



兆豐產物保險股份有限公司
Chung Kuo Insurance Company, Limited

兆豐產物生命科學綜合責任保險 Chung Kuo Life Science Liability Insurance

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107年12月21日兆產備字第1074300790號函備查

PLEASE READ THIS POLICY CAREFULLY TO DETERMINE YOUR RIGHTS AND RESPONSIBILITIES.

Throughout this policy the words "you" and "your" refer to the **First Named Insured** and all other Named Insureds, if any, shown in the Declarations, and any other person or organization qualifying as a Named Insured under this Policy. The words "we", "us" and "our" refer to the Company providing this insurance. The word "insured" means any person or organization qualifying as such under **SECTION II – WHO IS AN INSURED**. Other words and phrases that appear in **bold** type have special meaning. Refer to **SECTION VI – DEFINITIONS**.

The following coverages apply if purchased by the **First Named Insured** as shown on the Declarations.

SECTION I – COVERAGE PART INSURING AGREEMENTS

In consideration of the payment of the policy premium when due and in reliance upon the statements contained in the Application and any other supplemental materials and information submitted to us, and subject to all of the terms, conditions, exclusions and limitations of this Policy and the **KNOWN CRITICAL FACTS REPORTING REQUIREMENT** set forth in **COMMON COVERAGE PROVISIONS** below, we agree with you as follows:

A. COVERAGE PART A – PRODUCTS-COMPLETED OPERATIONS LIABILITY

1. BODILY INJURY AND PROPERTY DAMAGE – CLAIMS MADE COVERAGE

- a. We will pay all **damages** that the insured becomes legally obligated to pay for **bodily injury** or **property damage** included within the **products-completed operations hazard**.
- b. We will also pay all **defense costs** to defend a **claim** seeking such **damages**.
- c. This Coverage applies only if:
 - (1) A **claim** for such **bodily injury** or **property damage** is first made against the insured during the policy period or, if applicable, the **extended reporting period**; and
 - (2) The **bodily injury** or **property damage** takes place:
 - on or after the **retroactive date** and
 - before the end of the policy period.

2. COVERAGES ADDRESSED BY OTHER COVERAGE PARTS

Coverage above does not apply to **bodily injury** or **property damage** caused by or directly

resulting from participation in a **clinical trial**, or which is otherwise covered under **COVERAGE PART C – CLINICAL TRIAL COVERAGE**.

B. COVERAGE PART B – PREMISES OPERATIONS LIABILITY – OCCURRENCE COVERAGE

1. We will pay all **damages** that the insured becomes legally obligated to pay for **bodily injury** or **property damage** not included within the **products-completed operations hazard** caused by an **occurrence**.
2. We will also pay all **defense costs** to defend a **claim** seeking such **damages**.
3. This Coverage Part applies only if the **bodily injury** or **property damage** takes place during the policy period.

4. COVERAGES ADDRESSED BY OTHER COVERAGE PARTS

This Coverage Part does not apply to **bodily injury** or **property damage**:

- a. Falling within the **products-completed operations hazard** or otherwise covered under **COVERAGE PART A – PRODUCTS-COMPLETED OPERATIONS LIABILITY**; or
- b. Based upon or arising out of a **clinical trial** or otherwise covered under **COVERAGE PART C – CLINICAL TRIAL COVERAGE**.

C. COVERAGE PART C – CLINICAL TRIAL COVERAGE

SUBPART 1. CLINICAL TRIAL BODILY INJURY OR PROPERTY DAMAGE LIABILITY – CLAIMS MADE COVERAGE

- a. We will pay all **damages** that the insured becomes legally obligated to pay for **bodily injury or property damage** caused by, or directly resulting from participation in, an **approved clinical trial**.
- b. We will also pay all **defense costs** to defend a **claim** seeking such **damages**.
- c. This Coverage Subpart applies only if:
 - (1) A **claim** for such **bodily injury or property damage** is first made against the insured during the policy period or, if applicable, the **extended reporting period**;
 - (2) The **bodily injury or property damage** takes place:
 - on or after the **retroactive date**; and
 - before the end of the policy period; and
 - (3) The **clinical trial participant**, if a claimant, was not first exposed to the material tested in the **approved clinical trial** prior to the **retroactive date**.

SUBPART 2. MEDICAL MONITORING EXPENSE COVERAGE IN THE ABSENCE OF PHYSICAL INJURY, SICKNESS OR DISEASE FOLLOWING SUSPENSION OF CLINICAL TRIAL – CLAIMS MADE COVERAGE

- a. We will pay all **damages** that the insured becomes legally obligated to pay for **medical monitoring expense** caused by, or directly resulting from participation in, an **approved clinical trial**.
- b. We will also pay all **defense costs** to defend a **claim** seeking such **damages**.
- c. This Coverage Subpart applies only if:
 - (1) A **claim** for such **medical monitoring expense** is first made against the insured during the policy period or, if applicable, the **extended reporting period**;
 - (2) The claimant was not first exposed to the product or material requiring claimant to incur **medical monitoring expense** prior to the **retroactive date** or after the suspension of the **approved clinical trial**; and
 - (3) The **clinical trial** is placed on hold or is suspended by:
 - (a) The Taiwan Food and Drug Administration;

- (b) A comparable governmental entity outside Taiwan having jurisdiction over the **clinical trial**; or
 - (c) The Named Insured;
- for the sole reason, expressed in writing, that human subjects are or would be exposed to an unreasonable and significant risk of illness or injury if the **clinical trial** were continued.

D. COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY FOR ECONOMIC INJURY – CLAIMS MADE COVERAGE

1. We will pay all **damages** that the insured becomes legally obligated to pay for **economic injury** caused by an unintentional:
 - error;
 - act; or
 - omissionon the part of the insured while conducting your business, if such error, act or omission causes any of the following:
 - **Your product** to become defective, deficient, inadequate or dangerous; or
 - **Your work** to be performed in a manner inconsistent with, or **your product** to not function as required by, the terms and conditions of a written agreement executed by the Named Insured prior to such error, act or omission.
2. We will also pay all **defense costs** to defend a **claim** seeking such **damages**.
3. This Coverage Part applies only if:
 - a. A **claim** for such **economic injury** is first made against the insured during the policy period or, if applicable, the **extended reporting period**; and
 - b. The **economic injury** takes place
 - on or after the **retroactive date**; and
 - before the end of the policy period.

4. COVERAGES ADDRESSED BY OTHER COVERAGE PARTS

This Coverage Part does not apply to any injury, damage, expense or cost otherwise covered under any other Coverage Part or Subpart of or endorsement attached to this Policy.

COMMON COVERAGE PROVISIONS

APPLICABLE TO ONE OR MORE COVERAGE PARTS

DEFENSE OBLIGATIONS

1. For any Coverage Part or Subpart under which we have an obligation to pay **defense costs**, we will have the right but no duty to defend the insured against any **claim** seeking **damages** under such Coverage Part or Subpart · whether or not a **suit** has been filed. We have the right to select counsel to defend the insured against any such **claim**.
2. We may at our discretion investigate any **claim** or **occurrence** and defend or settle any **claim** or **suit** that may result. We shall have the right to designate legal counsel for the investigation, adjustment or defense of any **claims** or **suits**.
3. Our obligation to pay defense costs ends when we have used up the applicable limit of insurance as set forth in **SECTION III – LIMITS OF INSURANCE**.

