend you at our expense, the attorney fees and all other litigation expenses we must pay to that counsel are limited to the rates we actually pay to counsel we retain in the ordinary course of our business in the defense of similar “claims” or “suits” in the community where the “claim” arose or is being defended.
  - 4. We have the right to require that such counsel have certain minimum qualifications with respect to their competency including experience in defending “claims” or “suits” similar to the one against you, and to require such counsel, to have errors and omissions insurance coverage. As respects any such counsel, you agree that you and that counsel will timely respond to our requests for information regarding the “claim” or “suit”.
  - 5. You may at anytime, by your signed consent, freely and fully waive your right to select independent counsel.

## SECTION IV – CONDITIONS

### 1. Bankruptcy

Bankruptcy or insolvency of the insured or of the insured's estate will not relieve us of our obligations under this policy.

### 2. Duties In The Event Of Occurrence, Claim Or Suit

#### a. Notice of an Occurrence

You must see to it that we are notified promptly of an "occurrence". To the extent possible, notice should include:

- (1) How, when and where the "occurrence" took place; and
- (2) The names and addresses of any injured persons and witnesses; and
- (3) The nature and location of any injury or damage arising out of the "occurrence".

Notice of an "occurrence" is not notice of a "claim".

#### b. Notice of Claim

If a "claim" is received by any insured, you must:

- (1) Immediately record the specifics of the "claim" and the date received; and
- (2) Notify us in writing within thirty (30) days.

#### c. Assistance and Cooperation of the Insured

You and any other involved insured must:

- (1) Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the "claim" or "suit"; and
- (2) Authorize us to obtain records and other information; and
- (3) Cooperate with us in the investigation or "settlement" of the "claim" or defense against the "suit"; and
- (4) Assist us, upon our request, in the enforcement of any right against any person or organization which may be liable to the insured because of injury or damage to which this insurance may also apply.

#### d. Obligations at the Insured's Own Cost

No insured will, except at that insured's own cost, voluntarily make a payment, assume any obligation, or incur any expense, other than for first aid, without our consent.

#### e. Knowledge of an Occurrence, Claim or Suit

Knowledge of an "occurrence", "claim" or "suit" by an agent, servant or "employee" of yours or any other person shall not in itself constitute knowledge by you, unless an "executive officer", corporate attorney, corporate risk manager or individual charged with responsibility for your insurance administration shall have received notice from said agent, servant, "employee" or any other person.

### f. Failure to Report a Claim

Your failure to report a "claim" to us will not invalidate coverage under this policy if you inadvertently reported the "claim" to another insurer. However, you must report any such "claim" to us promptly once you become aware of such error.

### 3. Defense and Settlement of a Claim or Suit

We will have the right to investigate and conduct negotiations and enter into "settlement" or compromise of any "claim" or "suit" as we deem expedient under this insurance or the applicable "self-insured retention".

### 4. Self-Insured Retention

Your obligations under the "self-insured retention" are:

- a. With regard to any sums you pay toward your self-insured retention, you must provide us with the following:

- (1) copies of any bills paid, and any documents we reasonably require to support payment of such bills, and
- (2) copies of the check/draft in payment of such bills.

You must provide us with such documentation within ninety (90) days of the date such expenses are paid. We will credit toward your "self-insured retention" all reasonable sums paid by you. However, we will not credit toward your "self-insured retention" any payment evidence of which is submitted more than ninety (90) days from the date such payment was issued.

- b. If we make payment on your behalf, we will bill you within thirty (30) days of such payment. All sums billed are due within thirty (30) days. Your failure to remit the amount billed will be grounds for termination of your coverage. Return premiums will be applied to the amount owed. Any return premiums in excess of the amount of money you owe us will be returned to you. In the event additional money remains outstanding, you will be responsible for paying the balance.

### 5. Legal Action Against Us

No person or organization has a right under this Coverage Part:

- a. To join us as a party or otherwise bring us into a "suit" asking for "damages" from an insured; or
- b. To sue us on this policy unless all of its terms have been fully complied with.

A person or organization may sue us to recover on an "agreed settlement" or on a final "judgment" against an insured, but we will not be liable for "damages" that are not payable under the terms of this policy or that are in excess of the applicable limit of insurance.

Any disputes between any insured and us as to whether there is coverage under this policy must be filed in the courts of the United States of America (including its commonwealths, territories and possessions).

## 6. Non-Admitted or Compulsory Insurance

- a. If a "suit" is brought in a part of the "coverage territory" that is outside the United States of America (including its territories and possessions) and we are prevented by law, or otherwise, from defending the insured, the insured will initiate a defense of the "suit". We will reimburse the insured, under Section 3.B - Defense Expenses, for any reasonable and necessary post-tender expenses incurred for the defense of a "suit" seeking "damages" to which this insurance applies, that we would have paid had we been able to exercise our right and duty to defend.

If the insured becomes legally obligated to pay sums because of "damages" to which this insurance applies in a part of the "coverage territory" that is outside the United States of America (including its territories and possessions), and we are prevented by law, or otherwise, from paying such sums on the insured's behalf, we will reimburse the insured for such sums, upon reasonable proof that payment was made by the insured.

