



## Life Sciences Liability

**Insured Name**

TDM USA INC.  
9183 FLINT WAY  
PARK CITY, UT 84098-5853

**Policy Effective Date**

08/01/2019

**Producer Name**

RISK PLACEMENT SERVICES INC  
1975 RESEARCH PKWY STE 230  
COLORADO SPRINGS, CO 80920-1026

**Claim Services**

To file a claim contact us at:

Email:	HPReports@CNA.com
Fax#:	800-446-8632
Mailing Address:	Life Sciences CNA Claims Reporting P.O. Box 8317 Chicago, IL 60680-8317

**Risk Control Services**

To learn more about our award winning Risk Control Services and how to improve your bottom line, call 866-262-0540 or email us at [riskcontrolwebinfo@cna.com](mailto:riskcontrolwebinfo@cna.com).



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POLICY DECLARATIONS

**NOTICE: THIS IS A CLAIMS MADE POLICY. THE COVERAGE AFFORDED BY THIS POLICY IS LIMITED TO CLAIMS FIRST MADE AGAINST THE INSURED DURING THE POLICY PERIOD AND REPORTED TO THE COMPANY IN ACCORDANCE WITH THE COMMON CONDITIONS, THE SECTION ENTITLED DUTIES IF THERE IS A CLAIM. DEFENSE COSTS COVERED BY THIS POLICY ARE INCLUDED WITHIN THE LIMIT OF LIABILITY. THE INSURED SHOULD READ THE ENTIRE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES AND WHAT IS AND WHAT IS NOT COVERED.**

Named Insured and Mailing Address

**Named Insured**

TDM USA INC.

**Mailing Address**

9183 FLINT WAY  
PARK CITY, UT 84098-5853

Policy Information

**Policy Number:** ADT 6071846730

**Renewal of:** ADT 6071846730

**Policy Issued by**

Continental Casualty  
151 N Franklin St  
Chicago, IL 60606

Producer Information

**Producer**

RISK PLACEMENT SERVICES INC  
1975 RESEARCH PKWY STE 230  
COLORADO SPRINGS, CO 80920-1026

**Producer Processing Code:** 978-039981

Policy Period

**08/01/2019 to 08/01/2020** at 12:01 a.m. Standard Time at the **First Named Insured's** mailing address shown above.

Forms and Endorsements Attached to this Policy

**See SCHEDULE OF FORMS AND ENDORSEMENTS**

Limits of Liability and Deductibles

	Limits of Liability		Deductible	
	Each Claim	In the Aggregate	Each Claim	In the Aggregate
<b>Policy Aggregate</b>	N/A	\$3,000,000	N/A	\$100,000
<b>Products-Work Hazard Coverage</b>	\$1,000,000	\$3,000,000	\$25,000	\$100,000
<b>Mitigation Expenses Sublimit</b>	\$250,000	\$250,000	N/A	N/A

**To Report a Loss**

- Dial toll-free #1 (844)777-8323 or visit our
- Website: <https://my.rpsins.com/claimsfnol>
- Contact Insurer directly (see policy section)

Form No: CNA73165XX (05-2015)  
Policy Declarations Page: 1 of 2  
Underwriting Company: Continental Casualty, 151 N Franklin St, Chicago, IL 60606

Policy No: ADT 6071846730  
Policy Effective Date: 08/01/2019  
Policy Page: 3 of 44



Limits of Liability and Deductibles				
	Limits of Liability		Deductible	
	Each Person	In the Aggregate	Each Person	In the Aggregate
<b>Class 1 Product Recall Expenses</b>	N/A	\$25,000	N/A	\$10,000
<b>Medical Expenses</b>	\$1,000	\$5,000	N/A	N/A

Premium		
	Revenue	Number of Test Subjects
<b>Premium Basis</b>	\$1,000,000	0
<b>Minimum Earned Premium</b>	25% of the Total Premium	
<b>Total Premium</b>	\$5,001.00	
<b>Total Amount Payable</b>	\$5,001.00	

Retroactive Date	
Retroactive Date 12:01 a.m. Standard Time at the <b>First Named Insured's</b> mailing address shown above.	
<b>Products-Work Hazard Coverage Retroactive Date</b>	08/01/2018

Coinsurance	
<b>Mitigation Expenses</b>	20%
<b>Product Recall Expenses</b>	10%

Notification Information	
All notices to the insurer required under the policy	
<b>Email Address:</b>	HPReports@CNA.com
<b>Fax #:</b>	800-446-8632
<b>Mailing Address:</b>	Life Sciences CNA Claims Reporting P.O. Box 8317 Chicago, IL 60680-8317

These Declarations, along with the completed and signed **Application**, the policy, and any written endorsements attached shall constitute the contract between the **Insureds** and the Insurer.



SCHEDULE OF FORMS AND ENDORSEMENTS

Endorsement Number	Form Name	Form Number	Form Edition Date
1	EXCLUSION OF CERTIFIED ACTS OF TERRORISM ENDORSEMENT	CNA71826XX	01-2015
2	INTRA-ARTICULAR USE EXCLUSION ENDORSEMENT	CNA73195XX	05-2015
3	SPECIFIED PRODUCTS EXCLUSION ENDORSEMENT	CNA73217XX	05-2015
4	CANCELLATION AND NON-RENEWAL ENDORSEMENT - UTAH	CNA73247UT	05-2015
5	BROAD MESH AND SIMILAR PRODUCTS EXCLUSION ENDORSEMENT	CNA76299XX	05-2015
6	SPECIFIED PRODUCTS EXCLUSION ENDORSEMENT 5 METAL ON METAL IMPLANT DEVICES	CNA78635XX	05-2015
	LIFE SCIENCES LIABILITY POLICY POLICY DECLARATIONS	CNA73165XX	05-2015
	LIFE SCIENCES LIABILITY POLICY GLOSSARY OF DEFINED TERMS	CNA73250XX	05-2015
	LIFE SCIENCES LIABILITY POLICY COMMON CONDITIONS	CNA73164XX	05-2015
	LIFE SCIENCES LIABILITY POLICY PRODUCTS-WORK HAZARD LIABILITY COVERAGE PART	CNA73251XX	05-2015



LIFE SCIENCES LIABILITY POLICY COMMON CONDITIONS

**NOTICE: THIS IS A CLAIMS MADE POLICY. THE COVERAGE AFFORDED BY THIS POLICY IS LIMITED TO CLAIMS FIRST MADE AGAINST THE INSURED DURING THE POLICY PERIOD AND REPORTED TO THE COMPANY IN ACCORDANCE WITH THE COMMON CONDITIONS, THE SECTION ENTITLED DUTIES IF THERE IS A CLAIM. DEFENSE COSTS COVERED BY THIS POLICY ARE INCLUDED WITHIN THE LIMIT OF LIABILITY. THE INSURED SHOULD READ THE ENTIRE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES AND WHAT IS AND WHAT IS NOT COVERED.**

The "Insurer" means the insurer named in the Declarations. Other key words and phrases that appear in **bold** type have special meanings. Refer to the **GLOSSARY OF DEFINED TERMS**. All headings are also in bold whether or not they contain defined terms. See the section entitled HEADINGS below.

In consideration of the payment of the premium, and in reliance upon the statements in the **application**, it is agreed as follows:

**ACTION AGAINST THE INSURER**

No action shall lie against the Insurer unless, as a condition precedent thereto, there shall have been full compliance with all the terms and conditions of this policy, nor until the amount of the **Insured's** obligations to pay shall have been finally determined either by judgment against the **Insured** after actual trial or by written agreement of the **Insured**, the claimant and the Insurer.

**ASSIGNMENT**

Assignment of interest under this policy is prohibited and shall not bind the Insurer unless and until its consent is endorsed hereon.

**BANKRUPTCY**

In the event of the **Insured Entity's** bankruptcy, insolvency, receivership or any refusal or inability of the **Insured Entity** to pay **damages** to which this policy applies, the insurance afforded by this policy shall not replace or supplement the deductible or self-insured retention but shall apply in the same manner as though the **Insured Entity** were willing and able to pay. In no event shall the Insurer assume the **Insured Entity's** responsibilities or obligations.

**CANCELLATION**

This policy may be canceled by the **First Named Insured** by surrender thereof to the Insurer or by mailing to the Insurer written notice stating when thereafter the cancellation shall be effective. This policy may be canceled by the Insurer by mailing to the **First Named Insured** at the address shown in this policy written notice stating when, not less than 90 days thereafter, such cancellation shall be effective except that for cancellation because of nonpayment of premium which shall be effective not less than 10 days after such notice is mailed to the **First Named Insured**. The mailing of such notice shall be sufficient proof of notice. The time of the surrender or the effective date and hour of cancellation stated in the written notice shall become the end of the **policy period**. Electronic delivery of such written notice either by the **First Named Insured** or by the Insurer shall be equivalent to mailing.

If the Insurer cancels this policy, a refund due shall be computed on a pro-rata basis and shall be promptly returned to the **First Named Insured**. However, if the **First Named Insured** cancels this policy, the refund due shall be 90% of the pro-rata unearned paid premium, or 75% of the total annual premium, whichever is less. The **First Named Insured** may elect in writing to the Insurer to have any return premium due the **Insured Entity** applied to the additional premium charged for the **extended reporting period** endorsement if available.

Premium adjustment may be made either at the time cancellation is effective or as soon as practicable after cancellation becomes effective, but payment or tender of unearned premium is not a condition of cancellation.

## CHANGE OF STATUS OF INSUREDS

### A. Takeover of the First Named Insured

In the event of a **takeover** of the **First Named Insured**, this policy shall automatically and without any notification terminate effective as of the date of such **takeover**, unless the Insurer is notified in writing of the **takeover** prior to the **takeover** effective date and agrees in writing to continue the policy beyond the effective date of **takeover** and the **First Named Insured** accepts any special terms, conditions and exclusions and pays any additional premium charge required by the Insurer.

### B. Cessation of Subsidiary

If any organization ceases to be a **subsidiary**, such **subsidiary** shall cease to be an **Insured** with respect to any **incident** that occurs after the date such entity ceased to be a **subsidiary** and all coverage under this policy for such **incidents** will cease on the effective date of such cessation without any notification, unless the Insurer is notified in writing of such cessation prior to the effective date thereof and agrees in writing to continue coverage for such **subsidiary**, and the **First Named Insured** accepts any special terms, conditions and exclusions and pays any additional premium charge required by the Insurer.

## CHANGES

Notice to or knowledge possessed by any person shall not effect a waiver or a change in any part of this policy or estop the Insurer from asserting any right under the terms of this policy. The policy's terms shall not be waived or changed except by an endorsement issued by and signed by an authorized representative of the Insurer.

## CLASS 1 PRODUCT RECALL EXPENSES PROOF OF LOSS

Solely with respect to a **class 1 product recall**, the **Insured Entity** must send the Insurer a signed, sworn proof of loss containing the information the Insurer requests to investigate the **class 1 product recall** and the **class 1 product recall expenses**. The **Insured Entity** must do this within 60 days after the Insurer's request. The Insurer may examine any **Insured** under oath, while not in the presence of any other **Insured** and at such times as may be reasonably required, about any matter relating to this insurance or the **class 1 product recall** or the **class 1 product recall expenses** incurred, including any **Insured's** books and records. In the event of an examination, any **Insured's** answers must be signed.

## CURRENCY

The limits, retentions, premiums and losses of this policy are payable in United States currency unless otherwise specified in the Declarations.