COVERAGE TERRITORY

This Policy applies to **loss** taking place, or arising out of an event or **occurrence** taking place in the Territory specified in the Declarations.

EXTENDED REPORTING PERIODS

1. When Extended Reporting Periods Apply

a. **Extended reporting periods** apply to all claims-made coverages where:

- (1) This Policy is canceled or not renewed by you or by us; or
- (2) We renew or replace this Policy with insurance that:
 - (a) Has a retroactive date later than the date shown in the Declarations; or
 - (b) Does not apply to **loss** covered on a claims-made basis.

b. **Extended reporting periods** do not extend the policy period or change the scope of coverage provided.

They apply only to **claims** for **loss** provided that such **loss**:

- (1) Is covered under a claims-made Coverage Part or Subpart or claims-made endorsement; and
- (2) Occurs before the end of the policy period, but not before the **retroactive date**, if any, shown in the Declarations.

c. Once in effect, **extended reporting periods** may not be canceled.

d. **Extended reporting periods** do not:

- (1) Apply to **claims** that are covered under any subsequent insurance you purchase, or that would be covered but for exhaustion of the amount of insurance applicable to such **claims**; or
- (2) Reinstate or increase the limits of insurance.

2. Basic Extended Reporting Period

a. A **basic extended reporting period** is automatically provided without additional charge.

This period starts with the end of the policy period and lasts for sixty (60) days.

b. **Claims** made against the insured during the **basic extended reporting period** are covered provided that:

- (1) The **loss** takes place before the expiration of the policy period;
- (2) **Claims** for such **loss** are reported to us, through written notice to our **claims** department, within sixty (60) days from the earlier of:
 - (a) The date the insured received notice of the **claim**; or
 - (b) The expiration of the policy period; and
- (3) The **loss** is otherwise covered under this Policy.

3. Supplemental Extended Reporting Period

a. A **supplemental extended reporting period** is provided under the following circumstances:

- (1) The **First Named Insured** may purchase a **supplemental extended reporting period** of five (5) years duration which shall commence immediately following the expiration of the **basic extended reporting period**.
- (2) This **supplemental extended reporting period** may only be purchased if the **First Named Insured**:
 - (a) Notifies us in writing prior to the expiration of the policy period that it has elected to purchase a **supplemental extended reporting period**; and
 - (b) The full premium for the **supplemental extended reporting period** is paid and received by us within thirty (30) days of:
 - providing such notice to us, or
 - the expiration of the policy period,whichever is sooner.

Once the premium is fully paid and received by us, the premium is fully earned, and the **supplemental extended reporting period** may not be cancelled by you or us.

b. At our sole discretion, we may make a longer **supplemental extended reporting period** available by endorsement.

- c. The premium charged for a **supplemental extended reporting period** of five (5) years duration shall be no greater than two hundred percent (200%) of the premium for this Policy.
- d. **Claims** made against the insured during the **supplemental extended reporting period** are covered provided that:
 - (1) The **loss** takes place before the expiration of the policy period;
 - (2) **Claims** for such **loss** are reported to us, through written notice to our **claims** department, within sixty (60) days from the earlier of:
 - (a) The date the insured received notice of the **claim**; or
 - (b) The expiration of the **supplemental extended reporting period**; and
 - (3) The **loss** is otherwise covered under this Policy.
- e. If a **supplemental extended reporting period** is purchased, we shall issue an endorsement setting forth the terms, not inconsistent with this Section, which shall apply to such period.

LOSS TO SAME PERSON OR ORGANIZATION

1. The following provision applies to all claims-made Coverage Parts or Subparts:
 - All **claims** for **damages** because of:
 - **bodily injury** to the same person, including **damages** claimed by any person or organization for care, loss of services, or death resulting at any time from the **bodily injury**;
 - **medical monitoring expense** applicable to the same person; or
 - **property damage** to the same person or organization;
 will be deemed to have been made at the time the first of those **claims** is made against any insured.
2. The following provision applies to all Coverage Parts or Subparts applicable to **bodily injury**: **Damages** because of **bodily injury** to any one person include **damages** claimed by any person or organization for care, loss of services or death resulting at any time from such **bodily injury** to that person.

KNOWN CRITICAL FACTS REPORTING REQUIREMENT

1. No coverage is afforded under this Policy for any **loss** connected to a **critical fact** known by an **Insured Representative** prior to the inception date of this Policy unless:
 - a. The **critical fact** is set forth in an endorsement listing covered known **critical facts**; or
 - b. If this is a **renewal policy**:
 - (1) The **critical fact** first becomes known to an **insured representative** after the **initial coverage date**; and
 - (2) You have reported the **critical fact** to us prior to the inception date of this **renewal policy**.

Loss is connected to a **critical fact** if such **loss** arises out of the **critical fact**, or if the facts and circumstances resulting in the **critical fact** also resulted in the **loss**.
A **critical fact** set forth in a document in the possession of an **Insured Representative** shall be considered known by the **Insured Representative**.
2. This requirement applies to all Coverage Parts and Subparts set forth above and any coverages added by Endorsement.

SECTION II – WHO IS AN INSURED

A. Named Insureds

The following persons or organizations are Named Insureds under this Policy:

1. Designated Named Insureds

The **First Named Insured** and all persons or organizations designated as Named Insureds in the Declarations of this Policy.

2. Subsidiaries of the First Named Insured

Any organization over which the **First Named Insured** maintains, either directly or indirectly, fifty percent (50%) or greater of the interests entitled to vote generally in the election of the governing body of such organization, at both of the following times:

- the beginning of the policy period; and
- the time of the **loss**.

3. Organizations Newly Acquired or Formed

Any organization the **First Named Insured** newly acquires or forms, and over which the **First Named Insured** maintains fifty percent (50%) or greater of the interests entitled to vote generally in the election of the governing body of such organization at both of the following times:

- The date of acquisition or formation of such organization during the policy period or, if acquired or formed before the policy period, then the inception date of the policy period; and
- The time of the **loss**;

but only if there is no other similar insurance available to the newly formed or acquired organization.

However, coverage under this provision is afforded only until the 90th day after the **First Named Insured** acquires or forms the organization or the end of the policy period, whichever is earlier.

B. Insureds Based Upon Association with Named Insured(s)

If the Named Insured is designated in the Declarations as:

1. A partnership (including a limited liability partnership) or joint venture, then the following are insureds:

- The Named Insured shown; and
- The partners or members and the spouses of such partners or members, but only with respect to the conduct of the Named Insured's business.

2. A limited liability company, then the following are insureds:

- The Named Insured shown and the members of the Named Insured, but only with respect to the conduct of the Named Insured's business; and
- The managers of the Named Insured, but only with respect to their duties as the Named Insured's managers.