- b. All payments or reimbursements we make for "damages" because of "judgments" or "settlements" will be made in U.S. currency at the prevailing exchange rate at the time the insured became legally obligated to pay such sums. All payments or reimbursements we make for expenses under Section 3.B - Defense Expenses will be made in U.S. currency at the prevailing exchange rate at the time the expenses were incurred.
- c. The insured must fully maintain any coverage required by law, regulation or other governmental authority during the policy period, except for reduction of the "Aggregate Limits" due to payments of "claims", "judgments" or "settlements".

The coverage provided by this insurance will not act as a substitute for any compulsory insurance.

Failure to maintain such coverage required by law, regulation or other governmental authority will not invalidate this insurance. However, this insurance will apply as if the required coverage by law, regulation or other governmental authority was in full effect.

## 7. Other Insurance

If other valid and collectible insurance is available to the insured for a loss we cover, our obligations are limited as follows:

### a. Primary Insurance

This insurance is primary except when Paragraph (b) below applies. If this insurance is primary, our obligations are not affected unless any of the other insurance is also primary. Then, we will share with all the other insurance by the method described in Paragraph (c) below.

### b. Excess Insurance

This insurance is excess over, and does not share with, any other insurance, whether primary, excess,

contingent or on any other basis, that is effective prior to the beginning of the policy period shown in the Declarations of this insurance and applies to "bodily injury" or "property damage" included within the "products/completed operations hazard" on other than a claims-made basis, if:

- (1) No "retroactive date" is shown in the Declarations of this insurance; or
- (2) The other insurance has a policy period which inceptioned before and continues after, the "retroactive date" shown in the Declarations of this insurance; or
- (3) the insured's liability to pay "damages" is determined in a "suit" brought outside the United States of America (including its commonwealths, territories and possessions) or that is coverage required by law, regulation or other governmental authority in a part of the "coverage territory" that is outside the United States of America (including its territories and possessions).

When this insurance is excess, we will have no duty to defend the insured against any "suit" if any other insurer has a duty to defend the insured against that "suit". If no other insurer defends, we will undertake to do so, but we will be entitled to the insured's rights against all those other insurers.

When this insurance is excess over other insurance, we will pay only our share of the amount of the loss, if any, that exceeds the sum of:

- (1) The total amount that all such other insurance would pay for the loss in the absence of this insurance; and
- (2) The total of all deductible or self-insured amounts under all the other insurance; and
- (3) The "self-insured retention" of this policy.

We will share the remaining loss, if any, with any other insurance, unless it was bought specifically to apply in excess of the Limits of Insurance shown in the Declarations of this policy.

### c. Method of Sharing

If all of the other insurance permits contribution by equal shares, we will follow this method also. Under this approach each insurer contributes equal amounts until it has paid its applicable limit of insurance or none of the loss remains, whichever comes first.

If any of the other insurance does not permit contribution by equal shares, we will contribute by limits. Under this method, each insurer's share is based on the ratio of its applicable limit of insurance to the total applicable limits of insurance of all insurers.

## 8. Premium Audit

- a. We will compute all premiums for this policy in accordance with our rules and rates.
- b. Premium shown in this policy as advance premium is a deposit premium only. At the close of each policy period we will compute the audited earned premium for that period and send notice to the "first named

insured". If the sum of the advance premiums paid for the policy period is less than the audited earned premium, we will invoice the "first named insured" for the additional premium. The due date for remitting any additional audit premium is the date shown as the due date on the invoice. If the sum of the advance premiums paid for the policy period is greater than the audited earned premium, we will return the excess to the "first named insured".

- c. The "first named insured" must keep records of the information we need for premium computation, and send us copies at such times as we may request.

## 9. Representations

By accepting this policy, you agree:

- a. The statements in the Declarations are accurate and complete; and
- b. Those statements are based upon representations you made to us; and
- c. We have issued this policy in reliance upon your representations; and
- d. Your failure to disclose all hazards relating to the conduct of your business existing as of the inception date of this policy shall not prejudice you with respect to the coverage afforded by this policy provided such failure or omission is not intentional.

## 10. Separation Of Insureds

Except with respect to the Limits of Insurance, and any rights or duties specifically assigned in this Coverage Part to the "first named insured", this insurance applies:

- a. As if each "named insured" were the only insured; and
- b. Separately to each insured against whom "claim" is made or "suit" is brought.

## 11. Your Right To Claim And Occurrence Information

Upon request, we will provide the "first named insured" shown in the Declarations the following information relating to this and any preceding products/completed operations liability claims-made policy we have issued to you during the previous five (5) years:

- a. A list or other record of each "occurrence", not previously reported to any other insurer, of which we were notified in accordance with Paragraph (2.a) of Section IV - Duties In The Event Of Occurrence, Claim Or Suit Condition in Products/Completed Operations Liability Conditions. We will include the date and brief description of the "occurrence" if that information was in the notice we received.
- b. A summary by policy year, of payments made and amounts reserved stated separately, under the "Aggregate Limit".