## DEFENSE

### A. Duty to Defend

The Insurer has the right and duty to defend in the **Insured's** name and on the **Insured's** behalf any covered **claim** even if any of the allegations of such **claim** are groundless, false or fraudulent. The Insurer shall have the right to make such investigation, defense and settlement of a **claim** (including any **claim** within the deductible) as is deemed necessary by the Insurer. The Insurer will designate or, at its option, approve, counsel to defend the **claim**. If a **claim** is subject to arbitration or mediation, the Insurer shall be entitled to exercise all of the **Insured's** rights in the choice of arbitrators or mediators and in the conduct of any arbitration or mediation proceeding involving such **claim**.

### B. Exhaustion of Limits

The Insurer is not obligated to investigate, defend, pay or settle, or continue to investigate, defend, pay or settle a **claim** after the applicable limit of the Insurer's liability has been exhausted by payment of **damages** or **defense costs** or by any combination thereof or after the Insurer has deposited the remaining available limits of liability into a court of competent jurisdiction. In such case, the Insurer shall have the right to



withdraw from the further investigation, defense, payment or settlement of such **claim** by tendering control of said investigation, defense or settlement of the **claim** to the **Insured**.

**DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR A POTENTIAL CLASS 1 PRODUCT RECALL**

**A. Notice of Circumstance**

Except as set forth in paragraph **B.** below, if, during the **policy period**, the **Insured Entity** reports a **circumstance** for which there may be coverage under this policy, and the **Insured Entity** gives the Insurer written notice containing:

1. what happened and the **insured work, insured product** or the **professional services** or activities the **Insured Entity** performed that might give rise to a **claim**;
2. the nature of any possible injury or **damages**;
3. how the **Insured Entity** first became aware of such **circumstance**;
4. the identity of the specific **Insureds** allegedly responsible for such specific **professional services** or activities; and
5. the nature of the potential monetary damages or non-monetary relief that may be sought in consequence of such specific **professional services** or activities,

then any **claim** otherwise covered that may subsequently be made against an **Insured** during the **coverage relationship**, or during the automatic **extended reporting period**, arising out of such **circumstance** shall be deemed to have been made against such **Insured** on the date the Insurer received written notice of the **circumstance**.

**B. Mandatory Notice of Advisory Memorandum, Class 1 Product Recall or Boxed Warning**

Any **circumstance** that is an **advisory memorandum, class 1 product recall** or **boxed warning** must be reported to the Insurer at the time of each such **advisory memorandum, class 1 product recall** or **boxed warning**.

**C. Related Circumstances**

If, during the **coverage relationship**, the **Insured Entity** reports any **advisory memorandum, class 1 product recall** or **boxed warning**, pursuant to the requirements set forth in paragraphs **A.** or **B.** above, then all **claims** subsequently made against an **Insured** and arising out of any defect or deficiency which is the subject of such **advisory memorandum, class 1 product recall** or **boxed warning**, shall be deemed to be **related claims**. All such **related claims** shall be deemed to be a single **claim** subject to the limits of liability set forth in the policy in effect when such **advisory memorandum, class 1 product recall** or **boxed warning** was reported to the Insurer pursuant to the requirements set forth in paragraphs **A.** or **B.** above.

**DUTIES IF THERE IS A CLAIM**

It is a condition precedent to coverage that the **Insured**:

- A.** notify the Insurer as soon as reasonably possible of any **claim**. Such must be in writing and be sent to the attention of CNA Healthcare Claims at the e-mail address or phone number set forth in the Policy Declarations. Such notice must be given to the Insurer as soon as reasonably possible but in no event later than ninety days (90) after termination or expiration of the **coverage relationship**, or during the **extended reporting period**, if applicable;
- B.** specify the names and addresses of the persons making a **claim** against the **Insured** and provide the Insurer with information on the time, place and nature of the **claim**;
- C.** promptly forward to the Insurer all documents that the **Insured** receives in connection with the **claim**;
- D.** fully cooperate with the Insurer or its designee in the defense of a **claim**, including but not limited to





assisting the Insurer in the conduct of suits or other proceedings, settlement negotiations, and the enforcement of any right of contribution or indemnity against another who may be liable to the **Insured**. The **Insured** shall attend hearings and trials and assist in securing evidence and obtaining the attendance of witnesses; and

- E. refuse, except solely at the **Insured's** own cost, to voluntarily, without the Insurer's written approval, make any payment, admit liability, assume any obligation or incur any expense. If **damages** or **defense costs** are incurred by an **Insured** before written notice of such **claim** is given to the Insurer in accordance with this section, the Insurer will not be liable for any such amounts.

After the **Insured** reports a **claim** and the **Insured** has the right under any contract to either reject or demand arbitration or other alternative dispute resolution process, the **Insured** shall only do so with the Insurer's written consent.

### **ENTIRE CONTRACT**

By acceptance of this policy the **Insured Entity** agrees that:

- A. all of the information and statements provided to the Insurer by the **Insured Entity** are true, accurate and complete and shall be deemed to constitute material representations made by all of the **Insureds**;
- B. this policy is issued in reliance upon the **Insured Entity's** representations;
- C. this policy, endorsements thereto, together with the completed and signed **application** (which is deemed to be incorporated herein) embody all of the agreements existing between the **Insureds** and the Insurer and shall constitute the entire contract between the **Insureds** and the Insurer; and
- D. the willful or intentional misrepresentation of any material matter by the **Insured Entity** or its agent will render this policy null and void and relieve the Insurer from all liability herein.

### **ESTATES, LEGAL REPRESENTATIVES AND SPOUSES**

The estates, heirs, legal representatives, assigns, spouses and any **domestic partner** of natural person **Insureds** shall be considered **Insureds** under this policy; provided, however, coverage is afforded to such estates, heirs, legal representatives, assigns and spouses only for a **claim** arising solely out of their status as such and, in the case of a spouse or **domestic partner**, where such **claim** seeks damages from marital community property, jointly held property or property transferred from the **Insured** to the spouse or **domestic partner**.

### **EXTENDED REPORTING PERIODS**

#### **A. Automatic 90 Day Extended Reporting Period**

The Insurer will provide an automatic, non-cancelable **extended reporting period** of 90 days (or 5 years with respect to any **claim** that the **Insured Entity** reported to the Insurer as a **circumstance** during the **coverage relationship** in accordance with the **COMMON CONDITIONS**, the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR POTENTIAL CLASS 1 PRODUCT RECALL**) starting with the end of the **policy period** if no other insurance purchased by the **Insured Entity** to replace this policy applies or would apply but for the exhaustion of the applicable limit of liability.

#### **B. Optional Extended Reporting Period**

If the **Insured Entity** or the Insurer cancels or non-renews this policy for any reason the above 90 day reporting period may be substituted by an **extended reporting period** endorsement for a period up to 60 months from the end of the **policy period** or the effective date of cancellation or non-renewal, if the **Insured Entity** makes a written request for an **extended reporting period** within 90 days after the end of the **policy period** or the effective date of cancellation and pays the required additional premium within said 90 days.

#### **C. Extended Reporting Period Premium**

The required Additional Premium shall not exceed 200% of the adjusted Annual Premium.



**D. Extended Reporting Period Not a New Policy**

An **extended reporting period** shall not be construed to be a new policy and shall otherwise be governed by all of the terms and conditions of this policy.

**E. Extended Reporting Period Limits of Liability**

No **extended reporting period** will reinstate or increase the limits of liability specified in the Declarations.

**HEADINGS**

The descriptions in the headings of this policy are solely for convenience, and form no part of the terms and conditions of coverage.

**INSPECTION AND AUDIT**

The Insurer shall be permitted but not obligated to inspect the **Insured Entity's** property and operations at any time. Neither the Insurer's right to make inspections nor the making thereof nor any report thereon shall constitute an undertaking, on behalf of or for the benefit of the **Insured Entity** or others, to determine or warrant that such property or operations are safe or healthful, or are in compliance with any law, rule or regulation.

The Insurer may examine and audit the **Insured Entity's** books and records at any time during the **policy period** and extensions thereof and within three years after the final termination of the policy as far as they relate to the subject matter of this insurance.

**LIMITS OF LIABILITY AND DEDUCTIBLE**

**A.** The Limits of Liability of each **coverage part** are subject to the terms and provisions of this Section.

**B. Policy Aggregate Limits of Liability**

The Limits of Liability for each **coverage part**, as applicable, are subject to the Policy Aggregate Each **Claim** and Aggregate Limits of Insurance as specified in the Policy Declaration. As such, any each **claim** and aggregate limits of insurance in the Policy Declarations are limits of liability which are included within and not in addition to the Policy Aggregate Limits of Insurance.

**C. Supplementary Benefits Limits - Mitigation Expenses Sublimits of Liability**

**1. Sublimit of Liability—each Claim or Circumstance**

Subject to paragraph **2.** below, the sublimit of liability of the Insurer for **mitigation expenses** for each **claim** or **circumstance** shall not exceed the **mitigation expenses** sublimit set forth in the Declarations.

**2. Sublimit of Liability—in the Aggregate**

The sublimit of liability of the Insurer for **mitigation expenses** for all **claims** or **circumstances** shall not exceed the amount stated in the Declarations as the aggregate.

The **mitigation expenses** sublimits set forth in the Declarations are included within and are not in addition to the each **claim** and all **claims** Policy Aggregate limits of liability. As such, the **mitigation expenses** sublimits erode the each **claim** and all **claims** Policy Aggregate limits of liability set forth in the Declarations. All **mitigation expenses**:

- a. arising out of the same **wrongful act** or **related wrongful acts** or;
- b. arising out of the same **occurrence** or **related occurrences**,

are subject to the applicable limits of liability of the policy in effect at the time the first request for **mitigation expenses** was made.

**D. Deductible**

- 1. Any applicable deductible shall be paid by the **Insured Entity**, or upon its failure to pay, jointly and

severally by all **Insureds**. The limits of liability set forth in the Declarations or in this policy are in addition to and in excess of the applicable deductible. If the Insurer, in the exercise of its discretion and without any obligation to do so, pays any amount in excess of the applicable limits of liability or within the amount of a deductible, the **Insured Entity**, or upon its failure to pay, the **Insureds**, jointly and severally, shall be liable to the Insurer for any and all such amounts and, upon demand, shall pay such amounts to the Insurer.

## 2. Policy Each Claim and in the Aggregate

The Policy Aggregate each **claim** and aggregate deductibles, if any, shown in the Declarations apply to **damages** and **defense costs** for each **claim** and to all **claims** in the aggregate. As such, any each **claim** and aggregate deductible in any applicable **Coverage Part** erodes the Policy Aggregate each **claim** and aggregate deductibles and are not in addition to such deductibles.

### E. Mitigation Expenses Coinsurance Percentage

The **Insured Entity** must pay a coinsurance percentage of all **mitigation expenses** paid by the Insurer. The coinsurance percentage is 20% for **mitigation expenses** unless a different amount is set forth in the Declarations. This coinsurance percentage is in addition to any applicable deductible. The Insurer is liable to pay the remaining percentage of the **mitigation expenses** up to the applicable limits of liability and in excess of any applicable deductible and coinsurance percentage.

### F. Multiple Insureds, Claims and Claimants

The limits of liability shown in the Declarations or above and subject to the provisions of this policy are the amounts the Insurer will pay as **damages**, **defense costs**, **mitigation expenses**, applicable **class 1 product recall expenses** or applicable **medical payments** regardless of the number of **Insureds**, **claims** made, **circumstances** reported; **class 1 product recalls** or persons or entities making **claims**.

### G. Related Claims

If, during the **policy period**, a **claim** is made and if either the **Insured Entity** or the Insurer declares in writing to the other that such **claim** is likely to give rise to subsequent **related claims**, then such **claim** and all such subsequent **related claims**, shall be deemed a single **claim**. The limits of liability applicable to such single **claim** are the limits of liability in effect for the policy in which the declaration was made.