3. An organization other than a partnership, joint venture or limited liability company, then the following are insureds:

- The Named Insured shown;
- The **executive officers** and directors of the Named Insured, but only with respect to their duties as such officers or directors;
- The stockholders of the Named Insured, but only with respect to their liability as stockholders ; and
- The managers of the Named Insured, but only with respect to their duties as the Named Insured's managers.

C. Other Insureds

1. Employees and Volunteer Workers

- a. Your **employees** other than:

- Your **executive officers** (if you are an organization other than a partnership, joint venture or limited liability company); or
 - Your managers (if you are a limited liability company);
- are insureds, but only for acts within the scope of their employment by you or while performing duties related to the conduct of your business; and
- b.** Your **volunteer workers** are insureds, but only while performing duties related to the conduct of your business.
- c.** No **employee** or **volunteer worker** is an insured for:
- (1) Loss:**
- To you;
 - To your partners or members (if you are a partnership or joint venture);
 - To your members (if you are a limited liability company);
 - To a co-**employee** while in the course of his or her employment or performing duties related to the conduct of your business; or
 - To your other **volunteer workers** while performing duties related to the conduct of your business;
- (2) Loss** to the spouse, child, parent, brother or sister of that co-**employee** or **volunteer worker** as a consequence of Paragraph **c.(1)** above;
- (3) Loss** for which there is any obligation to share **damages** with or repay someone else who must pay **damages** because of the **Loss** described in Paragraphs **c.(1)** or **(2)** above; or
- (4) Property damage** to property:
- Owned, occupied or used by, or
 - Rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose by you, any of your **employees**, **volunteer workers**, any partner or member (if you are a partnership or joint venture), or any member (if you are a limited liability company).

2. Lessors of Equipment

- a.** Any person or organization from which you lease equipment is an insured for the lessor's liability for **loss** in the form of **bodily injury or property damage**, but only if:
- (1)** You have agreed to add such person or organization as an insured for such **loss** pursuant to a written contract you entered into with that person or organization prior to the event which resulted in the **loss** for which coverage is sought; and
- (2)** Liability for such **loss** is caused, in whole or in part, by your maintenance, operation or use of such equipment.
- b.** Such persons or organizations are insureds only to the extent, and for the limits of insurance, required by the contract; however, the following shall also apply:
- (1)** In no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy;
- (2)** No such person or organization is an insured with respect to liability for which the person or organization has agreed to assume the liability of another to pay **loss**, unless the person or organization would be liable in the absence of such agreement;
- (3)** If a person or organization is an insured under this Paragraph **2.**, then the term "you" or "your" as used in all exclusions applicable to this Policy shall also mean such person or organization, and all exclusions applicable to the Named Insured shall also apply to such person or organization; and
- (4)** No such person or organization is an insured with respect to any:
- **Loss** arising out of such person or organization's sole negligence; or
 - **Occurrence** that takes place, or, in the case of claims-made coverage, **loss** that occurs or **claim** that is made against the insured, after the equipment lease

expires.

- c. A person's or organization's status as an insured under this Paragraph 2. ends when their contract or agreement with you for such leased equipment ends.

3. Lessors of Premises

- a. Any person or organization from which you lease premises is an insured for the lessor's liability for **loss** in the form of **bodily injury** or **property damage**, but only if:
 - (1) You have agreed to add such person or organization as an insured for such **loss** pursuant to a written contract you entered into with that person or organization prior to the event which resulted in the **loss** for which coverage is sought; and
 - (2) Liability for such **loss** is caused, in whole or in part, by the ownership, maintenance or use of that part of the premises leased to you.
- b. Such persons or organizations are insureds only to the extent, and for the limits of insurance, required by the contract; however, the following shall also apply:
 - (1) In no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy;
 - (2) No such person or organization is an insured with respect to liability for which the person or organization has agreed to assume the liability of another to pay **loss**, unless the person or organization would be liable in the absence of such agreement;
 - (3) If a person or organization is an insured under this Paragraph 3., then the term "you" or "your" as used in all exclusions applicable to this Policy shall also mean such person or organization, and all exclusions applicable to the Named Insured shall also apply to such person or organization; and
 - (4) No such person or organization is an insured with respect to any:
 - **Loss** arising out of such person or organization's sole negligence;
 - **Occurrence** that takes place, or, in the case of claims-made coverage, **loss** that occurs or **claim** that is made against the insured, after you cease to be a tenant in the leased premises; or
 - Structural alterations, new construction or demolition operations performed by or on behalf of such person or organization.

4. Vendors

- a. Any person or organization which is a vendor of **your product** is an insured for the vendor's liability for **loss** in the form of **bodily injury**, or **property damage** but only if:
 - (1) You have agreed to add the vendor as an insured for such **loss** pursuant to a written contract you entered into with the vendor prior to the event which resulted in the **loss** for which coverage is sought;
 - (2) The **loss** arises out of **your product** distributed or sold in the regular course of the vendor's business; and
 - (3) The vendor is not a **life science contractor**.
- b. Such vendors are insureds only to the extent, and for the limits of insurance, required by the contract; however, the following shall also apply:
 - (1) In no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy; and
 - (2) If a vendor is an insured under this Paragraph 4., then the term "you" or "your" as used in all exclusions applicable to this Policy shall also mean the vendor as insured, and all exclusions applicable to a Named Insured shall also apply to the vendor.
- c. No vendor is an insured for **loss**:
 - (a) Which the vendor is obligated to pay by reason of the assumption of liability in a contract or agreement; however, this limitation does not apply to liability for which the vendor would have in the absence of an agreement;
 - (b) Based upon or arising out of:

- (i) Any expressed warranty or representation unauthorized by you;
- (ii) Any physical or chemical change in **your product** made intentionally by the vendor;
- (iii) Repackaging of **your product**:
Except when unpacked solely for the purpose of inspection, demonstration, testing, or the substitution of parts under instructions from the manufacturer, and then repackaged in the original container;
- (iv) Any failure to make such inspections, adjustments, tests or servicing that 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 **your product**, or any failure to remove from sale or distribution **your product** once the shelf life or expiration date of such product has been reached;
- (v) Demonstration, installation, servicing or repair operations regarding **your product**:
Except such operations performed at the vendor's premises in connection with the sale of **your product**;
- (vi) **Your product** which, after distribution or sale by you, has been labeled or relabeled or used as a container, ingredient or part of any other thing or substance, by or for the vendor;
- (vii) The sale or distribution of **your product** under the name of the vendor;
- (viii) The sole negligence of the vendor for its own acts or omissions or those of its employees or anyone else acting on its behalf; however, this exclusion does not apply to the exceptions set forth in Subparagraphs **4c(b)(iii)** and **(v)** above, or to those inspections, adjustments, tests or servicing the vendor has agreed to undertake or normally undertakes in the usual course of business, in connection with the distribution or sale of **your product**;
- (c) If the vendor is the same person or organization from which you have acquired **your product**, or any ingredient, part or container, entering into, accompanying or containing **your product**; or
- (d) If the vendor dispenses, distributes, furnishes or sells a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food to any health care provider for the purpose of providing **healthcare services** to others.