Amounts reserved are based on our judgment. They are subject to change and should not be regarded as ultimate settlement values.

You must not disclose this information to any claimant or any claimant's representative without our consent.

If we cancel or elect not to renew this policy, we will provide the information listed in this condition no later than thirty (30) days before the date of policy cancellation or termination.

In other circumstances, we will provide this information only if we receive a written request from the "first named insured" within sixty (60) days after the end of the policy period. In this case, we will provide this information within forty-five (45) days of receipt of the request.

We compile "claim" and "occurrence" information for our own business purposes and exercise reasonable care in doing so. In providing this information to the "first named insured", we make no representations or warranties to insureds, insurers, or others to whom this information is furnished by or on behalf of any insured. Cancellation or nonrenewal will be effective even if we inadvertently provide inaccurate information.

## 12. Transfer Of Rights Of Recovery Against Others To Us

If the insured has rights to recover all or part of any payment we have made under this policy, those rights are transferred to us. The insured must do nothing after loss to impair them. At our request, the insured will bring "suit" or transfer those rights to us and help us enforce them.

## 13. Transfer of Control of Defense

a. If we conclude that, based on "occurrences", "claims", or "suits" which have been reported to us and to which this insurance may apply is likely to be used up in the payment of "judgments" or "settlements", we will notify the "first named insured", in writing, to that effect.

b. When a limit of insurance has actually been used up in the payment of "judgments" or "settlements":

(1) We will notify the "first named insured" in writing promptly that:

- (a) Such a limit has actually been used up; and
- (b) Our duty to defend "suits" seeking damages subject to that limit has also ended.

(2) We will initiate, and cooperate in, the transfer of control, to any appropriate insured of all "claims" and "suits" seeking "damages" which are subject to that limit and are reported to us before that limit is used up, and that the insured must cooperate in the transfer of control of said "claims" and "suits".

We agree to take such steps, as we deem appropriate, to avoid a default in or continue the defense of, such "suits" until such transfer is completed, provided the appropriate insured is cooperating in completing such transfer.

We will take no action whatsoever with respect to any "claims" or "suit" seeking damages that would have been subject to that limit, had it not been used up, if the "claim" or "suit" is reported to us after that limit of insurance has been used up.

(3) The "first named insured", and any other insured involved in a "suit" seeking damages subject to

that limit, must arrange for the defense of such “suit” within such time period as agreed to between the appropriate insured and us. Absent any such agreement, arrangements for the defense of such “suit” must be made promptly.

- c. The “first named insured” will reimburse us for expenses we incur in taking those steps we deem appropriate in accordance with Paragraph (b.2) above. The duty of the “first named insured” to reimburse us will begin on:
  - (1) The date on which the applicable limit of insurance is used up if we sent notice in accordance with Paragraph (a) above; or
  - (2) The date on which we sent notice in accordance with Paragraph (b.1) above, if we did not send notice in accordance with Paragraph (a) above.

#### 14. When We Do Not Renew

If we decide not to renew this policy, we will mail or deliver to the “first named insured” shown in the Declarations and to the producer of record, advance written notice of the nonrenewal, stating the reason for nonrenewal, not less than sixty (60) days before the expiration date.

If notice is mailed, proof of mailing will be sufficient proof of notice.

#### SECTION V – EXTENDED DISCOVERY PERIODS

- 1. We will provide one or more Extended Discovery Periods, as described below, if:
  - a. This Coverage Part is canceled or not renewed for any reason, except for non-payment of premium; or
  - b. We renew or replace this Coverage Part with other insurance that:
    - (1) Has a “retroactive date” later than the date shown in the Declarations of this Coverage Part; or
    - (2) Does not apply to “bodily injury” or “property damage” on a claims-made basis.
- 2. Extended Discovery Periods do not extend the policy period or change the scope of coverage provided. They apply only to “claims” for “bodily injury” or “property damage” that occurs before the end of the policy period but not before the “retroactive date”, if any, shown in the Declarations.

Once in effect, Extended Discovery Periods may not be cancelled.

A “claim” first made during the Basic Extended Discovery Period will be deemed to have been made on the last day of the policy.

Extended Discovery Periods do not reinstate or increase the Limits of Insurance.

- 3. A Basic Extended Discovery Period is automatically provided without additional charge. This period starts with the end of the policy period and lasts for:
  - a. Six (6) years, with respect to “claims” because of “bodily injury” and “property damage” arising out of an “occurrence” reported to us, not later than ninety

(90) days after the end of the policy period, in accordance with Paragraph (2.a.) of Section IV – Duties In The Event Of Occurrence, Claim Or Suit Condition; and

- b. Ninety (90) days, with respect to “claims” arising from “occurrences” not previously reported to us.

The Basic Extended Discovery Period does not apply to “claims” that are covered under any subsequent insurance you purchase, or that would be covered but for the exhaustion of the amount of insurance applicable to such “claims”.