### H. Defense costs within Limits

**Defense costs** are included within and erode the applicable limit of liability. **Defense costs** with respect to a **claim** will be paid first and payment will reduce the amount available to pay **damages**.

### NOTICE OF POTENTIAL CLASS 1 PRODUCT RECALL

The **Insured Entity** must see to it that the Insurer is notified as soon as practicable in writing of any incident that leads the **Insured Entity** to believe a **class 1 product recall** is likely to occur, whether or not the **class 1 product recall expenses** are likely to exceed the **class 1 product recall expenses** deductible shown in the policy or in the Declarations. Notice should include how, when and where the incident took place; the names and addresses of injured persons or witnesses to the incident that may lead to a **class 1 product recall**; and the estimated **class 1 product recall expenses**.

### OTHER INSURANCE OR RISK TRANSFER ARRANGEMENTS

If the **Insured** is entitled to be indemnified or otherwise insured in whole or in part by any other insurance, self insurance or indemnity agreement for any **claim** or **incident** which otherwise would have been indemnified in whole or in part by this policy, the limits of liability specified in the Declarations shall apply in excess of, and shall not contribute to a **claim** or **incident** covered by such other insurance. This paragraph does not apply to any other insurance that was bought specifically to apply in excess of the Limits of Liability shown in the Declarations of this policy.

The Insurer will have no duty under this policy to defend the **Insured** against any **claim** if any other insurer has



a duty to defend the **Insured** against that **claim**. If no other insurer defends, the Insurer will undertake to do so, but it will be entitled to the **Insured's** rights against all those other insurers.

Solely with respect to any person or organization insured pursuant to the **GLOSSARY OF DEFINED TERMS**, paragraph **H.** of the definition of **Insured**, the insurance afforded by this policy is primary.

#### **PREMIUM**

All premium charges under this policy will be computed according to the rules, rates and rating plans that apply at the effective date of the current **policy period**.

The **Insured Entity** shall maintain records of such information as it is necessary for auditable premium computation and shall send copies of such records to the Insurer at the end of the **policy period** and at such times during the **policy period** as the Insurer may direct. Subsequent to audit by the Insurer, the **Insured Entity** shall forward to the Insurer any additional premiums warranted by such audit.

#### **SEPARATION OF INSUREDS**

Except with respect to the Limits of Insurance, and any rights or duties specifically assigned in this policy to the **First Named Insured**, this insurance applies as if each of the **Insured Entities** were the only **Insured Entity** and separately to each **Insured** against whom a **claim** is made.

#### **SOLE AGENT**

The **First Named Insured** is authorized to act on behalf of all **Insureds** with respect to giving or receiving notice of cancellation, non-renewal, premium or charges in this policy or request for an **extended reporting period** endorsement.

#### **SUBROGATION**

If any **Insured Entity** has rights to recover amounts from another, those rights are transferred to the Insurer to the extent of its payment. The **Insured Entity** must do everything necessary to secure these rights and must do nothing after a **claim** is made to jeopardize them. The Insurer hereby waives subrogation rights against the **Insured Entity's** client to the extent that the **Insured Entity** had, prior to a **claim** or **circumstance**, a written agreement to waive such rights.

The amount recovered as subrogation shall be apportioned in the inverse order of payment of **damages** to the extent of the actual payment. **Defense costs** shall be apportioned in the ratio of respective recoveries.

#### **TERRITORY**

This insurance applies anywhere in the world, provided the **Insured's** responsibility to pay **damages** is determined in a suit on the merits brought in the United States of America (including its possessions and territories), Canada or Puerto Rico, or in a settlement to which the Insurer agrees.

#### **TRADE AND ECONOMIC SANCTIONS**

This policy does not provide coverage for an **Insured**, transaction or that part of loss that is uninsurable under the laws or regulations of the United States concerning trade or economic sanctions.

#### **WHEN A CLAIM IS DEEMED MADE**

Except as set forth in the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR A POTENTIAL CLASS 1 PRODUCT RECALL claim** is deemed made on the earliest of the following:

- A.** in the case of a demand, on the earlier of an **executive officer's** or Insurer's receipt of such demand; or
- B.** in the case of a civil proceeding in a court of law or equity, or arbitration, on the date of service upon or other receipt by the **Insured Entity** of a complaint against the **Insured Entity** in such proceeding or arbitration.



IN WITNESS WHEREOF, the Insurer has caused this policy to be signed by its Chairman and Secretary, but this policy shall not be binding upon the Insurer unless completed by the attachment of the Declarations and signed by a duly authorized representative of the Insurer.

Chairman of the Board

Secretary

## LIFE SCIENCES LIABILITY POLICY GLOSSARY OF DEFINED TERMS

The following defined words shall have the same meaning throughout this policy, whether expressed in the singular or the plural. Wherever appearing in bold print in this policy:

**ADVERTISEMENT**

**Advertisement** means a notice that is broadcast or published to the general public or specific market segments about the **Insured Entity's** goods, products or services for the purpose of attracting customers or supporters. For the purposes of this definition:

- A. notices that are published include material placed on the Internet or on similar electronic means of communication; and
- B. regarding web-sites, only that part of a web-site that is about the **Insured Entity's** goods, products or services for the purposes of attracting customers or supporters is considered an **advertisement**.

**ADVISORY MEMORANDUM**

**Advisory memorandum** means a written communication issued by the **Insured Entity** or on its behalf to healthcare professionals, customers, product users, suppliers, vendors or the public at large informing them of an actual or alleged defect or deficiency in an **insured product** or in its labeling. An **advisory memorandum** is deemed to be a **circumstance** and provided it is reported in accordance with the reporting requirements of the **COMMON CONDITIONS**, the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR POTENTIAL CLASS 1 PRODUCT RECALL**.

**APPLICATION**

**Application** means all signed applications for this policy and for any policy in an uninterrupted series of policies issued by the Insurer or any affiliate of the Insurer of which this policy is a renewal or replacement. **Application** includes any materials submitted or required to be submitted therewith. An "affiliate of the Insurer" means an insurer controlling, controlled by or under common control with the Insurer.

**ASBESTOS**

**Asbestos** means the mineral in any form whether or not the **asbestos** was at any time airborne as a fiber, particle or dust, contained in or formed a part of a product, structure or other real or personal property, carried on clothing, inhaled or ingested, or transmitted by any other means.

**AUTOMOBILE**

**Automobile** means a land motor vehicle, trailer or semi-trailer designed for travel on public roads, including any attached machinery or equipment. But **automobile** does not include **mobile equipment**.

**BIOLOGICAL PRODUCTS**

**Biological products** mean any virus, therapeutic serum, toxin, antitoxin, or analogous product that is:

- A. recognized in the official National Formulary, the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia, Compendium of Pharmaceuticals & Specialties, any provincial formulary, and any supplement to any of these or the equivalent of such documents in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure or any function of the human body; or
- C. is a component of any product described in paragraph **A.** or **B.** above.

However, **biological product** does not include any **pharmaceutical drug, medical device, nutraceutical** or food.



### **BODILY INJURY**

**Bodily injury** means bodily injury, sickness or disease sustained by a person, including death resulting from such injuries. **Bodily injury** also means mental injury, mental anguish or shock sustained by that person as a result of such bodily injury, sickness or disease. **Bodily injury** also means bodily injury, sickness, disease, mental injury, mental anguish or shock sustained by any relative of that person as result of such **bodily injury**.

### **BOXED WARNING**

**Boxed warning** means any notice required by the Food and Drug Administration pursuant to 21 CFR 201. 57(a) (4) and (c) (1) or by any foreign equivalent of such. A **boxed warning** is deemed to be a **circumstance** and provided it is reported in accordance with the reporting requirements of the **COMMON CONDITIONS**, the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR POTENTIAL CLASS 1 PRODUCT RECALL**.

### **CIRCUMSTANCE**

**Circumstance** means an **incident** reported during the **policy period** from which an **executive officer** reasonably expects that a **claim** could be made.

### **CLAIM**

**Claim** means:

- A. a demand for money or services; or
  - B. a civil proceeding or an arbitration proceeding or any appeal therefrom,
- against the **Insured** and alleging an **incident**. A **claim** does not include a **circumstance**.

### **CLASS 1 PRODUCT RECALL**

**Class 1 product recall** means removal or correction of an **insured product** by the **Insured Entity**, where the **Insured Entity**, the **United States Food and Drug Administration** or any foreign equivalent has determined that the **insured product** poses a situation in which there is a reasonable probability that the use of or exposure to such **insured product** will cause serious adverse health consequences or death.

A **Class 1 product recall** is deemed to be a **circumstance** and provided it is reported in accordance with the reporting requirements of the **COMMON CONDITIONS**, the section entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR POTENTIAL CLASS 1 PRODUCT RECALL**.

### **CLASS 1 PRODUCT RECALL EXPENSES**

**Class 1 product recall expenses** means reasonable and necessary expenses incurred:

- A. in connection with **insured products** that have been physically relinquished to others and manufactured, processed, packaged, handled, distributed, or sold by the **Insured Entity**;
- B. with the Insurer's prior written consent;
- C. as a result of a **Class 1 product recall**; and
- D. for:
  - 1. any communication costs incurred to announce the withdrawal, including but not limited to:
    - a. telephone, radio, television, and internet announcements; and
    - b. production costs of the announcements, such as printing costs, stationary, envelopes and postage;
  - 2. transporting **insured product** from any purchaser, distributor or user, to locations designated by the **Insured Entity**;
  - 3. transporting the **Insured Entity's employees** to any purchaser, distributor or user in order to effectuate

reasonable and necessary on-site repairs due to a **Class 1 product recall**;

4. remunerating the **Insured Entity's employees** for overtime to perform the actions in **1., 2., or 3.** above, and, if necessary, the cost to hire and pay additional persons other than its regular **employees** to perform these actions;
5. properly disposing of **insured product**, including packaging that cannot be reused; or
6. renting temporary locations used to store **insured product**.

However, **Class 1 product recall expenses** do not include **mitigation expenses** or **medical expenses**.

#### **CLINICAL TRIAL**

**Clinical trial** means an organized study, test or written protocol that uses human subjects to establish the effectiveness, bioequivalence or safety of **insured products**.

#### **CLINICAL TRIAL CONSULTANT**

**Clinical trial consultant** means any medical intern, resident, technician, nurse, physician or other medical professional, who provides advice to a **clinical trial investigator**.

#### **CLINICAL TRIAL CONSULTANT SERVICES**

**Clinical trial consultant services** mean professional advice or demonstration of procedures performed by a **clinical trial investigator** in connection with a **clinical trial** as outlined in the written protocol of such **clinical trial**.

#### **CLINICAL TRIAL INVESTIGATOR**

**Clinical trial investigator** mean the individuals who provide services in the **clinical trial** testing of **insured products** as outlined in the written protocol of such **clinical trial**. **Clinical trial investigators** do not include human test subjects in the **clinical trial**.

#### **CONTRACT RESEARCH ORGANIZATION**

**Contract research organization** means any entity that provides **professional services** in connection with, or that organizes or runs **clinical trials**.

#### **COVERAGE PART**

**Coverage part** means only those coverage parts designated as included in the Declarations.

#### **COVERAGE RELATIONSHIP**

**Coverage relationship** means that period of time beginning on the effective date and time of the first policy issued by the Insurer to the **First Named Insured** of which this policy is a renewal in a consecutive series of renewals and the cancellation or nonrenewal of the last such consecutive renewal policy issued by the Insurer to the **First Named Insured**, where there has been no gap in coverage.