5. Life Science Contractors

- a. The following life science contractors, whether:

- (1) Clinical trial contractors,
- (2) Product sales contractors or
- (3) Product service contractors;

are insureds for the **life science contractor's** liability for **loss** in the form of **bodily injury, property damage, or medical monitoring expense**, but only if:

- (a) The **loss** is caused, in whole or in part, by **your work or your product**;
 - (b) The **life science contractor** is no more than fifty percent (50%) at fault for the **loss**; and
 - (c) You have agreed to add the **life science contractor** as an additional insured for such **loss** pursuant to a written contract you entered into with the **life science contractor** prior to the **loss**.
- b. Such **life science contractors** are insureds only to the extent, and for the limits of insurance, required by the contract; however, the following shall also apply:
 - (1) In no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy;

- (2) No **life science contractor** is an insured with respect to liability for which the **life science contractor** has agreed to assume the liability of another to pay **loss**, unless the **life science contractor** would have such liability in the absence of such agreement; and
- (3) If a **life science contractor** is an insured under this Paragraph 5., then the term “you” or “your” as used in all exclusions applicable to this Policy shall also mean **life science contractors**, and all exclusions applicable to the Named Insured shall also apply to **life science contractors**.

6. Insured by Contract – Blanket Additional Insured

- a. Any person or organization not otherwise identified as an insured under any other provision of this Policy, or any endorsement attached thereto, is an insured for liability for **loss** in the form of **bodily injury, property damage, or medical monitoring expense**, but only if:
 - (1) You have agreed to add such person or organization as an additional insured for such **loss** pursuant to a written contract you entered into with the person or organization prior to the event which resulted in the **loss** for which coverage is sought; and
 - (2) Such person or organization is vicariously liable for **your work or your product**, and is not at fault, either in whole or in part.
- b. Such persons or organizations are additional insureds only to the extent, and for the limits of insurance, required by the contract; however, the following shall also apply:
 - (1) In no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy;
 - (2) No such person or organization is an additional insured with respect to liability for which the person or organization has agreed to assume the liability of another to pay **loss**, unless the person or organization would be liable in the absence of such agreement; and
 - (3) If a person or organization is an insured under this Paragraph 6., then the term “you” or “your” as used in all exclusions applicable to this Policy shall also mean such person or organization, and all exclusions applicable to you shall also apply to such person or organization.

D. General Limitations as to Insured Status

- 1. Except to the extent set forth above, no person or organization is an insured with respect to the conduct of any person or organization that is not designated as a Named Insured in the Declarations.
- 2. In the event you acquire or have in the past acquired the assets, business or organization of another person or organization, either directly or indirectly, then the following shall apply: No person or organization is an insured under this policy with respect to:
 - (1) The ownership, maintenance or use of any such assets, business or organization; or
 - (2) The conduct of any such person or organization whose assets, business or organization you acquire;
 - for any **loss** that occurred, in whole or in part;
 - a) Before the date of acquisition of such assets, business or organization; and
 - b) If the acquisition took place during the policy period, later than:
 - ninety (90) days after the date of acquisition; or
 - the end of the policy period;
 - whichever comes first.
- 3. In the event that during the policy period you form a new organization, then no person or organization is an insured with respect to the conduct of such organization for any **loss** that

occurred, in whole or in part, later than:
· ninety (90) days after the date the organization was formed; or
· the end of the policy period;
whichever comes first.

SECTION III – LIMITS OF INSURANCE

A. Applicable Rules

1. The limits of insurance shown in the Declarations and the rules below fix the most we will pay regardless of the number of:
 - a. Insureds;
 - b. **Claims** made or **suits** brought; or
 - c. Persons or organizations making **claims** or bringing **suits**.
2. The limits of insurance of this Policy apply separately to each consecutive annual period and to any remaining period of less than 12 months, starting with the beginning of the policy period shown in the Declarations, unless the policy period is extended after issuance for an additional period of less than 12 months. In each such case, the additional period will be deemed part of the last preceding period for purposes of determining the limits of insurance.
3. Notwithstanding any other provision of this Policy, the purchase of an **extended reporting period** shall not under any circumstances increase or reinstate the limits of insurance set forth in this Policy unless such increase or reinstatement is specifically provided for by endorsement.

B. Applicable Limits

1. Overall Policy Aggregate Limit

- a. The Overall Policy Aggregate Limit is the most we will pay for the sum of:
 - all **damages for loss**;
 - all **loss** we must pay; and
 - all **defense costs** which erode any other limit of insurance covered under this Policy.
- b. This Overall Policy Aggregate Limit applies regardless of the amount of any General or Individual Aggregate Limits or Individual Coverage Part Limits applicable to one or more Coverage Parts or Subparts.
- c. The General Aggregate Limit, the Products-Completed Operations Aggregate Limit, the Clinical Trial Aggregate Limit, the Errors and Omissions Aggregate Limit and all other aggregate or individual limits set forth in this Policy or any endorsement attached thereto are subject to the Overall Policy Aggregate Limit. Any obligation we have under this Policy, including any duty to defend, ends once the Overall Policy Aggregate Limit has been satisfied by the payment of **damages for loss, loss we must pay, or defense costs**.

2. General Aggregate Limit

- a. The General Aggregate Limit is the most we will pay for the sum of:
 - All **damages for loss** and associated **defense costs** we must pay under **COVERAGE PART B – PREMISES OPERATIONS LIABILITY**;
 - All **loss** we must pay for **DAMAGE TO PREMISES RENTED TO YOU**; and
 - All **damages, loss** or expense we must pay under any other coverages afforded under this Policy or by endorsement, unless a separate aggregate limit is established to

apply to such other coverages.

- b. The General Aggregate Limit is subject to the Overall Policy Aggregate Limit and any Individual Limits.

3. Products-Completed Operations Aggregate Limit

- a. The Products-Completed Operations Aggregate Limit is the most we will pay for the sum of:

- (1) All **damages for loss** and associated **defense costs** we must pay under **COVERAGE PART A – PRODUCTS-COMPLETED OPERATIONS LIABILITY**;
- (2) All **damages for loss** and associated **defense costs** we must pay under: **COVERAGE PART C – CLINICAL TRIAL COVERAGE**:
 - **SUBPART 1. CLINICAL TRIAL BODILY INJURY AND PROPERTY DAMAGE LIABILITY**; and
 - **SUBPART 2. MEDICAL MONITORING EXPENSE**;

- b. The Products-Completed Operations Aggregate Limit is subject to the Overall Policy Aggregate Limit and any Individual Coverage Part or Subpart Limits.

4. Clinical Trial Aggregate Limit

- a. The Clinical Trial Aggregate Limit is the most we will pay for the sum of all **damages for loss** and associated **defense costs** covered under **COVERAGE PART C – CLINICAL TRIAL COVERAGE**

- **SUBPART 1. CLINICAL TRIAL BODILY INJURY AND PROPERTY DAMAGE LIABILITY**; and
- **SUBPART 2. MEDICAL MONITORING EXPENSE**.

- b. The Clinical Trial Aggregate Limit is subject to the Overall Policy Aggregate Limit, the Products-Completed Operations Aggregate Limit and any applicable Individual Coverage Part or Subpart Limits.