- 4. An optional Supplemental Extended Discovery Period of up to six (6) years duration is available, with respect to “claims” arising from “occurrences” not previously reported to us, but only by an endorsement and for an extra charge. This supplemental period starts when the Basic Extended Discovery Period, set forth in Paragraph (3.b) above ends.

You must give us a written request for the endorsement within ninety (90) days after the end of the policy period. The Supplemental Extended Discovery Period will not go into effect unless you pay the additional premium promptly when due.

We will determine the actual premium for the Supplemental Extended Discovery Period Endorsement in accordance with our rules and rates. In doing so, we may take into account the following:

- a. The exposures or hazards insured against; and
- b. Previous types and amounts of insurance; and
- c. Limits of Insurance available under this Coverage Part for future payment of “damages”; and
- d. Other related factors.

The additional premium will not exceed 200% of the annual premium for the Coverage Part and is fully earned when the Supplemental Extended Discovery endorsement takes effect.

This endorsement shall set forth the terms, not inconsistent with this Section, applicable to the Supplemental Extended Discovery Period, including a provision to the effect that the insurance afforded for “claims” first received during such period is excess over any valid and collectible insurance available under policies in force after the Supplemental Extended Discovery Period starts.

#### SECTION VI – DEFINITIONS

- 1. “**Advisory Memorandum**” means any communication issued by you to inform health professionals or other appropriate persons or firms of a risk of harm from a product in commercial use.
- 2. “**Aggregate Limit**” means the most we will pay for sum of all damages under Section 1.A – Products/Completed Operations Bodily Injury and Property Damage Liability and Section 1.B – Medical Expenses – Clinical Testing.
- 3. “**Authorized Representative**” means anyone who will accept responsibility for a “medical device”, in-vitro diagnostic, or “cosmetic” product imported into the European Union in the event of an accident (incident/near incident). In addition, the Authorized Representative is

legally obliged to operate a vigilance system on behalf of the manufacturer in the event of a batch recall or other quality problem.

4. **“Agreed Settlement”** means a settlement and release of liability approved by us, the insured and the claimant or the claimant's legal representative.
5. **“Biologic”** or **“Biological Product”** means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine, or derivative of arsphenamine, or any other trivalent organic arsenic compound), applicable to the prevention, treatment or cure of a disease or condition of human beings.
6. **“Bodily injury”** means bodily injury, sickness or disease sustained by a person, including death resulting from any of these at any time. “Bodily injury” also means mental anguish, mental injury, disability, shock, fright or humiliation sustained by that person or by any relative of that person as a result of such “bodily injury”, sickness or disease.
7. **“Claim”** means a:
  - a. demand received by any insured for money or services; or
  - b. notice received by any “insured” resulting from an “occurrence” that may result in a demand for money or services; or
  - c. service of “suit”, or notice received of the initiation of arbitration or other proceedings against you.
8. **“Clinical testing”** means any pre-clinical evaluation (bench and animal testing) or clinical trial or healthy volunteer study approved by a competent regulatory authority, carried out on humans with the intention of verifying the safety, efficacy, bioavailability or other properties of a “medical device,” “drug,” “biologic,” or other diagnostic or therapeutic product or process including “compassionate use”, or “expanded access program” or “named patient program”.
9. **“Compassionate use”** means the emergency use of a “medical device”, “drug” or “biological product”, other than the diagnostic or therapeutic product that is the subject of “clinical testing,” during a clinical trial on a human” test subject” in need of medical intervention because of a life threatening medical condition, if:
  - a. such human “test/trial subject” is incapable of giving “informed consent”, either directly or through an authorized legal representative; and
  - b. no generally accepted treatment for the life threatening medical condition is available; and
  - c. there is insufficient time to obtain government regulatory approval for such use; and
  - d. such use is in strict compliance with all applicable laws, rules and regulations.
10. **“Contract or clinical research organization”** means a person or an organization who is contracted to design, manage, monitor or analyze pre-clinical testing and “clinical testing” for a “sponsor”. The duties can include, but may not be limited to, recruitment and enrollment of clinical “investigators”, investigational sites and “test/trial subjects”; design and general medical supervision of new study protocols (including the informed consent documents) for treatment of new indications; collection and evaluation of clinical data and preparation of regulatory filings with/for government agencies.
11. **“Cosmetic”** means an article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.
12. **“Coverage territory”** means anywhere in the world, including the regions of space beyond Earth and its atmosphere, with the exception of any country or jurisdiction which is subject to trade or other economic sanction or embargo by the United States of America--- Department of Commerce’s Bureau of Industry and Security and/or Department of Treasury’s Office of Foreign Assets Control.
13. **“Damages”** means money whose payment is ordered by a court or an administrative tribunal to a plaintiff, excluding any (1) fines, (2) penalties, (3) taxes, or (4) the return of or restitution of fees, profits or charges for services rendered.