#### **DAMAGES**

**Damages** mean judgments, awards and settlements, provided any settlement is made with the Insurer's prior written consent. **Damages** do not include:

- A. fees, costs and expenses (including **mitigation expenses**) paid or incurred or charged by the **Insured**, no matter whether claimed as restitution of specific funds, forfeiture, financial loss, set-off or otherwise, and injuries that are a consequence of any of the foregoing;
- B. civil or criminal fines, sanctions, penalties or forfeitures, whether pursuant to law, statute, regulation or court rule;
- C. the multiplied portion of multiplied awards imposed pursuant to any statute or regulation requiring such awards;



- D. injunctive or declaratory relief;
- E. any amount that is not insurable under any applicable law;
- F. or any amounts for which an **Insured** is liable due to an act or omission in knowing violation of any written contract or agreement; or
- G. plaintiff's attorney fees associated with any of the above.

Notwithstanding paragraph **E.** above, **damages** shall include, subject always to this policy's other terms, conditions and limitations, punitive and exemplary damages. Enforceability of this paragraph shall be governed by such applicable law that most favors coverage for such punitive or exemplary damages.

### **DEFENSE COSTS**

**Defense costs** mean:

- A. fees charged by attorneys designated by the Insurer or by the **Insured** with the Insurer's prior written consent;
- B. all other reasonable and necessary fees, costs and expenses resulting from the investigation, adjustment, defense and appeal of a covered **claim** if incurred by the Insurer, or by the **Insured** with the Insurer's prior written consent, including, but not limited to, premiums for any appeal bond, attachment bond or similar bond but without any obligation of the Insurer to apply for or furnish any such bond;
- C. prejudgment interest awarded against the **Insured Entity** on that part of a judgment the Insurer pays. If the Insurer makes an offer to pay the applicable limit of liability, will not pay any prejudgment interest based on that period of time after such offer; or
- D. interest on the full amount of a judgment that accrues after entry of the judgment and before the Insurer has paid, offered to pay or deposited in court the part of the judgment that is within the applicable limit of liability.

However, **defense costs** do not include:

1. salaries, loss of earnings or other remuneration by or to any **Insured**;
2. fees and expenses of independent adjusters engaged by the Insurer or salaries of the Insurer's officials or **employees**, other than fees and expenses charged by the Insurer's employed attorneys who may be designated to represent the **Insured** with the **Insured's** consent; or
3. mitigation expenses.

### **DOMESTIC PARTNER**

**Domestic partner** means any person qualifying as such under any federal, state or local laws or under the **Insured Entity's** employee benefit plans.

### **EMPLOYEE**

**Employee** means any person whose work or service is directed and controlled by the **Insured Entity**. It includes a leased worker, a volunteer and a temporary worker.

### **EXECUTIVE OFFICER**

**Executive officer** means a person holding any of the officer positions created by the **Insured Entity's** charter, constitution, by-laws or any other similar governing document and its in-house general counsel, corporate risk manager and any **employee** who is responsible for its insurance or claim reporting.

### **EXTENDED REPORTING PERIOD**

**Extended reporting period** means:

- A. with respect to the **Products-Work Hazard Coverage**, the period of time after the end of the **policy period** for the reporting of **claims** to the Insurer that are made against the **Insured** during the applicable **extended reporting period** arising out of an **occurrence** causing **bodily injury** or **property damage**, which injury or damage took place on or after any applicable Retroactive Date and prior to the end of the **policy period**, or arising out of an offense giving rise to **personal and advertising injury**, which offense took place on or after any applicable Retroactive Date and prior to the end of the **policy period**;
- B. with respect to the **Professional Services Coverage**, the period of time after the end of the **policy period** for reporting **claims** to the Insurer that are made against an **Insured** during the applicable **extended reporting period** arising out of **wrongful acts** that took place on or after any applicable Retroactive Date and prior to the end of the **policy period**.

#### **FIRST NAMED INSURED**

**First Named Insured** means the entity first listed as a **Named Insured** in the Declarations.

#### **FORCE MAJEURE**

**Force majeure** means the following unforeseen circumstances if and to the extent they prevent the **Insured Entity** from completing **insured product** or **insured work**: fire; flood; earthquake; epidemic; epizootic; other natural or man-caused calamities; military operations; decisions of governmental authorities; war or civil insurrection.

#### **HAZARDOUS PROPERTIES**

**Hazardous properties** include radioactive, toxic or explosive properties.

#### **IMPAIRED PROPERTY**

**Impaired property** means tangible property, other than **insured product** or **insured work**, that cannot be used or is less useful because:

- A. it incorporates **insured product** or **insured work** that is known or thought to be defective, deficient, inadequate or dangerous; or
- B. the **Insured Entity** has failed to fulfill the terms of a contract or agreement;

if such property can be restored to use by:

1. the repair, replacement, adjustment or removal of **insured product** or **insured work**; or
2. the **Insured Entity's** fulfilling of the terms of the contract or agreement.

#### **INCIDENT**

**Incident** means a **wrongful act**, an **occurrence**, or an offense giving rise to **personal and advertising injury**.

#### **INSTITUTIONAL REVIEW BOARD**

**Institutional review board** means a board, committee (including an ethics committee) panel or similar group designated, directed or requested by a person or organization to review or approve **clinical trials**.

#### **INSURED**

**Insured** means the **Insured Entity** and:

- A. any individual who was, is or becomes the **Insured Entity's** officer, director, member or manager (of a limited liability company), or partner but:
  1. with respect to **products-work hazard claims**, solely with respect to the conduct of the **Insured Entity's** business; or
  2. with respect to **professional liability claims**, solely with respect to **professional services** rendered on the **Insured Entity's** behalf.

- B. the **Insured Entity's** stockholders, but only with respect to their liability as stockholders.
- C. the **Insured Entity's employees**, but:
  - 1. with respect to **products-work hazard claims**, only for acts within the scope of their employment or while performing duties related to the conduct of the **Insured Entity's** business; or
  - 2. with respect to **professional liability claims**, solely with respect to **professional services** rendered to others on the **Insured Entity's** behalf.

However, none of these **employees** is an **Insured** for:

a. **bodily injury or personal and advertising injury:**

- i. to the **Insured Entity**, or to its directors, officers, members or managers, partners, or to a **co-employee** while such injured person is either in the course of his or her employment or performing duties related to the conduct of the **Insured Entity's** business;
- ii. to the spouse, **domestic partner**, child, parent, brother or sister of such injured person as a consequence of paragraph a. i. above; or
- iii. 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. i. or ii. above.

Voluntary participation as a human test subject in a **clinical trial** will not be deemed to be within the scope of employment or performance of duties as described in paragraph a. i. above.

b. **property damage** to property:

- i. owned, occupied or used; or
- ii. rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose;

by the **Insured Entity**, any of its **employees**, any partner or member (if the **Insured Entity** is a partnership or joint venture), or any member (if the **Insured Entity** is a limited liability company).

- D. any person (other than the **Insured Entity's employee**), or any organization while acting as the **Insured Entity's** real estate manager.
- E. **contract research organizations, medical or biotechnology advisors, clinical trial consultants, institutional review boards and clinical trial investigators** (other than the **Insured Entity** or its **employees**). However, no such person or organization is an **Insured** with respect to:
  - 1. any representation or warranty unauthorized by the **Insured Entity**;
  - 2. any physical or chemical change in **insured product** made intentionally by such person without the **Insured Entity's** consent; or
  - 3. such person or organization's rendering or failing to render **professional services** or advice, unless:
    - a. the injury or **damages** arises directly out of the use of **insured products** or **insured work**; and
    - b. the **professional service** or advice is within the scope of a **clinical trial** and is in accordance with written **clinical trial** protocol; and
    - c. the injury or **damages** do not arise out of such person or organization's willful violation of any law or regulation relating to the conduct of a **clinical trial**; and
    - d. the injury or **damages** arise out of the assumption of liability in a contract or agreement.
- F. **medical sales consultants**. However, no such person or organization is an **Insured** with respect to:
  - 1. any representation or warranty unauthorized by the **Insured Entity**;

2. any physical or chemical change in **insured product** made intentionally by such person without its consent;
  3. such person or organization's rendering or failing to render **professional services**; or
  4. such person or organization's rendering or failing to render advice, unless the injury or damage arises directly out of the use of **insured products**.
- G. persons or organizations who are vendors of **insured products**, but they are **Insureds** only with respect to their liability for **damages** resulting from the distribution or sale of **insured products** in the regular course of their business. However, no such person or organization is an **Insured** with respect to:
1. any representation or warranty unauthorized by the **Insured Entity**;
  2. any physical or chemical change in **insured product** made intentionally by the vendor;
  3. repackaging, unless unpacked solely for the purpose of inspection, demonstration, or testing, or the substitution of parts under instruction from the manufacturer and then repacked in the original container;
  4. 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 **insured products**;
  5. demonstration, installation, servicing or repair operations, except such operations performed at the vendor's premises in connection with the sale of **insured products**; or
  6. such vendor's rendering or failing to render **professional services**.

Further, no person or organization from whom the **Insured Entity** has acquired **insured products**, or any container, ingredient or part entering into, accompanying or containing **insured products**, is an **Insured** under this provision.

- H. any other person or organization to whom or to which the **Insured Entity** is obligated by virtue of a written contract, agreement or permit to provide such insurance as afforded by this policy, but only with respect to liability arising out of **insured product** or **insured work** performed by the **Insured Entity** or on its behalf for that **Insured**. However, this provision does not apply:
1. unless the written contract or agreement has been executed, or the permit has been issued, prior to the **bodily injury, property damage, personal and advertising injury** or any other injury. The contract or agreement will be considered executed when the **Insured's** performance begins, or when it is signed, whichever happens first; or
  2. to any person or organization:
    - a. for **bodily injury, property damage, personal and advertising injury** or any other injury arising out of such person's or organization's sole negligence; or
    - b. included as an **Insured** by an endorsement issued by the Insurer and made a part of this policy.

#### **INSURED CONTRACT**

**Insured contract** means that part of any written contract or agreement pertaining to the **Insured Entity's** operations or facilities under which the **Insured Entity** assumes the tort liability of another to pay **damages** because of **bodily injury** or **property damage** to a third person or organization, provided such contract or agreement is made prior to the **bodily injury, property damage** or such other injury. Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.

#### **INSURED ENTITY**

**Insured Entity** means any **Named Insured** and any **subsidiary** or any **newly acquired subsidiary**.

### INSURED PRODUCT

**Insured product** means any goods or products:

- A. manufactured, developed, designed, created, or tested;
- B. sold, leased, licensed, rented, handled, marketed, distributed to others; or
- C. disposed of;

by the **Insured Entity** or others on the **Insured Entity's** behalf, including but not limited to:

- 1. **biological products, pharmaceutical drugs, medical devices, nutraceuticals**; or
- 2. products that are used, or are intended for use in **clinical trials**, health care or the providing of **professional services**; or
- 3. containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.

**Insured product** includes:

- a. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of **insured product**; and
- b. the providing of or failure to provide warnings or instructions.

### INSURED WORK

**Insured work** means:

- A. work performed by the **Insured Entity** or on its behalf solely in connection with **insured product** or solely in connection with its **clinical trials**, including, but not limited to testing, review, installation, maintenance, or repair of **insured product** or in connection with its **clinical trials**; and
- B. materials, parts or equipment furnished in connection with such work, operations or services.

**Insured work** includes:

- 1. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation, safety or maintenance of **insured work**; and
- 2. the providing of or failure to provide warnings or instructions.

### LOADING OR UNLOADING

**Loading or unloading** means the handling of property:

- A. after it is moved from the place where it is accepted for movement into or onto an aircraft, watercraft or **automobile**;
- B. while it is in or on an aircraft, watercraft or **automobile**; or
- C. while it is being moved from an aircraft, watercraft or **automobile** to the place where it is finally delivered.