5. Errors and Omissions Aggregate Limit

- a. The Errors and Omissions Aggregate Limit is the most we will pay for the sum of all **damages for loss** and associated **defense costs** under **COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY**.

- b. The Errors and Omissions Aggregate Limit is subject to the Overall Policy Aggregate Limit.

6. Individual Coverage Part or Subpart Limits

- a. If an Individual Limit is stated in the Declarations for any Coverage Part or Subpart, then the Individual Limit is the most we will pay for the sum of all **damages for loss** and associated **defense costs** we must pay, whichever applies, under that Coverage Part or Coverage Subpart. The Individual Limit is subject to all applicable aggregate limits and the Overall Policy Aggregate Limit.

- b. Subject to Paragraph **B.2.** above, the each occurrence limit is the most we will pay for the sum of **Damages for loss** under **COVERAGE PART B – PREMISES OPERATIONS LIABILITY** for **loss** arising out of any one **occurrence**.

- c. Subject to Paragraph **B.2.** or **B.4.** above, whichever applies, the Damage to Premises Rented to You Limit is the most we will pay under **COVERAGE PART B – PREMISES OPERATIONS LIABILITY** or **COVERAGE PART C – CLINICAL TRIAL COVERAGE** for **damages** for property damage to any one premises, while rented to you or temporarily occupied by you, with permission of the owner.

C. Associated Defense Costs

The payment of associated **defense costs** under:

- **COVERAGE PART A – PRODUCTS-COMPLETED OPERATIONS LIABILITY;**
- **COVERAGE PART B – PREMISES OPERATIONS LIABILITY**
- **COVERAGE PART C – CLINICAL TRIAL COVERAGE;** and
- **COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY;**

shall count against and reduce the available limits of insurance applicable to those Coverage Parts.

D. Non-Cumulation of Limits of Insurance

If any **loss** or associated **defense costs** covered under this Policy is also covered in whole or in part under any other insurance policy issued by us prior to the inception date of this Policy, and both this Policy and such other insurance policy cover the insured for any **loss** or associated **defense costs** arising out of:

1. Substantially the same or related general harmful conditions or substances, or repeated or continuous exposure to substantially the same or related general harmful conditions or substances, or
2. Any **loss** which extends over a period of days, weeks, months or longer; then the limits of insurance of this Policy shall be reduced by any amounts due to the insured on **account** of such prior insurance policy. Such limits of insurance shall be reduced regardless of whether such **loss**: (a) extends over more than one policy period; or (b) arises as a result of one or more **occurrence** or event.

In no event shall we pay more for such **loss** and associated **defense costs** covered under this Policy and all such other insurance policies than the limits of insurance set forth in the Declarations of this Policy reduced by any applicable **deductible** or retention amount.

This provision shall not be construed as providing additional coverage under this Policy or providing coverage where excluded under any other provision of this Policy including any endorsements attached to it. All other terms, conditions, definitions and exclusions shall remain the same.

SECTION IV – EXCLUSIONS

The following exclusions apply to all **loss** unless otherwise stated below. Where an exclusion applies to **loss**, it shall also apply to any covered **defense costs** associated with such **loss**.

COMMON POLICY EXCLUSIONS

This insurance does not apply to:

a. Abuse or Molestation

Loss arising out of any:

1. Actual or threatened abuse or molestation, by anyone, of any person while in the care, control or custody of any insured; or
2. Employment, investigation, supervision, or reporting to or failure to report to the proper authorities, or hiring, retention, or discharge of or failure to discharge a person for whom any insured is or ever was legally responsible and whose conduct would be excluded in subparagraph 1. above.

b. Aircraft, Auto or Watercraft

Loss arising out of the ownership, maintenance, use or entrustment to others of any aircraft, **auto** or watercraft owned or operated by or rented or loaned to any insured, including but not limited to:

1. The operation or **loading or unloading** of such aircraft, **auto** or watercraft; and
2. Any liability arising out of the supervision, hiring, employment, training or monitoring of others by that insured.

This exclusion does not apply to:

- (a) A watercraft while ashore on premises you own or rent;
- (b) Parking an **auto** on, premises you own or rent, provided the **auto** is not owned by or rented or loaned to you or the insured;
- (c) **Bodily injury or property damage** arising out of:
 - (1) The operation of machinery or equipment that is attached to, or part of, a land vehicle that would qualify under the definition of **mobile equipment** if it were not subject to a compulsory or financial responsibility law or other motor vehicle insurance law in the state where it is licensed; or
 - (2) The operation of any of the machinery or equipment listed in Paragraph **f.(2)** or **f.(3)** of the definition of **mobile equipment**.

c. Antitrust/Unfair Competition/Consumer Fraud

Loss based upon, arising out of or in any way related to any actual or alleged:

1. Antitrust violation, restraint of trade, price-fixing, or monopolistic practices;
2. Unfair competition;
3. Piracy;
4. False, deceptive, or unfair trade practices;
5. Consumer fraud; or
6. Violation of consumer protection laws.

In the event a **claim** is made or **suit** is brought against the insured alleging:

- Any **loss** excluded in Paragraphs **c.1.**, **2.** or **3.** above; and
- Any other **loss**;

then this exclusion shall apply to preclude coverage for the entire claim or suit even if any portion of the **claim** or **suit** would have been covered or a duty to defend the insured owed by us in the absence of such allegations.

d. Asbestos

Loss based upon or arising out of:

1. The actual, alleged, threatened or suspected existence, presence, inhalation, absorption or ingestion of or the contact with, exposure to or use of asbestos in any form, in whole or in part, including but not limited to:
 - (a) The installation, storage or handling of asbestos;
 - (b) The manufacture, distribution, sale, application or consumption of asbestos or goods or products containing asbestos;
 - (c) The removal, cleaning up, abatement, testing for, monitoring, containment, treatment, transportation or disposal of or in any way responding to or assessing the effects of asbestos by any insured or any other person or entity;
 - (d) The presence or alleged presence of asbestos in any structures, manufacturing processes, or products, or in the air, soil or groundwater;
 - (e) The use of asbestos in **your product** or **your work** or the work or product of any person or organization for which you may be legally responsible;
 - (f) Any directions, supervision, instructions, recommendations, warnings or advice given or which should have been given with respect to asbestos; or
2. Any **claim** or **suit** by or on behalf of a governmental entity 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 asbestos.

As used in this exclusion, asbestos includes any form of the mineral known as asbestos, including any material, waste, equipment, device, product or good containing asbestos, or any

dust or particles containing asbestos, whether or not the asbestos is friable and whether or not the asbestos is in or on any thing or structure or in the air, soil, or groundwater.

e. Batch or Integrated Occurrences

Loss, products or work covered under any “extended coverage”, “batch” or “integrated occurrence” language in any other policy, including language in any other policy designed to cover **claims**, related **claims** or other events which commenced or occurred prior to the policy period, unless we specifically agree to provide coverage for such **loss**, products or work in an endorsement attached to this Policy.

f. Biological Agents (Including Mold and Other Fungi)

1. **Loss** which would not have occurred, in whole or in part, but for the actual, alleged or threatened contact with, exposure to, existence of, or presence of, any **biological agents** on or within a building or structure, or at or from any premises, site or location which is or was at any time owned or occupied by, or rented or loaned to, any insured, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such **loss**; and
2. **Loss** arising out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, remediating or disposing of, or in any way responding to, or assessing the effects of, **biological agents** by any insured or by any other person or entity.