“Damages” because of “bodily injury” includes payment for care, loss of services or death resulting at any time from the “bodily injury”.
14. **“Data Safety Monitoring Committee”** means an independent group of experts external to a study established by the “sponsor” to assess at intervals the progress of “clinical testing,” the safety data, and the critical efficacy endpoints, and to recommend to the “sponsor” whether to continue, modify, or stop a trial.
15. **“Defense expenses”** means the reasonable and necessary costs and expenses of investigation, adjustment, appraisal, defense and appeal paid or incurred by the insured or the company, in respect of the “settlement”, litigation or arbitration of a covered “claim” or “suit” under this policy. “Defense expenses” also include:
  - a. All expenses we incur; and
  - b. The premium for any bonds to release attachments, but only for bond amounts within the applicable limit of insurance. We do not have to obtain or furnish these bonds; and
  - c. All reasonable expenses incurred by the insured at our request to assist us in the investigation or defense of the “claim” or “suit”, including actual loss of earnings up to \$1000 a day because of time off from work, but not including salaries of our employees or the insured’s “employees”; and
  - d. All court costs taxed against the insured in the “suit”. However, these payments do not include attorneys’ fees and attorneys’ expenses taxed against the insured; and
  - e. Prejudgment interest awarded against the insured on that part of the “judgment” we pay. If we make an offer to pay the applicable limit of insurance, we will not pay any prejudgment interest accruing after the offer; and

- f. All interest on the full amount of any “judgment” that accrues after entry of the “judgment” and before we have paid, offered to pay, or deposited in court the part of the “judgment” that is within the applicable limit of insurance.
16. **“Dietary supplement”** means a product that is intended to supplement the diet and bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical (excluding tobacco), an amino acid, a dietary substance for use by people to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any of the above; is intended for ingestion in pill, capsule, tablet or liquid form; is not represented for use as a conventional food or as the sole item of a meal or diet; and is labeled as a “dietary supplement”.
17. **“Director”** means a member of a group of persons chosen to control or govern the affairs of a corporation or company. The whole of the directors collectively forms the board of directors.
18. **“Drug”** means any of the following products:
- a substance recognized in an official “pharmacopoeia” or “formulary”; or
  - a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or
  - a substance other than food intended to affect the structure or function of the body; or
  - a substance intended for use as an ingredient of a medicine but not a device or a component, part, or accessory of a device.
19. **“Employee”** means a person employed by you under an express or implied contract and the employer has the right to control the work performed. “Employee” includes a “leased worker” but not a “temporary worker”.
20. **“Expanded Access Program” or “Named Patient Program”** means any program that allows patients who do not qualify for clinical trials to access new medications for treatment purposes before those medications have been licensed for marketing in their country, if no suitable alternative is available or exists.
21. **“Executive officer”** means a person holding any of the officer positions created by your charter, constitution, by-laws or any other similar governing document.
22. **“First Named Insured”** means the person or entity listed first on the policy Declarations page as an insured. This primary or first named insured is granted certain rights and responsibilities that do not apply to the policy's other “named insureds”, such as premium payment obligations, notice of loss requirements, and the receipt of cancellation notice and return premiums.
23. **“Formulary”** means a manual containing a list of medicines that are approved for prescription throughout a country. It includes key information on the composition, description, selection, prescribing, dispensing and administration of medicines.
24. **“Impaired property”** means tangible property, other than “your product” or “your work”, that cannot be used or is less useful because it incorporates “your product” or “your work” that is known or thought to be defective, deficient, inadequate or dangerous if such property can be restored to use by the repair, replacement, adjustment or removal of “your product” or “your work”.
25. **“Informed consent”** means consent by a “test/trial subject” to a surgical or medical procedure, or participation in “clinical testing,” after being informed of the relevant medical facts and the risks involved. This process includes subject recruitment materials, verbal instructions, written materials, question and answer sessions and agreement documented by signature.
26. **“Institutional Review Board”** means any board, committee, or other group, and each of its members thereof, formally designated by an institution, to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving subjects and established to protect the rights and welfare of human subjects in such investigations.
27. **“Insured contract”** means any written contract or written agreement relating to that part of the conduct of your business as involves the manufacturing, selling or distributing of “your product,” and under which you agree to indemnify another person or organization for tort liability. “Tort liability” means liability for “bodily injury” or “property damage” incurred by such person or organization and that would otherwise be imposed by law upon such person or organization in the absence of such written contract or written agreement. This paragraph does not apply to any agreement to indemnify a person or organization for the sole negligence of such person or organization.
- The terms “written contract” and “written agreement” include an oral contract and oral agreement, provided such contract or agreement is reduced to writing and signed by you and such person or organization within 90 days after such contract or agreement has been orally entered into.
28. **“Investigator”** means an individual, or the responsible leader of a team of individuals, under whose direction a test product is administered or dispensed to, or used in connection with, a “test/trial subject”.
29. **“In-vitro diagnostic”** means any reagents, instruments, and systems intended for use in diagnosis of disease or other condition, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or the condition resulting from a disease. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.
30. **“Judgment”** means the official decision of a court or administrative tribunal that finally adjudicates the respective rights and claims of the parties to a “suit”.
31. **“Leased worker”** means a person leased to you by a labor leasing firm under an agreement between you and the labor leasing firm, to perform duties related to the conduct of your business. “Leased worker” does not include a “temporary worker”.