However, **loading or unloading** does not include the movement of property by means of a mechanical device, other than a hand truck, that is not attached to the aircraft, watercraft or **automobile**.

### MANAGEMENT CONTROL

**Management control** means:

- A. owning interests representing more than 50% of the voting, appointment or designation power for the selection of a majority of: the Board of Directors of a corporation; the management committee members of a joint venture; the managing or general partners of a partnership, or the members of the management board of a limited liability company; or

- B. having the right, pursuant to the **First Named Insured's** by-laws, charter, operating agreement, Partnership Agreement or similar documents, to elect, appoint or designate:
  - 1. a majority of: the Board of Directors of a corporation; the management committee of a joint venture; or the members of the management board of a limited liability company, or
  - 2. the general partners of a limited partnership or one or more managing partners of a partnership other than a limited partnership.

#### **MEDICAL DEVICE**

**Medical device** means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, component part or accessory that is:

- A. subject to United States Food and Drug Administration regulation, Health Canada regulation or the equivalent of such regulations in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans; or
- C. intended to affect the structure or any function of the human body,

that does not achieve its primary intended purposes through chemical or biological action within or upon the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

However, **medical device** does not include any **pharmaceutical drug, biological product, nutraceutical** or food.

#### **MEDICAL EXPENSES**

**Medical expenses** means reasonable expense for necessary:

- A. first aid administered at the time of an accident;
- B. medical, surgical, x-ray and dental services, including prosthetic devices; and
- C. ambulance, hospital, professional nursing and funeral services.

#### **MEDICAL OR BIOTECHNOLOGY ADVISORS**

**Medical or biotechnology advisors** means an entity or individuals, other than the **Insured Entity** or its **employees**, who are serving, or have served as the **Insured Entity's** advisor or consultant in a review of the design or development of **insured products**.

#### **MEDICAL SALES CONSULTANT**

**Medical sales consultant** means an entity or individuals (other than the **Insured Entity** or its **employees**) providing advice or demonstrating procedures in connection with the sale or distribution of **insured products** provided that such consultant does not render any direct patient care or **medical services**.

#### **MEDICAL SERVICES**

**Medical services** mean dental, medical, mental, nursing, surgical, x-ray or other similar service performed by a medical intern, resident, technician, nurse, physician or other medical professional, and the furnishing of food, beverages, medications or appliances in connection with such services, and the postmortem handling of human bodies.

#### **MITIGATION EXPENSES**

**Mitigation expenses** means reasonable and necessary fees, costs and expenses incurred by the **Insured Entity** as a result of a **circumstance** in the **Insured Entity's** efforts to minimize potential **damages** for which the **Insured Entity** might become liable due to a **claim** arising out of such **circumstance**. **Mitigation expenses** do not include fees, costs or expenses incurred to comply with any governmental or regulatory requirement, **class 1 product**



recall expenses or medical expenses. Mitigation expenses do not include damages or defense costs.

### **MOBILE EQUIPMENT**

**Mobile equipment** means any of the following types of land vehicles, including any attached machinery or equipment:

- A. bulldozers, farm machinery, forklifts and other vehicles designed for use principally off public roads;
- B. vehicles maintained for use solely on or next to premises the **Insured Entity** owns or rents;
- C. vehicles that travel on crawler treads;
- D. vehicles, whether self-propelled or not, maintained primarily to provide mobility to permanently mounted:
  - 1. power cranes, shovels, loaders, diggers or drills; or
  - 2. road construction or resurfacing equipment such as graders, scrapers or rollers;
- E. vehicles not described in **A.**, **B.**, **C.**, or **D.** above that are not self-propelled and are maintained primarily to provide mobility to permanently attached equipment of the following types:
  - 1. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment; or
  - 2. cherry pickers and similar devices used to raise or lower workers;
- F. vehicles not described in **A.**, **B.**, **C.**, or **D.** above maintained primarily for purposes other than the transportation of persons or cargo.

However, self-propelled vehicles with the following types of permanently attached equipment are not **mobile equipment** but will be considered **automobiles**:

- 1. equipment designed primarily for:
  - a. snow removal;
  - b. road maintenance, but not construction or resurfacing; or
  - c. street cleaning;
- 2. cherry pickers and similar devices mounted on **automobile** or truck chassis and used to raise or lower workers; and
- 3. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment.

However, **mobile equipment** does not include any land vehicles that are subject to a compulsory or financial responsibility law or other motor vehicle insurance law in the state where it is licensed or principally garaged. Land vehicles subject to a compulsory or financial responsibility law or other motor vehicle insurance law are considered **automobiles**.

### **NAMED INSURED**

**Named Insured** means any entity listed as such in the Declarations.

### **NEWLY ACQUIRED SUBSIDIARY**

**Newly acquired subsidiary** means any entity, newly formed or acquired by the **First Named Insured** or any **subsidiary** during the **policy period** but only for 90 days after such formation or acquisition. In order for coverage to continue beyond such 90 day period, the Insurer must have specifically agreed in writing to add such entity as a **subsidiary** to the policy by endorsement specifying the terms and conditions of its coverage.

### NUCLEAR FACILITY

**Nuclear facility** means:

- A. any **nuclear reactor**;
- B. any equipment or device designed or used for: separating the isotopes of uranium or plutonium; processing or utilizing **spent fuel**; or handling, processing or packaging **nuclear waste**;
- 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 any **Insured** at the premises where such equipment is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof; or 250 grams of uranium 235;
- D. any structure, basin, excavation, premises or place prepared or used for the storage or disposal of **nuclear 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 MATERIAL

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

### NUCLEAR REACTOR

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

### NUCLEAR WASTE

**Nuclear waste** means waste material:

- A. containing **by-product material** other than the tailings or waste produced by the extraction or concentration of uranium or thorium from ore processed primarily for its **source material** content; and
- B. resulting from the operation by any person or organization of a **nuclear facility** included within paragraphs 1. and 2. of the definition of **nuclear facility**;

used for such operations.

### NUTRACEUTICAL

**Nutraceutical** means a dietary supplement as defined by the Natural Health Products Regulations, the Food and Drug Act or the United States Dietary Supplement Health and Education Act, whether intended for ingestion or topical application. However, **nutraceutical** does not include any **pharmaceutical drug, biological product or medical device**.

### OCCURRENCE

**Occurrence** means an accident, including continuous or repeated exposure to the same general harmful conditions. An **occurrence** will be deemed to have occurred on the earliest date:

- A. **insured product** or **insured work** giving rise to such **claim** was first ingested, implanted, applied or otherwise used;
- B. a **claim** is made alleging **bodily injury** or **property damage** resulting from **insured product** or **insured work**;
- C. a professional medical opinion is rendered that provides a basis for a **claim** under the coverage provided;
- D. **medical expenses** are incurred as a result of **bodily injury**;
- E. death occurs as a result of exposure to **insured product** or **insured work**;
- F. removal or replacement of **insured product**; or



G. an advisory memorandum, class 1 product recall or boxed warning is issued.

#### **PERSONAL AND ADVERTISING INJURY**

**Personal and advertising injury** means injury, including consequential **bodily injury**, arising out of one or more of the following offenses:

- A. false arrest, detention or imprisonment;
- B. malicious prosecution or abuse of process;
- C. wrongful eviction from, wrongful entry into, or the invasion of the right of private occupancy of a room, dwelling or premises that a person occupies committed by or on behalf of its owner, landlord or lessor;
- D. 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;
- E. oral or written publication, in any manner, of material that violates a person's right of privacy;
- F. the use of another's advertising idea in the **Insured Entity's advertisement**; or
- G. infringing upon another's copyright, trade dress or slogan in the **Insured Entity's advertisement**.

#### **PHARMACEUTICAL DRUGS**

**Pharmaceutical drugs** mean a synthetic or natural chemical;

- A. recognized in the official National Formulary, the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia, Compendium of Pharmaceuticals & Specialties, any provincial formulary or any supplement to any of these or the equivalent of such documents in any foreign jurisdiction;
- B. intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure of any function of the human body; or
- C. as a component of any product described in paragraph A. or B. above.

However, **pharmaceutical drug** does not include any **biological product, medical device, nutraceutical** or food.

#### **POLICY PERIOD**

**Policy period** means the period of time shown in the Declarations of this policy or as amended by endorsement or cancellation.

#### **POLLUTANTS**

**Pollutants** mean any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapor, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned or reclaimed.

#### **POTENTIAL CLAIM**

**Potential claim** means:

- A. with respect to the **Products-Work Hazard Coverage, bodily injury or property damage** arising out of an **occurrence**, or rising out of an offense giving rise to **personal and advertising injury**, that any **executive officer** has reason to believe would give rise to a **claim**;
- B. with respect to the **Professional Services Coverage**, an act, error or omission in the rendering of **professional services** that any **executive officer** has reason to believe would give rise to a **claim**.

#### **PRODUCTS-WORK HAZARD**

**Products-work hazard** means:

- A. **bodily injury or property damage** arising out of **insured product or insured work**; or

**B. personal and advertising injury** but solely to the extent such **personal and advertising injury** arises out of the **Insured Entity's clinical trials**.

However, **products-work hazard** does not include **bodily injury** or **property damage** arising out of:

1. the transportation of property, unless the **bodily injury** or **property damage** arises out of a condition in or on a vehicle created by the **loading or unloading** of it; or
2. the existence of tools, uninstalled equipment, or abandoned or unused materials.

#### **PRODUCTS-WORK HAZARD CLAIM**

**Products-work hazard claim** means a **claim** alleging a **products-work hazard**.

#### **PROFESSIONAL LIABILITY CLAIM**

**Professional liability claim** means a **claim** alleging a **wrongful act** in the rendering of, or the failure to render, **professional services** but solely to the extent such **claim** alleges injury other than **bodily injury, property damage** or **personal and advertising injury**.

#### **PROFESSIONAL SERVICES**

**Professional services** mean those services performed by the **Insured Entity**, or by any other **Insured** on its behalf, for a fee or other remuneration, provided such services are specified in a written contract or agreement for the performance of **professional services** between the **Insured Entity** and its client, which contract was entered into prior to the date of the **wrongful act** giving rise to the **claim** and after the **retroactive date**.

**Professional services** also include:

- A.** services incidental to those services specified in such written contract or agreement which incidental services must be done to fulfill the contract and are agreed to by the **Insured Entity** orally or in writing after the execution of the written contract or agreement and prior to the date of the **wrongful act** giving rise to the **claim**; and
- B.** **clinical trial consultant services**.

However, **professional services** do not include **medical services**.

#### **PROPERTY DAMAGE**

**Property damage** means:

- A.** physical injury to tangible property, including the loss of use thereof. 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 has not been physically injured or destroyed. All such loss of use shall be deemed to occur at the time of the **occurrence** that caused it.

#### **RELATED CLAIMS**

**Related claims** means all **claims**:

- A.** arising out of the same **wrongful act** or **related wrongful acts**; or
- B.** arising out of the same **occurrence** or the same **related occurrences**; or
- C.** arising out of the same offense or the same **related offense**.

#### **RELATED OCCURENCE**

**Related occurrence** is an **occurrence** giving rise to **bodily injury** or **property damage** which **bodily injury** or **property damage** is attributable directly, indirectly or allegedly to the same, actual or alleged event, condition, cause, defect, hazard, advice or decision in the design, formulation, manufacturing, distribution, sale, testing, use, operation, maintenance, repair or replacement of **insured product** or **insured work**. Such **related occurrence** exists regardless of:

- A. when or where such **bodily injury** or **property damage** occurs; or
- B. the number of such **bodily injuries** or **property damage**.