However Paragraph 1. of this exclusion does not apply to **loss** within the **products-completed operations hazard** caused by **biological agents** that are, are on, or are contained in, a good or product intended for bodily consumption or use as a medical product or device.

g. Contractual Liability

Loss for which the insured is **obligated** to pay by reason of the assumption of liability in a contract or agreement.

This exclusion does not apply to liability to which this insurance otherwise applies for:

1. Any liability for **loss** that the **insured** would have in the absence of the contract or agreement; or
2. Liability for **loss** in the form of **bodily injury, property damage, or medical monitoring expense**, otherwise covered under this Policy, where such liability for **loss** of another person or organization is assumed in an **insured contract**, provided that the event or **occurrence** resulting in such **loss** occurs after the execution of the **insured contract**.

h. Distribution of Materials in Violation of Statutes

Loss arising directly or indirectly out of any actual or alleged violation of any statute, law, ordinance or regulation enacted anywhere in the world relating to sending, transmitting, communicating or distribution of material or information.

i. Employer’s Liability

Loss in the form of **bodily injury** to, or **medical monitoring expense** to monitor:

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

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

This **exclusion** does not apply to liability where otherwise covered under this Policy:

(a) Assumed by the insured under an **insured contract**; or

(b) Arising out of the **employee's** voluntary participation in an **approved clinical trial**.

j. Employment Practices

1. **Loss** to a person arising out of any:

(a) Refusal to employ that person;

(b) Termination of that person's employment; or

(c) Employment-related practices, policies, acts or omissions, including but not limited to coercion, demotion, evaluation, assignment or reassignment, transfer, discipline, hiring or the handling of employment references, defamation, harassment, humiliation, malicious prosecution, invasion or other violation of any right of privacy, occupancy or publicity, or discrimination directed at that person based upon race, color, creed, religion, political belief, age, physical type, physical or mental limitation or handicap, medical condition, sex or sexual orientation, or upon any other basis directed at that person; or

2. The spouse, child, parent, brother or sister of that person as a consequence of **loss** to that person at whom any of the employment-related practices described in Paragraphs **1.(a), (b) or (c)** above is directed.

This exclusion applies:

- Whether the injury-causing event described in Paragraphs **1.(a), (b) or (c)** above occurs before employment, during employment or after employment of that person;
- Whether the insured may be liable as an employer or in any other capacity; and
- To any obligation to share **damages** with or repay someone else who must pay **damages** because of the injury.

k. Healthcare Services

Loss based upon or arising out of the rendering or failure to render **healthcare services**.

This exclusion does not apply to the following where otherwise covered under this Policy:

- **Bodily injury** or **economic injury**, where applicable, caused by a defect, deficiency, inadequacy or dangerous condition in **your product**;
- **Bodily injury** caused by first aid services, including cardiopulmonary resuscitation, other than in connection with an **approved clinical trial**;
- **Bodily injury, medical monitoring expense** or **economic injury**, where applicable, resulting from services performed in connection with an **approved clinical trial** provided that such services are within the scope of, and specifically described within, the applicable written protocol for such trial; or
- **Economic injury** covered under **COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY FOR ECONOMIC INJURY** caused by advice provided by you with respect to the use of **your product**.

l. Intellectual Property Rights

Loss based upon, arising out of or in any way related to any actual or alleged assertion, infringement or violation, by any person or entity including the insured, of any intellectual property rights, including but not limited to the following:

1. A copyright, patent, trademark, intellectual design right, collective trade mark, certification mark or service mark or any similar such protections or rights (whether or not any of the foregoing are registered);
2. A trade secret or other type of formula, practice, process, design, instrument, pattern or compilation of information regarded by a business as confidential or proprietary;
3. Trade dress or any right protecting any interest in a name, symbol, slogan, style of doing business, or any similar such expression, likeness or idea; or
4. The use of another's name or product in your e-mail address, domain name or metatag, or

any other similar tactics to mislead another's potential customers.

In the event a **claim** is made or **suit** is brought against the insured alleging:

- A **loss** concerning intellectual property rights as described above; and
- Any other **loss**;

then this exclusion shall apply to preclude coverage for the entire **claim** or **suit** even if any portion of the **claim** or **suit** would have been covered or a duty to defend the insured owed by us in the absence of the allegations concerning intellectual property rights.

m. Intentional, Fraudulent or Criminal Acts

Loss based upon or arising out of:

1. Any criminal or fraudulent acts committed by or at the direction of, or with the consent or knowledge of the insured;
2. The insured's intentional disregard of, or deliberate, willful or intentional non-compliance with, any applicable national, provincial, regional or local law, regulation or ordinance, or any legal or administrative complaint, notice letter, instruction or direction issued by any governmental entity; or
3. Any other act intended by the insured to cause **loss**, in whole or in part; however, this Subparagraph **m.3.** does not apply to the known side effects of **your product** or a product on which **your work** was performed, so long as such side effects are reported to the appropriate governmental authority as soon as reasonably possible after they become known to the insured.

If the **loss** is based upon or arising out of the acts referenced in Subparagraphs **m.1.- 3.** above by an **Insured Representative** of any Named Insured, then this exclusion shall apply to all insureds; otherwise this exclusion shall apply only to the insured responsible for such action.

n. Mobile Equipment

Loss arising out of:

1. The transportation of **mobile equipment** by an **auto** owned or operated by or rented or loaned to **any** insured; or
2. **The** use of **mobile equipment** in, or while in practice for, or while being prepared for, any prearranged racing, speed, demolition, or stunting activity.

o. Named Insured v. Named Insured

Any **claim** or **suit** by a Named Insured against any other Named Insured.

p. Nuclear or Radioactive Material

Loss arising out of any:

- ionising radiation or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel; or
- radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof.

With respect to **Coverage Parts A. B. and D.** only, this exclusion does not apply to **bodily injury** or **property damage** caused by radioactive isotopes used as a component of or in connection with a medical device or used in medical research.

q. Pollution

1. **Loss** based upon or arising out of the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of **pollutants** at any time.
2. Any **loss**, cost or expense arising out of any:
 - (a) Request, demand, order or statutory or regulatory requirement that any insured or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to, or assess the effects of, **pollutants**; or
 - (b) **Claim** or **suit** by or on behalf of a governmental authority for **damages** because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying or

neutralizing, or in any way responding to, or assessing the effects of, **pollutants**.

r. Professional Liability other than Healthcare Services

Loss based upon or arising out of the rendering of or failure to render any **professional service** other than **healthcare services**, by the insured or on the insured's behalf, whether or not such **professional service** is ordinary to the insured's profession and regardless of whether or not a **claim** or **suit** is brought by a client or any other person or organization.

