



### 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:

- 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.

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### **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**:

- the Insured Entity reports the claim or 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 claim or 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 **claim** or **circumstance** for which the **Insured Entity** is incurring **mitigation expenses**.

Payment of **mitigation expenses** is not an acknowledgment by the Insurer that the **claim** reported pursuant to paragraph 1. above, or 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:

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### 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.

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#### 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.

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# 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
- 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.

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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. Latex

based on or arising out of the actual, alleged or threatened, inhalation of, ingestion of, contact with, exposure to, existence of, or presence of latex allergens.

#### 9. 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.

## 10. 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,

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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.

#### 11. 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**.

### 12. 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

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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**.

#### 13. 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**.

### 14. 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.

### 15. 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.

## 16. 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.

#### 17. 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.

#### 18. Recall of Insured Product

for any loss, cost or expense incurred for the loss of use, withdrawal, recall, inspection, repair,

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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**.

### 19. 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

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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.

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