**RELATED OFFENSE**

**Related offense** means all offenses giving rise to **personal and advertising injury** that are logically or causally connected by any common fact, **circumstance**, situation, transaction or event.

**RELATED WRONGFUL ACTS**

**Related wrongful acts** mean all acts or omissions in the rendering of or failure to render **professional services** that are logically or causally connected by any common fact, **circumstance**, situation, transaction, event, advice or decision.

**SOURCE MATERIAL, SPECIAL NUCLEAR MATERIAL AND 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**

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

**SUBSIDIARY**

**Subsidiary** means any entity in which the **First Named Insured**, directly or indirectly, had **management control** on the inception date of this policy. On the date during the **policy period** that the **First Named Insured** ceases to have such **management control** of such entity, such entity shall cease to be a **subsidiary** under the terms of this policy. In such event, coverage will be provided to such **subsidiary** under the policy but only with respect to **incidents** that occur prior to such date in accordance with all other terms and conditions of this policy. No coverage will be afforded under the policy with respect to **claims** made against such **subsidiary** based on any **incident** that occurred on or subsequent to such date.

**TAKEOVER**

**Takeover** means:

- A. the acquisition by another entity or person, or group of entities or persons acting in concert, of:
  - 1. the ownership or control of voting stock of the **First Named Insured** resulting in such entity, person or group owning or controlling more than 50% of the voting stock of the **First Named Insured**; or
  - 2. assets of the **First Named Insured** resulting in such entity, person or group owning more than 50% of the total consolidated assets of the **First Named Insured** as of the date of the **First Named Insured's** most recent audited consolidated financial statement prior to such acquisition;
- B. the merger of the **First Named Insured** into another entity such that the **First Named Insured** is not the surviving entity; or
- C. the consolidation of the **First Named Insured** with another entity.

**WRONGFUL ACT**

**Wrongful act** means any actual or alleged negligent act, error or omission in the rendering of **professional services** by any **Insured** on the **Insured Entity's** behalf.

LIFE SCIENCES LIABILITY POLICY PRODUCTS-WORK HAZARD LIABILITY COVERAGE PART

**COVERAGE - Products-Work Hazard Coverage**

The Insurer will pay all amounts in excess of the deductible up to the limit of liability that the **Insured** becomes legally liable to pay as **damages** as a result of:

- A. **bodily injury or property damage** caused by an **occurrence** and arising out of a covered **products-work hazard claim**; or
- B. **personal and advertising injury** arising out of a covered **products-work hazard claim** but solely to the extent such **personal and advertising injury** is caused by an offense and arises out of a **clinical trial**.

provided that coverage applies to **claims** only if:

- 1. such **claim** is both first made against the **Insured** during the **policy period**, or during the **extended reporting period**, if any, and reported to the Insurer in accordance with the **COMMON CONDITIONS**, the section entitled **DUTIES IF THERE IS A CLAIM**;
- 2. prior to the effective date of the **coverage relationship**, no **executive officer** knew or had a basis to believe:
  - a. that any **bodily injury or property damage** had occurred. If any **executive officer** knew, prior to the **coverage relationship**, that any **bodily injury or property damage** had occurred, then any continuation, change or resumption of such **bodily injury or property damage** during or after the **coverage relationship** will be deemed to have been known prior to the **coverage relationship**; or
  - b. that any offense giving rise to **personal and advertising injury** had occurred, in whole or in part;
- 3. prior to the effective date of this policy:
  - a. no **Insured** gave notice to a prior insurer of any **potential claim or related claim**; and
  - b. neither an **Insured** nor the Insurer made a written declaration of a **related claim**; and
- 4. such **occurrence**, or such offense, first occurred on or after the retroactive date, if any, specified in the Declarations.

An **executive officer** will be deemed to know:

- a. that such **bodily injury or property damage** occurred, at the earliest time when such **executive officer**:
  - i. reports the **bodily injury or property damage** to the Insurer or any other insurer;
  - ii. receives a **claim** arising out of the **bodily injury or property damage**; or
  - iii. becomes aware by any other means that the **bodily injury or property damage** has occurred or has begun to occur;
- b. that such offense had occurred, on the date of the first utterance or dissemination or, if there is no dissemination or utterance, on the first date of the activity giving rise to a **claim**.

In addition, the Insurer will pay all **defense costs** in excess of the deductible and up to the limit of liability in connection with a covered **claim**. **Defense costs** are included within and erode both the limits of liability and the deductible.

## SUPPLEMENTARY BENEFITS

### A. Mitigation Expenses

The Insurer will reimburse the **Insured Entity** for **mitigation expenses** up to the **mitigation expenses** sublimits of liability and subject to any applicable coinsurance percentage provided that prior to incurring any **mitigation expenses**:

1. the **Insured Entity** reports the **circumstance** for which the **Insured Entity** intends to incur such **mitigation expenses** in accordance with the section entitled **COMMON CONDITIONS**, the paragraphs entitled **DUTIES AND RIGHTS IN THE EVENT OF A CIRCUMSTANCE OR A POTENTIAL CLASS 1 PRODUCT RECALL** and **DUTIES IF THERE IS A CLAIM**;
2. the **Insured Entity** provides the Insurer with details of the action being contemplated by the **Insured Entity** to minimize any potential **damages** arising out of such **circumstance** and the amount of **mitigation expenses** that are contemplated in connection with such action;
3. the Insurer provides written approval of any **mitigation expenses** prior to such **mitigation expenses** being incurred. No **mitigation expenses** will be approved by the Insurer that are requested less than five business days prior to the planned incurrence of such **mitigation expenses**; and,
4. the **Insured Entity** cooperates with the Insurer in addressing the **circumstance** for which the **Insured Entity** is incurring **mitigation expenses**.

Payment of **mitigation expenses** by the Insurer is not an acknowledgment by the Insurer that a **claim** resulting from the **circumstance** reported pursuant to paragraph 1. above, is a covered **claim**.

### B. Class 1 Product Recall Expenses Reimbursement

The Insurer will reimburse the **Insured Entity** for **class 1 product recall expenses** in excess of the **class 1 product recall expenses** deductible and up to the **class 1 product recall expenses** sublimit of liability and subject to any applicable coinsurance percentage provided that the **class 1 product recall** is initiated during the **policy period** and, prior to the **policy period**, no **executive officer** had prior knowledge of any potential need for such **class 1 product recall**.

### C. Medical Payments

The Insurer will reimburse the **Insured Entity** for **medical expenses** up to the **medical expenses** limit of liability for **bodily injury** caused by an accident that happens in connection with the conduct of a **clinical trial**, provided that:

1. the accident takes place during the **policy period**;
2. the **medical expenses** are incurred by any **Named Insured** and reported to the Insurer within one year of the date of the accident;
3. the injured **clinical trial** test subject submits to examination, at the Insurer's expense, by physicians of the Insurer's choice as often as the Insurer reasonably requires; and
4. such **bodily injury** is not otherwise excluded under the policy.

The Insurer will make these payments regardless of fault.

## LIMITS OF LIABILITY AND DEDUCTIBLES

Subject to **Policy Aggregate Limits of Liability and Deductible** section of the Common Terms and Conditions and the Policy Each Claim and Aggregate Limits of Liability and Deductibles, if any, as set forth on the Declarations:

**A. Limit of Liability—Each Products-Work Hazard Claim**

Subject to paragraph B. below, the limit of liability of the Insurer for **damages** and **defense costs** for each **products-work hazard claim** shall not exceed the amount stated in the Declarations for the **Products-work hazard Coverage** – each **claim limit**.

**B. Limit of Liability– Products-Work Hazard Claim in the Aggregate**

The limit of liability of the Insurer for **damages** and **defense costs** for all **products-work hazard claims** shall not exceed the amount stated on the Declarations as the **Products-work hazard Coverage** aggregate limit.

**C. Supplementary Payment – Mitigation Expenses**

The application of the limits of liability for **mitigation expense** is set forth in the **Common Conditions** and the applicable **mitigation expenses** limits of liability and deductibles are set forth in the Declarations.

**D. Supplementary Benefits Limits - All Class 1 Product Recall Expenses and Medical Expenses**

**1. All Class 1 Product Recall Expenses in the Aggregate**

The sublimit of liability of the Insurer for all **class 1 product recall expenses** shall not exceed \$25,000 in the aggregate unless a different amount is stated in the Declarations. The **class 1 product recall expenses** sublimit set forth in the Declarations is included within and is not in addition to all **products-work hazard claims** in the aggregate limit of liability set forth in the Declarations. As such the **class 1 product recall expenses** sublimit erodes the all **products-work hazard claims** in the aggregate limit of liability set forth in the Declarations.

**2. All Medical Expenses Per Person And in the Aggregate**

**a. Limit of Liability—each person**

Subject to paragraph b. below, the limit of liability of the Insurer for all **medical expenses** for each injured **clinical trial** test subject shall not exceed \$1,000 per injured test subject unless another amount is shown in the Declarations.

**b. Limit of Liability—in the aggregate**

The limit of liability of the Insurer for all **medical expenses** in the aggregate shall not exceed \$5,000 regardless of the number of injured **clinical trial** test subjects, unless another amount is shown in the Declarations.

The **Medical Expenses** Limits are in addition to the “each claim” and the “all claims in the aggregate” limits of liability set forth in the Declarations.

**E. Deductible**

**1. Each Products-Work Hazard Claim and in the Aggregate**

- a. The each **products-work hazard claim** deductible shown in the Declarations, if any, applies to **damages** and **defense costs** for each **products-work hazard claim**.
- b. The aggregate **products-work hazard claim** deductible shown in the Declarations, if any, applies to **damages** and **defense costs** for all **products-work hazard claims** in the aggregate.

**2. All Class 1 Product Recall Expenses in the Aggregate**

The aggregate deductible for all **class 1 product recall expenses** is \$10,000 unless another amount is shown in the Declarations. The **class 1 product recall expenses** deductible is in addition to the each **products-work hazard claim** and aggregate deductible shown in the Declarations.



#### F. Class 1 Product Recall Expenses Coinsurance Provision

The **Insured Entity** must pay a coinsurance percentage of all **class 1 product recall expenses** paid by the Insurer. The coinsurance percentage is 10% for **class 1 product recall expenses** unless a different amount is set forth in the Declarations. This coinsurance percentage is in addition to any applicable deductible. The Insurer is liable to pay the remaining percentage of the **class 1 product recall expenses** up to the applicable limits of liability and in excess of any applicable deductible and coinsurance percentage.

#### EXCLUSIONS

This coverage part does not apply to any claim against any **Insured**:

#### A. Exclusions Applicable to Products–Work Hazard Claims

##### 1. Assumed Liability

based on or arising out of any actual or alleged **bodily injury, property damage or personal and advertising injury** for which any **Insured** is obligated to pay **damages** by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for **damages**:

- a. for which an **Insured** would have been liable in the absence of the contract or agreement; or
- b. 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 part of **defense costs** because of **bodily injury or property damage**, provided:
  - i. liability to such party for, or for the cost of, that party's defense has also been assumed in the same **insured contract**; and
  - ii. 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.

##### 2. Asbestos

based on or arising out of:

- a. the actual, alleged or threatened exposure at any time to **asbestos**, or
- b. any actual or alleged loss, cost or expense that may be awarded or incurred:
  - i. by reason of a **claim** for any such injury or damage; or
  - ii. in complying with a governmental direction or request to test for, monitor, clean up, remove, contain or dispose of **asbestos**.

##### 3. Banned Materials

based on or arising out of **insured product or insured work** that is manufactured, developed, designed, created, tested, sold, leased, licensed, rented, handled, marketed, distributed or disposed of by the **Insured Entity** or others on its behalf in known violation of any law, statute, ordinance or regulation.