However, this exclusion does not apply to:

1. **Loss** in the form of **economic injury** covered under **COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY FOR ECONOMIC INJURY**;
2. **Loss** resulting from **your work** as a **life science contractor**; or
3. Any other such **loss** where we specifically agree to provide coverage for the **loss** by endorsement attached to this Policy.

s. Recall of Products, Work or Impaired Property

Loss incurred by you or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

1. **Your product** or any property or product containing or incorporating **your product**;
2. **Your work** or any property on which **your work** is or was performed; or
3. **Impaired property**;

regardless of whether such use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal is performed by any insured or others.

However, this exclusion does not apply to **Bodily injury** caused by:

- (a) The removal of a medical device implanted, or tissues, organs or biological material transplanted, into human beings where such removal is a result of a **Class I Product Recall**, including the medical expenses incurred to conduct the removal; or
- (b) The removal of a medical device implanted into a **clinical trial participant** at the direction of the participant where such removal is the result of a device malfunction, including the medical expenses incurred to conduct the removal.

Economic injury sustained by others, covered under **COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY FOR ECONOMIC INJURY**, resulting from the loss of use of:

- (a) **Your product**;
- (b) Property containing or incorporating **your product**; or
- (c) Property on which **your work** was performed;

in connection with the ownership, maintenance or use of **your product** or **your work**.

t. Specific Disease

Loss based upon, **arising** out of or in any way related to any disease, condition or sickness listed in the Schedule below; however, this exclusion shall only apply where such disease, condition or sickness is caused by:

1. **Your product**
 - a. where **your product** is, or contains, blood, blood components, or tissue; or
 - b. where **your product** is a medical device that is inserted or implanted into the body; or
2. **Your work**; or
3. The failure of **your product** or **your work** to prevent, or reduce or control the effects of, such disease, condition or sickness, as intended.

Scheduled Diseases

- Acquired Immune Deficiency Syndrome (AIDS)
- Hepatitis
- Transmissible Spongiform Encephalopathy (TSE)

u. Specific Products

Loss based upon, arising out of or in any way related to any good or product listed in the Schedule below, including but not limited to any good or product containing a similar chemical formulae or which is a derivative of any listed good or product.

Scheduled Products

- Birth Control or Fertility Goods or Products
- Bisphosphonates
- Cold therapy products
- Di-(2-ethylhexyl) Phthalate (DEHP) used in goods or products approved for neonatal patients
- Diethylstilbestrol (DES) except where used in prescription products)
- Ephedra (Ephedrine or pseudoephedrine except where used in prescription products)
- Hormone Replacement Products approved for menopause treatment, or which is intended to be used for such treatment
- Isotretinoin
- Live Virus Vaccines
- Mercury product (Internal Use)
- Mesh Implants
- Metal-on-metal implant
- Metoclopramide
- Opioids
- Pain pumps
- Phentermine used in combination with fenfluramine (including but not limited to Pondimin) or dexfenfluramine (Redux)
- Phospho soda, sodium phosphate, or any phospho soda or sodium phosphate based agents
- Rosiglitazone
- Selective Serotonin Reuptake Inhibitor (SSRI) products
- Silicone products (Implanted)
- Testosterone replacement products approved for testosterone deficiency treatment or which is intended to be used for such treatment
- Thalidomide
- Vaccines approved for persons under eighteen (18) years of age.

Among the above scheduled products:

Cold therapy product means any device that operates by pumping liquid through a plastic bag or other receptacle and is applied to the body to reduce temperature;

Mercury product (Internal Use) means any good or product containing mercury where such good or product is or is intended to be implanted, ingested, injected, inhaled or absorbed.

Mesh implant means surgical mesh or other similar product or woven fabric either temporarily implanted into a human;

Metal on metal implant means any knee, hip or other joint implant, replacement or resurfacing system and the component parts of any of the foregoing ("implant") where: (1) a part of the implant designed for motion is made of metal; and (2) the moving part, while either at rest or in motion, contacts another metal part of the implant that is designed for motion, or designed to meet or serve as a socket or contact surface against which the moving part comes to rest;

Pain pump means any infusion pump or other device where a part of the device or a line or tube connected to the device is inserted or implanted into the body to deliver pain

medication directly to a joint, tissue or other specific internal body part or area of the body;
and

Silicone product (implanted) means any good or product containing liquid or gel silicone which is intended to be or which is implanted.

v. Terrorism

Loss arising out of any act of terrorism, or any action in controlling, preventing, suppressing or in any way relating to any act of terrorism.

For the purpose of this insurance, an act of terrorism means an act, including but not limited to, the use of force or violence and/or the threat thereof, of any person or group(s) of persons, whether acting alone or on behalf of or in connection with any organisation(s) or government(s), committed for political, religious, ideological or similar purposes including the intention to influence any government and/or to put the public, or any section of the public, in fear.

If we allege that, by reason of this exclusion, any damages, loss, cost or expense is not covered by this insurance, then the burden of proving the contrary shall be upon you.

In the event this exclusion is found to be invalid, illegal or unenforceable, in whole or in part, such term or condition or part thereof shall be deemed not to apply to this exclusion. However, the validity, legality and enforceability of all other terms and conditions remain unchanged.

w. Unapproved Clinical Trials

Loss in connection with any **clinical trial** arising out of any exposure to material, upon or within human beings:

1. During the trial, unless the exposure has been approved by the governmental or regulatory authority having jurisdiction over the trial; or
2. After any governmental or regulatory authority having jurisdiction over the trial:
 - Places or imposes a hold on the trial;
 - Withdrawals approval of an Investigational New Drug Application, Investigational Device Exception Application or similar authorization applicable to the trial; or
 - Directs or orders that the trial be discontinued.

x. Unapproved Goods or Products

Loss based upon or arising out of any goods or products distributed, handled, manufactured or sold by, or disposed of by, the insured:

· before such goods or products have been approved for such distribution, handling, manufacture, sale or disposal; or

· after such goods or products have been declared unsafe;

by the appropriate governmental authority having jurisdiction over such distribution, handling, manufacturing, sale or disposal.

This exclusion only applies to such distribution, handling, manufacture, sale or disposal in the country where such goods or products have not yet been approved or have been declared unsafe.

y. War

Loss, however caused, arising, directly or indirectly, out of:

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

z. Workers' Compensation and Similar Laws

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

BUSINESS RISK EXCLUSIONS APPLICABLE TO PROPERTY DAMAGE

This **insurance** does not apply to:

a. Damage to Property

Property damage to:

1. Owned or Controlled Property

- (a) Property you own, rent, lease or occupy, including any costs or expenses incurred by you, or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;
- (b) Property loaned to you; or
- (c) Personal property in the care, custody or control of the insured including but not limited to:
 - (1) Property held by you or on your behalf for sale or entrusted to you for safekeeping or storage;
 - (2) Property on your premises for purposes of performing operations on such property by you or on your behalf; or
 - (3) Tools or equipment used by you or on your behalf in performing operations.

This exclusion does not apply to **property damage** to premises, including the contents of such premises, rented to you for a period of 7 or fewer consecutive days. A separate limit of insurance applies to Damage To Premises Rented To You as described in **SECTION III – LIMITS OF INSURANCE**.

2. Alienated Property

Premises you sell, give away or abandon, if the **property damage** arises out of any part of those premises; however, this exclusion does not apply if the premises are **your work** and were never occupied, rented or held for rental by you.