**32. “Medical device”** means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, and which is:

- a. recognized in an official national “formulary” or “pharmacopoeia”, or any supplement to them; or
- b. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or animals; or
- c. intended to affect the structure or any function of the body of humans or animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of humans or animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

**33. “Medical Ethics Committee”** means any independent and properly constituted competent body and each member thereof whose responsibility is to ensure that the safety, well-being and human rights of the subjects who are participating in a clinical investigation are protected.

**34. “Named Insured”** means any entity or individual named in the Declarations.

**35. “Nutraceutical”** means a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease.

**36. “Occurrence”** means an accident, including continuous or repeated exposure to substantially the same general harmful conditions.

As regards, “products/completed operations hazard” and with respect to “bodily injury” or “property damage,” the date of “bodily injury” or “property damage is deemed to be the earliest of the date:

- a. a professional medical opinion is rendered which provides a basis for a claim or “suit” under the coverage provided; or
- b. medical expenses are incurred as a result of injury or damage; or
- c. death occurs from exposure to “your product”; or
- d. of removal or replacement of an implantable product; or
- e. of the “advisory memorandum” initiated by you; or
- f. of exposure.

**37. “Pharmacopoeia”** means a book published by the authority of a government or a medical or pharmaceutical society that contains a description of chemicals, drugs, and other substances and how they are to be used.

**38. “Products/completed operations hazard”:**

- a. includes all “bodily injury” and “property damage” occurring away from premises you own or rent arising out of “your work” or “your product” including products that are still in your physical possession that are being used for active demonstration or trial purposes, but no other products in your care, custody, or control.

- b. includes “bodily injury” and “property damage” arising out of products being rented, leased, loaned, or held for sale, demonstration or trial purposes by you.

- c. includes “bodily injury” and “property damage” arising out of “clinical testing” of “your product”.

- d. does not include “your work” that has not yet been completed or abandoned. However, “your work” will be deemed completed at the earliest of the following times:

- (1) When all of the work called for in your contract has been completed; or
- (2) When all of the work to be done at the job site has been completed if your contract calls for work at more than one job site; or
- (3) When that part of the work done at a job site has been put to its intended use by any person or organization other than another contractor or subcontractor working on the same project; or
- (4) Work that may need service, maintenance, correction, repair or replacement, but which is otherwise complete, will be treated as completed.

**39. “Product Registries”** means any independent or government-organized systems that use observational study methods to collect uniform data (clinical and other) to evaluate the specified outcomes, effectiveness, comparative clinical effectiveness, and appropriateness of “medical devices”, pharmaceuticals, or “biologics” for human populations defined by a particular disease, condition, or exposure, and that serve predetermined scientific, clinical, or policy purpose(s). Registry databases are the files derived from the registries.

**40. “Property damage”** means:

- a. Physical injury to tangible property, including all resulting loss of use of that property. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or
- b. Loss of use of tangible property that is not physically injured. All such loss of use shall be deemed to occur at the time of the “occurrence” that caused it.

For the purposes of this insurance, electronic data is not tangible property.

As used in this definition, electronic data means information, facts or programs stored as or on, created or used on, or transmitted to or from, computer software, including systems and applications software, hard or floppy disks, CD-ROMS, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

**41. “Retroactive date”** means the date specified as such in the Declarations.

**42. “Scientific Advisory Board”** means a body composed of medical specialists and each thereof, established to (1) review any new “medical device,” “drug,” “biologic,” or other diagnostic or therapeutic product or processes that have been presented to you or (2) provide advice on scientific or technological developments that affect the company.