For purposes of determining the applicability of this exclusion:

- a. the facts pertaining to and knowledge possessed by any natural person **Insured** shall not be imputed to any other natural person **Insured**; and
- b. only facts pertaining to and knowledge possessed by any **Insured** as set forth under paragraph A. of the definition of **Insured** in the **GLOSSARY OF DEFINED TERMS** shall be imputed to the **Insured Entity**.

#### 4. Dishonest, Fraudulent, Criminal, Malicious Act or Intentionally Wrongful Acts

based on or arising out of any actual or alleged dishonest, fraudulent, criminal, malicious or intentionally wrongful act by any **Insured**. The Insurer shall provide the **Insured** with a defense of such **claim** unless or until the dishonest, fraudulent, criminal, malicious or intentionally wrongful act has been determined by any trial verdict, court ruling, regulatory ruling or legal admission, whether appealed or not. Such defense will not waive any of its rights under this policy. Criminal proceedings are not covered under this policy regardless of the allegations made against an **Insured**.

For purposes of determining the applicability of this exclusion:

- a. the facts pertaining to and knowledge possessed by any natural person **Insured** shall not be imputed to any other natural person **Insured**; and
- b. only facts pertaining to and knowledge possessed by any **Insured** as set forth under paragraph **A.** of the definition of **Insured** in the **GLOSSARY OF DEFINED TERMS** shall be imputed to the **Insured Entity**.

#### 5. Distribution or Recording of Material or Information in Violation of Statutes

**bodily injury, property damage or personal and advertising injury** arising out of any actual or alleged violation of:

- a. the Telephone Consumer Protection Act (TCPA), including any amendment of or addition to such law;
- b. the CAN-SPAM Act of 2003, including any amendment of or addition to such law;
- c. the Fair Credit Reporting Act (FCRA), and any amendment of or addition to such law, including the Fair and Accurate Credit Transaction Act (FACTA);
- d. any statute, ordinance, regulation or law other than the TCPA, CAN-SPAM Act of 2003, or FCRA, including FACTA, and their amendments and additions, that addresses, prohibits, or limits the printing, dissemination, disposal, collecting, recording, sending, transmitting, communicating or distribution of material or information; or
- e. any statute, ordinance, regulation or law which prohibits or limits the conversion or consumption of another's tangible property or electronic assets. For the purpose of this provision, electronic assets include but are not limited to minute allowances, text message allowances, and other electronic consumables.

#### 6. Employer's Liability

based on or arising out of any actual or alleged **bodily injury** to:

- a. the **Insured Entity's employee** arising out of and in the course of:
  - i. employment by the **Insured Entity**; or
  - ii. performing duties related to the conduct of its business; or
- b. the spouse, child, parent, brother or sister of that **employee** as a consequence of paragraph **a.** above.

This exclusion applies:

- a. whether the **Insured Entity** may be liable as an employer or in any other capacity; and
- b. to any obligation to share **damages** with or repay someone else who must pay **damages** because of the injury.



Voluntary participation as a human test subject in a **clinical trial** will not be deemed to be within the course of employment or performance of duties as described in paragraphs **a. i.** and **a. ii.** above.

**7. Expected or Intended Injury**

based on or arising out of any actual or alleged **bodily injury** or **property damage** expected or intended from the standpoint of any **Insured**. This exclusion does not apply to:

- a. **bodily injury** resulting from the use of reasonable force to protect persons or property; or
- b. **bodily injury** that is intended or can be expected to result from reasonable use of **insured product**.

**8. Medical Services**

for **medical services**. However, this exclusion does not apply to:

- a. physicians, dentists, nurses, emergency medical technicians or paramedics employed by the **Insured Entity** to the extent that they are rendering first aid or emergency care; or
- b. to any **products-work hazard claim** made against a **clinical trial investigator** and provided that the **clinical trial investigator** has not deviated from the written clinical trial protocol.

**9. Nuclear**

based on or arising out of:

- a. any actual or alleged **bodily injury, property damage** or any other injury including all forms of radioactive contamination of with respect to which an **Insured** under this policy is also an insured under a nuclear energy liability policy issued by the Nuclear Energy Liability Insurance Association, the Mutual Atomic Energy Liability Underwriters or the 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. or resulting from the **hazardous properties of nuclear material** and with respect to which:
  - i. any person or organization is required to maintain financial protection pursuant to the United States Atomic Energy Act of 1954 or the Canadian Nuclear Liability Act, the Nuclear Safety and Control Act or its Atomic Energy Act, or any amendment of the foregoing; or
  - ii. any **Insured** is, or had this policy not been issued would be, entitled to indemnity from the United States of America or the Government of Canada, or any agency thereof, under any agreement entered into by the United States of America or the government of Canada, or any agency thereof, with any person or organization.
  - iii. any actual or alleged **bodily injury, property damage** or any other injury resulting from the **hazardous properties of nuclear material**, if:
    - a.) the **nuclear material**:
      - (1) is at any **nuclear facility** owned by, or operated by or on behalf of, an **Insured**; or
      - (2) has been discharged or dispersed therefrom;
      - (3) is contained in **spent fuel** or **nuclear waste** at any time possessed, handled, used, processed, stored, transported or disposed of by or on behalf of an **Insured**; or
    - b.) the **bodily injury, property damage** or other injury 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 paragraph **iii.b.)** applies only to **property damage** to such **nuclear facility** and any property threat.

#### 10. Performance Delay

based on or arising out of any actual or alleged delay in delivery of or failure to complete **insured product** or **insured work**. This exclusion does not apply if there is any delay in delivery of or failure to complete **insured product** or **insured work** as a result of a **force majeure**; and

- a. any delay in delivery of or failure to complete **insured product** or **insured work** is not caused by the **Insured Entity's** actions or failure to act; and
- b. the **Insured Entity's** agreement to provide **insured product** or **insured work** was entered into prior to the onset of the **force majeure**.

#### 11. Personal and advertising injury

based on or arising out of any actual or alleged **personal and advertising injury**:

##### a. Breach of Contract

based on or arising out of any actual or alleged breach of contract, except an implied contract to use another's advertising idea in the **Insured Entity's advertisement**.

##### b. Electronic Chat Rooms or Bulletin Boards

based on or arising out of an electronic chat room or bulletin board the **Insured** hosts, owns, or over which the **Insured** exercises control.

##### c. Infringement of Intellectual Property Rights

based on or arising out of any actual or alleged 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 the **Insured Entity's advertisement**. However, this exclusion does not apply to infringement, in the **Insured Entity's advertisement** of copyright, trade dress or slogan.

##### d. Material Published with Knowledge of Falsity

based on or arising out of actual or alleged oral or written publication of material, if the **Insured** knew or should have know the material was false.

##### e. Quality or Performance of Goods – Failure to Conform to Statements

based on or arising out of any actual or alleged failure of goods, products or services to conform to any statement of quality or performance made in the **Insured Entity's advertisement**.

##### f. Unauthorized Use of Another's Name or Product

based on or arising out of any actual or alleged unauthorized use of another's name or product in the **Insured Entity's** e-mail address, domain name or metatag, or any other similar tactics to mislead another's potential customers.

##### g. Wrong Description of Prices

based on or arising out of any actual or alleged wrong description of the price of goods, products or services stated in the **Insured Entity's advertisement**.

## 12. Pollutants

based on or 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** by or on behalf of any governmental authority or others 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**.

## 13. Property Damage to Impaired Property

based on or arising out of any actual or alleged **property damage to impaired property** or property that has not been physically injured, arising out of:

- a. a defect, deficiency, inadequacy or dangerous condition in **insured product** or **insured work**; or
- b. a delay or failure by the **Insured Entity** or someone acting on its behalf to perform a contract or agreement in accordance with its terms.

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

## 14. Property Damage to Property the Insured Entity Owns or in its Care, Custody or Control

based on or arising out of any actual or alleged **property damage** to:

- a. property the **Insured Entity** owns, rents, or occupies, including any costs or expenses incurred by the **Insured Entity**, 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;
- b. premises the **Insured Entity** sells, gives away or abandons, if the **property damage** arises out of any part of those premises;
- c. property loaned to the **Insured Entity**;
- d. personal property in the care, custody or control of any **Insured**; or
- e. that particular part of real property on which the **Insured Entity** or any contractors or subcontractors working directly or indirectly on its behalf are performing operations, if the **property damage** arises out of those operations.

## 15. Property Damage to Insured Products

based on or arising out of any actual or alleged **property damage to insured products** arising out of such products or any part of such products.

## 16. Property Damage to Insured Work

based on or arising out of any actual or alleged **property damage to insured work** arising out of it or any part of it. This exclusion does not apply if the damaged work or the work out of which the damage arises was performed on the **Insured Entity's** behalf by a subcontractor.

## 17. Recall of Insured Product

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

- a. **insured product**;

- b. **insured work**; or
- c. **impaired property**;

if such product, work, or property is withdrawn or recalled from the market or from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition in it. However, this exclusion does not apply to any **claim** for **bodily injury**.

#### 18. War, Civil Insurrection

based on or arising out of any actual or alleged war, whether or not declared, or any act or condition incident to war. War includes civil war, insurrection, rebellion or revolution. This exclusion does not apply if there is any delay in delivery of or failure to complete **insured product** or **insured work** as a result of a **force majeure** that is war or civil insurrection; and

- a. any delay in delivery of or failure to complete **insured product** or **insured work** is not caused by the **Insured Entity's** actions or failure to act; and
- b. the **Insured Entity's** agreement to provide **insured product** or **insured work** was entered into prior to the onset of the **force majeure**.

#### B. Exclusions Applicable to Class 1 Product Recalls

This **coverage part** does not apply to any **class 1 product recall expenses** due to:

##### 1. Caprice

caprice or whim of any **Insured**.

##### 2. Chemical Change

deterioration, decomposition or transformation of a chemical nature, except if caused by an error in the design, manufacturing, processing, packaging, handling, distributing, labeling, storage or transportation of **insured product**.

##### 3. Faulty Formula

improper, inadequate or faulty formula or specifications, unless there is a reasonable probability that such improper, inadequate or faulty formula or specifications will cause **bodily injury** or **property damage**.

##### 4. Intended Purpose

failure of **insured product** to accomplish its intended purpose, including any breach of warranty of fitness, quality, efficacy or efficiency, whether written or implied.

##### 5. Loss of Reputation

loss of reputation, customer faith or approval, or any costs incurred to regain customer market, or any other consequential damages.

##### 6. Prior Circumstances

any fact, **circumstance** or situation that at the inception of the **policy period** or the date the **Insured Entity** relinquished **insured product** to others;

- a. was known to any **insured** or was reasonably foreseeable by any **insured**; and
- b. that would cause a reasonable person to believe a **class 1 product recall** would result.

##### 7. Redistribution or Replacement



redistribution or replacement of the withdrawn products by like products or substitutions.

**8. Shelf Life**

**insured product** exceeding its designated shelf life.

**9. Withdrawal of Similar Products**

the withdrawal of similar products or batches that are not defective, when a defect in another product or batch has been found.



EXCLUSION OF CERTIFIED ACTS OF TERRORISM ENDORSEMENT

It is understood and agreed as follows:

The **First Named Insured** has been previously notified of the availability of and the price for coverage of **certified acts of terrorism** under the Federal Terrorism Risk Insurance Act. The **First Named Insured** has opted to exclude such coverage from the applicable **coverage part**. This endorsement excludes such **certified acts of terrorism** from the applicable **coverage part**.

I. The following exclusion is added:

**TERRORISM**

The applicable **coverage part** does not apply to any injury or damage arising, directly or indirectly, out of a **certified act of terrorism**.

II. The following definitions are added:

- A. For the purposes of this endorsement, any injury or damage means any injury or damage covered under any **coverage part** to which this endorsement is applicable, and includes but is not limited to **bodily injury, property damage and personal and advertising injury**.
- B. **Certified act of terrorism** means an act that is certified by the Secretary of the Treasury, in consultation with the Secretary of Homeland Security and the Attorney General of the United States, to be an act of terrorism pursuant to the federal Terrorism Risk Insurance Act. The criteria contained in the Terrorism Risk Insurance Act for a **certified act of terrorism** include the following:
  - 1. The act resulted in insured losses in excess of \$5 million in the aggregate, attributable to all types of insurance subject to the Terrorism Risk Insurance Act; and
  - 2. The act is a violent act or an act that is dangerous to human life, property or infrastructure and is committed by an individual or individuals as part of an effort to coerce the civilian population of the United States or to influence the policy or affect the conduct of the United States Government by coercion.

All other terms and conditions of the policy remain unchanged.

This endorsement, which forms a part of and is for attachment to the policy issued by the designated Insurers, takes effect on the Policy Effective Date of said policy at the hour stated in said policy, unless another effective date (the Endorsement Effective Date) is shown below, and expires concurrently with said policy unless another expiration date is shown below.

Form No: CNA71826XX (01-2015)

Endorsement Effective Date:

Endorsement No: 1; Page: 1 of 1

Underwriting Company: Continental Casualty, 151 N Franklin St, Chicago, IL 60606

Endorsement Expiration Date:

Policy No: ADT 6071846730

Policy Effective Date: 08/01/2019

Policy Page: 38 of 44



INTRA-ARTICULAR USE EXCLUSION ENDORSEMENT

This endorsement modifies insurance provided under:

**Professional Liability Coverage Part**

**Products–Work Hazard Liability Coverage Part**

It is understood and agreed that the section entitled **EXCLUSIONS** of any **coverage part** is amended by the addition of the following new exclusion:

- This **coverage part** does not apply to any **claim** based on or arising out of the intra-articular use of any device to deliver any medication to the patient, including the intra-articular use of a pain pump or the intra-articular use of a continuous infusion device.

All other terms and conditions of the policy remain unchanged.

This endorsement, which forms a part of and is for attachment to the policy issued by the designated Insurers, takes effect on the Policy Effective Date of said policy at the hour stated in said policy, unless another effective date (the Endorsement Effective Date) is shown below, and expires concurrently with said policy unless another expiration date is shown below.

Form No: CNA73195XX (05-2015)

Endorsement Effective Date:

Endorsement No: 2; Page: 1 of 1

Underwriting Company: Continental Casualty, 151 N Franklin St, Chicago, IL 60606

Endorsement Expiration Date:

Policy No: ADT 6071846730

Policy Effective Date: 08/01/2019

Policy Page: 39 of 44



TDM USA INC.  
SPECIFIED PRODUCTS EXCLUSION ENDORSEMENT

This endorsement modifies insurance provided under:

**Products–Work Hazard Liability Coverage Part**

**Professional Liability Coverage Part**

It is understood and agreed that the section of the **coverage part** entitled **EXCLUSIONS** is amended by the addition of the following new exclusion:

This **coverage part** does not apply to any **claim** based on or arising out of the testing or other use of any product made of or containing any of the substances designated by a check in the corresponding box as follows:

- Dexfenfluramine;
- Fenfluramine;
- Phentermine;
- Thalidomide;
- Silicone Gel used as an injection or as a part of an implantable device;
- Accutane;
- Birth Control devices and medications;
- Diethylstilbestrol (DES);
- Swine Flu vaccine;
- Phenylpropanolamine;
- Testosterone;
- Latex;
- Other:

Opioids and opiates including any claim based on or arising out of any actual or alleged:

1. liability under, non-compliance with, or violation of, any federal, state, local, or foreign act, statute, regulation, ordinance, requirement, law, or common law, or
2. manufacturing, developing, monitoring, designing, creating, selling, leasing, licensing, renting, handling, marketing, branding, promoting, distributing, diverting or disposal of such product, or
3. improper warning or failure to warn including any warning of the adverse or addictive properties of such product,

by any Insured or by anyone for whose acts the Insured is liable.

Kratom

All other terms and conditions of the policy remain unchanged.

This endorsement, which forms a part of and is for attachment to the policy issued by the designated Insurers, takes effect on the Policy Effective Date of said policy at the hour stated in said policy, unless another effective date (the Endorsement Effective Date) is shown below, and expires concurrently with said policy unless another expiration date is shown below.

Form No: CNA73217XX (05-2015)

Endorsement Effective Date:

Endorsement No: 3; Page: 1 of 1

Underwriting Company: Continental Casualty, 151 N Franklin St, Chicago, IL 60606

Endorsement Expiration Date:

Policy No: ADT 6071846730

Policy Effective Date: 08/01/2019

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CANCELLATION AND NON-RENEWAL ENDORSEMENT - UTAH

Wherever used in this endorsement: 1) Insurer means "we", "us", "our" or the "Company" as those terms may be defined in the policy; and 2) Named Insured means the first person or entity named on the declarations page; and 3) "Insureds" means all persons or entities afforded coverage under the policy.

Any cancellation, non-renewal or termination provisions in the policy are deleted in their entirety and replaced with the following:

**CANCELLATION AND NON-RENEWAL**

**I. CANCELLATION**

- A. The Named Insured may cancel the policy at any time. To do so, the Named Insured must return the policy to the Insurer or any of its authorized representatives, indicating the effective date of cancellation; or provide a written notice to the Insurer, stating when the cancellation is to be effective.
- B. The Insurer has the right to cancel this policy at any time and for any reason within the first sixty (60) days. Such cancellation shall be effective ten (10) days after the Named Insured receives the notice of cancellation. If such notice is mailed, proof of mailing will be sufficient proof of notice that the Named Insured received the notice on the third business day after the date of mailing.
- C. After this policy has been in effect for sixty (60) days or more, it may be canceled for one of the following reasons:
  - 1. Non-payment of premium;
  - 2. Substantial change in the risk assumed if such change should not have been foreseen by the Insurer or contemplated in the rate;
  - 3. Substantial breach of contractual duties, conditions, or warranties;
  - 4. Policy obtained through material misrepresentation;
  - 5. attainment of the age specified as the terminal age for coverage.

The Insurer must mail via first class or deliver notice of cancellation at least ninety (90) days prior to the effective date of such cancellation. If cancellation is for non-payment of premium, the Insurer must mail via first class or deliver notice of cancellation at least ten (10) days prior to the effective date of such cancellation. All notices shall state the reason for cancellation.

**II. PREMIUM REFUND**

If this policy is cancelled, the Insurer will send the Named Insured any premium refund due. If the Insurer cancels the refund will be pro rata. If the Named Insured cancels, the refund may be less than pro rata. The cancellation will be effective even if the Insurer has not made or offered a refund.

**III. NON-RENEWAL**

The Insurer has the right to non-renew this policy effective of any Policy anniversary date. All notices of non-renewal must be mailed via first class mail or delivered to the Named Insured at the last mailing address known to the Insurer, at least thirty (30) days prior to the effective date of non-renewal and shall provide a specific explanation of the reasons for non-renewal.

**IV. ADDITIONAL REQUIREMENT**

- A. The Insurer will mail via first class mail or deliver a thirty (30) day written notice if the Insurer intends to renew on less favorable terms or at higher rates.



- B.** If the Insurer does not provide prior notification described above, the new terms or rates do not take effect until thirty (30) days after the notice is delivered or sent by first class mail, in which case the Named Insured may elect to cancel the renewal policy at any time during the thirty (30) day period.
- C.** This section does not apply if the only change that is adverse to the Insured is:
  - 1.** a rate increase generally applicable to the class of business to which the policy belongs;
  - 2.** a rate increase resulting from a classification change based on the altered nature or extent of the risk insured against; or
  - 3.** a policy form change made to make the form consistent with Utah law.

All other terms and conditions of the policy remain unchanged.

This endorsement, which forms a part of and is for attachment to the policy issued by the designated Insurers, takes effect on the Policy Effective Date of said policy at the hour stated in said policy, unless another effective date (the Endorsement Effective Date) is shown below, and expires concurrently with said policy unless another expiration date is shown below.

Form No: CNA73247UT (05-2015)

Endorsement Effective Date:

Endorsement No: 4; Page: 2 of 2

Underwriting Company: Continental Casualty, 151 N Franklin St, Chicago, IL 60606

Endorsement Expiration Date:

Policy No: ADT 6071846730

Policy Effective Date: 08/01/2019

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BROAD MESH AND SIMILAR PRODUCTS EXCLUSION ENDORSEMENT

This endorsement modifies insurance provided under:

**Professional Liability Coverage Part**

**Products–Work Hazard Liability Coverage Part**

It is understood and agreed that the following new exclusion is added:

This **coverage part** does not apply to any **claim** based on or arising out of the actual or alleged manufacture, development, design, creation, testing, sale, lease, licensing, handling, marketing, distribution, disposition or use of any product made of or containing surgical or implantable mesh or any similar product, whether biologic, synthetic or any combination thereof.

All other terms and conditions of the policy remain unchanged.

This endorsement, which forms a part of and is for attachment to the policy issued by the designated Insurers, takes effect on the Policy Effective Date of said policy at the hour stated in said policy, unless another effective date (the Endorsement Effective Date) is shown below, and expires concurrently with said policy unless another expiration date is shown below.

Form No: CNA76299XX (05-2015)

Endorsement Effective Date:

Endorsement No: 5; Page: 1 of 1

Underwriting Company: Continental Casualty, 151 N Franklin St, Chicago, IL 60606

Endorsement Expiration Date:

Policy No: ADT 6071846730

Policy Effective Date: 08/01/2019

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SPECIFIED PRODUCTS EXCLUSION ENDORSEMENT - METAL ON METAL IMPLANT DEVICES

This endorsement modifies insurance provided under:

**Professional Liability Coverage Part**

**Products–Work Hazard Liability Coverage Part**

It is understood and agreed that the section entitled **EXCLUSIONS** of the **coverage part** is amended by the addition of the following new exclusion:

This **coverage part** does not apply to any **claim** against any **Insured** based on or arising out of the actual or alleged manufacture, development, design, creation, testing, sale, lease, licensing, handling, marketing, distribution, disposition or use of:

- a. any hip implant, hip replacement or hip resurfacing system and the component parts thereof in which the femoral and acetabular articulating surfaces are made of a metal element or metal alloy in direct contact with each other;
- b. any knee implant, knee replacement or knee resurfacing system and the component parts thereof in which the femoral and tibial articulating surfaces are made of a metal element or metal alloy in direct contact with each other; or
- c. any joint implant, joint replacement or joint resurfacing system and the component parts thereof, no matter where used in the body, in which the articulating surfaces of the joint are made of a metal element or metal alloy in direct contact with each other.

All other terms and conditions of the policy remain unchanged.

This endorsement, which forms a part of and is for attachment to the policy issued by the designated Insurers, takes effect on the Policy Effective Date of said policy at the hour stated in said policy, unless another effective date (the Endorsement Effective Date) is shown below, and expires concurrently with said policy unless another expiration date is shown below.

Form No: CNA78635XX (05-2015)

Endorsement Effective Date:

Endorsement No: 6; Page: 1 of 1

Underwriting Company: Continental Casualty, 151 N Franklin St, Chicago, IL 60606

Endorsement Expiration Date:

Policy No: ADT 6071846730

Policy Effective Date: 08/01/2019

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