- 43. “Self-insured retention”** means the amount that you or any insured pays: (1) pursuant to “judgments” or “settlements”, as “damages” because of “bodily injury” or “property damage,” or (2) “defense expenses”, or (3) any combination of (1) and (2), with respect to each “occurrence” to which the insurance applies.
- 44. “Settlement”** means the resolution of a “claim” or “suit”. A “judgment” is not a “settlement”.
- 45. “Soap”** means a product whose bulk of nonvolatile matter consists of an alkali salt of fatty acids and the product’s detergent properties are due to the alkali-fatty acid compounds, and the product is labeled, sold and represented solely as “soap”.
- 46. “Sponsor”** means a person or organization who initiates or conducts, “clinical testing” or laboratory research and assumes responsibility for its administration and/or financing.
- 47. “Suit”** means a civil proceeding in which “damages” because of “bodily injury” or “property damage” to which this insurance applies are alleged. “Suit” includes:
- a. An arbitration proceeding in which such “damages” are claimed and to which the insured must submit or does submit with our consent; or
  - b. Any other alternative dispute resolution proceeding in which such “damages” are claimed and to which the insured submits with our consent.
- 48. “Temporary worker”** means a person who is furnished to you to substitute for a permanent “employee” on leave or to meet seasonal or short-term workload conditions.
- 49. “Test/trial subject”** means an individual who is a participant in “clinical testing,” either as a recipient of the diagnostic or therapeutic product(s) or as a control.
- 50. “Volunteer worker”** means a person who:
- a. Is not your “employee”; and
  - b. Donates his or her work; and
  - c. Acts at the direction of and within the scope of duties determined by you; and
  - d. Is not paid a fee, salary or other compensation by you or anyone else for their work performed for you.
- 51. “Warranty”** means an express or implied promise that something in furtherance of a contract is guaranteed by one of the contracting parties.
- 52. “Your product”:**
- a. **Means:**
    - (1) Any “medical device,” “drug,” “biologic,” “in-vitro diagnostic”, “cosmetic”, “soap”, “nutraceutical”, “dietary supplement”, other diagnostic or therapeutic products or processes other than real property, or, unless specifically excluded, any other product(s) other than real property designed, developed, manufactured, sold, handled, or distributed by:
      - (a) You; or
      - (b) Others trading under your name; or
    - (c) A person or organization whose business or assets you have acquired; and
    - (2) Containers (other than vehicles), materials, technology, parts or equipment furnished in connection with such goods or products; and
    - (3) Goods, products or equipment leased, loaned, or held for sale, demonstration or trial purposes.
  - b. **Includes:**
    - (1) “Warranties” or representations made at any time with respect to the fitness, quality, durability, performance or use of “your product”; and
    - (2) The providing of or failure to provide consultation or educational services, training, advice, warnings or instructions in the use and care of any products.
- 53. “Your work”:**
- a. **Means:**
    - (1) Work or operations performed by you or on your behalf; and
    - (2) Technology, materials, parts or equipment furnished in connection with such work or operations.
  - b. **Includes:**
    - (1) “Warranties” or representations made at any time with respect to the fitness, quality, durability, performance or use of “your work”; and
    - (2) The providing of or failure to provide consultation or educational services, training, advice, warnings or instructions in “your work”.



SERFF Tracking Number: MMCI-125888362 State: Arkansas  
Filing Company: Medmarc Casualty Insurance Company State Tracking Number: EFT \$50  
Company Tracking Number: MCIC-AR-111008  
TOI: 18.0 Product Liability Sub-TOI: 18.1000 Product Liab - Claims Made Only  
Product Name: Defense Outside  
Project Name/Number: /

## Supporting Document Schedules

**Satisfied -Name:** Uniform Transmittal Document-  
Property & Casualty

**Review Status:** Approved 12/09/2008

**Comments:**

**Attachment:**

(AR) transmittal for CG38C.pdf

Property & Casualty Transmittal Document



**Reserved for Insurance Dept. Use Only**

**Insurance Department Use Only**

a. Date the filing is received:

b. Analyst:

c. Disposition:

d. Date of disposition of the filing:

e. Effective date of filing:

New Business	
Renewal Business	

f. State Filing #:

g. SERFF Filing #:

h. Subject Codes

<b>3. Group Name</b>					<b>Group NAIC #</b>
<b>4. Company Name(s)</b>	<b>Domicile</b>	<b>NAIC #</b>	<b>FEIN #</b>	<b>State #</b>	
Medmarc Casualty Insurance Company	VT	22241	59-0615164		

**5. Company Tracking Number** MCIC-AR-111108F

Contact Info of Filer(s) or Corporate Officer(s) [include toll-free number]

6. Name and address	Title	Telephone #s	FAX #	e-mail
Nicole Calhoun	Regulatory Specialist	800-356-6886	703-652-1389	ncalhoun@medmarc.com

7. Signature of authorized filer

8. Please print name of authorized filer Nicole Calhoun

Filing information (see General Instructions for descriptions of these fields)

9. Type of Insurance (TOI)	18.0 Product Liability
10. Sub-Type of Insurance (Sub-TOI)	18.1000 Product Liab-Claims Made Only
11. State Specific Product code(s)(if applicable)[See State Specific Requirements]	
12. Company Program Title (Marketing title)	Medical Device Technology - Life Sciences Program
13. Filing Type	<input type="checkbox"/> Rate/Loss Cost <input type="checkbox"/> Rules <input type="checkbox"/> Rates/Rules <input checked="" type="checkbox"/> Forms <input type="checkbox"/> Combination Rates/Rules/Forms <input type="checkbox"/> Withdrawal <input type="checkbox"/> Other (give description)
14. Effective Date(s) Requested	New: 12/11/2008 Renewal: 12/11/2008
15. Reference Filing?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
16. Reference Organization (if applicable)	
17. Reference Organization # & Title	
18. Company's Date of Filing	11/11/2008
19. Status of filing in domicile	<input type="checkbox"/> Not Filed <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Authorized <input type="checkbox"/> Disapproved

## Property & Casualty Transmittal Document—

20. This filing transmittal is part of Company Tracking # MCIC-AR-111108F

21. Filing Description [This area can be used in lieu of a cover letter or filing memorandum and is free-form text]

Medmarc Casualty Insurance Company ("Medmarc Casualty" or the "Company") hereby submits the attached filing for use on all new and renewal business effective December 11, 2008 or upon your approval if sooner. The forms being filed are as follows:

CG 38 C 09 08, an independent products completed operations liability coverage form with defense costs outside from policy limits. This policy form replaces previously approved coverage form CG 38 C 06 96. Form CG 38 C 09 08 will be used for the Company's existing Medical Device Technology - Life Sciences Program.

The use of these forms does not result in an increase or decrease in rates. This filing is being made simultaneously over the next month in multiple states, including Vermont, our domicile state.

For informational purposes, please note that Medmarc Casualty Insurance Company is a specialty casualty insurance insurer and underwrites products liability for life sciences technology companies. Its parent company, Medmarc Mutual Insurance Company, was founded in 1979 by the medical device industry. Medmarc Casualty's new coverage form was developed as a part of an on-going effort to continually review and improve its insurance contract so as to accomplish its mission to serve the industry that founded the program.

[View Complete Filing Description](#)

22. Filing Fees (Filer must provide check # and fee amount if applicable)  
[If a state requires you to show how you calculated your filing fees, place that calculation below]

Check #: SERFF EFT  
Amount: 50.00

State retaliatory form filing fee \$50 x form filing = \$50

Refer to each state's checklist for additional state specific requirements or instructions on calculating fees.

\*\*\*Refer to the each state's checklist for additional state specific requirements (i.e. # of additional copies required, other state specific forms, etc.)

PC TD-1 pg 2 of 2

**FORM FILING SCHEDULE**

(This form must be provided ONLY when making a filing that includes forms)  
 (Do not refer to the body of the filing for the forms listing, unless allowed by state.)

<b>1. This filing transmittal is part of Company Tracking #</b>		MCIC-AR-111108F			
<b>2. This filing corresponds to rate/rule filing number</b> (Company tracking number of rate/rule filing, if applicable)					
<b>3.</b>	<b>Form Name /Description/Synopsis</b>	<b>Form # Include edition date</b>	<b>Replacement Or withdrawn?</b>	<b>If replacement, give form # it replaces</b>	<b>Previous state filing number, if required by state</b>
01	Products Completed Operations Liability Coverage Form	CG 38 C 09 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	CG 38 C 06 96	
02	Amendment of Coverage Territory - Exclusion of Foreign Countries	045 01 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	045 06 96	
03	Batch Clause	092 01 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	092 11 96	
04	Composite Rate	095 03 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	095 06 96	
05	Additional Insured - Controlling Interest	157 03 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	157 09 96	
06	Additional Insured - Designated Person or Organization	163 01 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	163 10 96	
07	Additional Insured - Primary Coverage	168 03 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	168 11 96	
08	Exclusion - Designated Person or Organization	180 01 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	180 11 96	
09	Exclusion - Aircraft Products	190 01 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	190 11 96	
10	Extended Discovery Period - Unlimited and Replenishment of Limits	243 09 08	<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	243 11 96	

PC FFS-1

## RATE/RULE FILING SCHEDULE

(This form must be provided ONLY when making a filing that includes rate-related items such as Rate; Rule; Rate & Rule; Reference; Loss Cost; Loss Cost & Rule or Rate, etc.)

(Do not refer to the body of the filing for the component/exhibit listing, unless allowed by state.)

<b>1.</b>	<b>This filing transmittal is part of Company Tracking #</b>	
<b>2.</b>	<b>This filing corresponds to form filing number</b> (Company tracking number of form filing, if applicable)	

Rate Increase     
  Rate Decrease     
  Rate Neutral (0%)

<b>3.</b>	<b>Filing Method (Prior Approval, File &amp; Use, Flex Band, etc.)</b>	
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4a. Rate Change by Company (As Proposed)							
Company Name	Overall % Indicated Change (when applicable)	Overall % Rate Impact	Written premium change for this program	# of policyholders affected for this program	Written premium for this program	Maximum % Change (where required)	Minimum % Change (where required)

4b. Rate Change by Company (As Accepted) For State Use Only							
Company Name	Overall % Indicated Change (when applicable)	Overall % Rate Impact	Written premium change for this program	# of policyholders affected for this program	Written premium for this program	Maximum % Change	Minimum % Change

5. Overall Rate Information (Complete for Multiple Company Filings only)			
		COMPANY USE	STATE USE
5a	Overall percentage rate indication (when applicable)		
5b	Overall percentage rate impact for this filing		
5c	Effect of Rate Filing – Written premium change for this program		
5d	Effect of Rate Filing – Number of policyholders affected		

<b>6.</b>	Overall percentage of last rate revision	
<b>7.</b>	Effective Date of last rate revision	
<b>8.</b>	Filing Method of Last filing (Prior Approval, File & Use, Flex Band, etc.)	

9.	Rule # or Page # Submitted for Review	Replacement or withdrawn?	Previous state filing number, if required by state
01		<input type="checkbox"/> New <input type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	
02		<input type="checkbox"/> New <input type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	
03		<input type="checkbox"/> New <input type="checkbox"/> Replacement <input type="checkbox"/> Withdrawn	