3. Other Real Property

That particular part of real property on which you or any contractors or subcontractors working directly or indirectly on your behalf are performing operations, if the **property damage** arises out of those operations.

4. Property that must be Restored, Repaired or Replaced

That particular part of any property that must be restored, repaired or replaced because **your work** was incorrectly performed on it; however, this exclusion does not apply to **Property damage** included within the **products-completed operations hazard**.

b. Damage to Property Impaired or Property not Physically Injured

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

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

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

c. Damage to Your Product

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

d. Damage to Your Work

Property damage to your work arising out of it or **any** part of it and included in the

products-completed operations hazard.

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

EXCLUSIONS SPECIFIC ONLY TO ECONOMIC INJURY

This insurance does not apply to **loss** in the form of **economic injury**:

a. Delay

Based upon or arising out of any delay in:

1. Delivery of, or failure to deliver, **your product**; or
2. Performance of, or failure to commence, **your work**;
or any part or phase of **your product** or **your work**.

b. Disappearance, Theft or Security Breach

Based **upon** or arising out of any actual, alleged or threatened:

1. Burglary, inventory shortage or shrinkage, mysterious disappearance, robbery or theft;
2. Security breach of, unauthorized access to or unauthorized use of:

- **Your product**;
- Any property containing or incorporating **your product**;
- Any property on which **your work** is or was performed;
- Any software, data or other information in electronic form; or
- Any equipment, parts, programs or systems involving the use of computers, the internet, or any networks or websites, or which are designed or used for communication or information;

by any **person** or organization (including any insured), regardless of whether this insurance would otherwise apply to all or part of any such actual or alleged injury in the absence of any such actual, alleged or threatened breach, access or use.

c. Financial Impairment of Insureds

Based upon or arising out of any bankruptcy, insolvency or other financial impairment of any insured.

d. Financial or Investment Services

Based upon or arising out of the rendering of or failure to render **financial or investment services**, regardless of whether a **claim** is made or a **suit** is brought by any client of the insured or by any other person or organization, and regardless of whether any such **financial or investment services** is ordinary to any insured's profession.

e. Governmental Claims or Proceedings

Based upon, arising out of or in any way related to any **claim**, proceeding, investigation, order or regulation made by or on behalf of any governmental entity.

This exclusion does not apply to **economic injury** sustained by a governmental entity resulting from such entity's ownership, maintenance or use of **your product** or **your work**.

f. Liquidated Damages

In the form of liquidated damages to the extent such liquidated damages exceed the actual damages to the insured's client.

g. Maintenance of Contracts or Licenses

Based upon or arising out of any actual, alleged or threatened:

- Failure to effect, maintain, procure or secure, in whole or in part; or
- Cancellation, lapse, modification, nonrenewal, revocation, suspension or other impairment, in whole or in part:

of any bond, insurance, lease, license, order, permit or other contract or agreement that any insured is obligated to maintain, procure or secure in connection with **your product** or **your work**.

h. Other Specialized Professional Services

Based upon or arising out of the performance of or failure to perform any **professional services** in the following areas:

- Accounting;
- Insurance;
- Actuarial;
- Legal;
- Architectural; or
- Surveying.

This exclusion applies regardless of whether a **claim** is made or **suit** is brought by any client of an insured or by any other person or organization, and regardless of whether any such **professional services** is ordinary to any insured's profession.

i. Product or Work Support

Based upon or arising out of any actual, alleged or threatened decision by any insured not to provide or support **your product** or **your work**, or to cease such provision or support.

j. Securities Laws

Based upon or arising out of the actual or alleged violation of any law, whether created or imposed by a legislative or regulatory body or by a court, either in whole or in part, and which is designed to address certain activities in connection with any offering, selling, purchasing, registration or trading of any instrument or other evidence of credit or ownership, including but not limited to such activities designed to prevent or prohibit fraudulent, unfair or other similar such practices or require the disclosure of information.

k. Value of Money

Based upon or arising out of the loss of value of money that is commingled, injured or damaged, incorrectly processed, lost, misappropriated or misplaced in connection with any actual or failed processing, receipt, retention or transmission of such money, whether by electronic means or otherwise.

SECTION V – CONDITIONS

1. Bankruptcy

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

2. Compliance with Applicable Economic and Trade Sanction Laws

No insurer shall be deemed to provide cover and no insurer shall be liable to pay any claim or provide any benefit hereunder to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose that insurer to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions laws or regulations of the European Union, United Kingdom or the United States of America.

3. Duties in the Event of Occurrence, Claim or Suit

a. You must see to it that our **claims** department is notified in writing as soon as practicable of an **occurrence, critical fact** or **loss** which may result in a **claim**. To the extent possible, notice should include:

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

Notice of an **occurrence, critical fact** or **loss** is not notice of a **claim**.

b. If a **claim** is received by any insured, you must:

- (1) Immediately record the specifics of the **claim** and the date received; and
- (2) Notify us as soon as practicable by sending written notice of the **claim** to our **claims** department.

c. You and any other involved insured must:

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

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

e. We may at our discretion exercise our right to assume the investigation, adjustment, or defense of any **claim**. In case of our exercise of that right, the insured, on demand by us, shall promptly reimburse us for any element of **loss** or **defense costs** falling within any self-insured retention or **deductible** applicable to this Policy. In the event we assume the defense of a **claim**, and it is later determined that a **claim** is not covered under the Policy, we have the right to seek reimbursement of **defense costs** paid to the extent permitted by law.

f. We shall have the right to select counsel wherever we exercise the right to defend the insured, or are required to pay **defense costs** under this Policy. In the event we are obligated by law to allow the insured to select counsel, our obligation to pay **defense costs** is limited to the amount generally charged for such services by our panel counsel in the jurisdiction where the lawsuit is being litigated for the type of case for which counsel is being retained. In addition, such counsel selected by the insured shall have substantially similar qualifications and expertise as our panel counsel in the jurisdiction where the lawsuit is being litigated for the type of case for which counsel is being retained.

g. The insured shall not admit liability or settle any **claim** or **suit** without our consent.

4. Legal Action Against Us

No person or organization has a right under this Policy:

a. To join us as a party or otherwise bring us into a **suit** asking for **damages** from an insured;

or

b. To sue us on this insurance unless all of its terms have been fully complied with.

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

As used in this paragraph, an agreed settlement means a settlement and release of liability signed by us, the insured and the claimant or the claimant's legal representative.

5. Other Insurance

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

a. **Primary Insurance**

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

b. Excess Insurance

(1) Errors and Omissions Coverage

For any **loss** falling within **COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY FOR ECONOMIC INJURY**, this insurance is excess over any other insurance, whether primary, excess, contingent or on any other basis.

(2) Claims-Made Coverage Parts

For any Coverage Part of this Policy for which coverage is afforded on a claims-made basis, this insurance is excess over any of the other insurance, whether primary, excess, contingent or on any other basis:

That is effective prior to the beginning of the policy period shown in the Declarations of this insurance and applies to **loss** on other than a claims-made basis, if:

- No **retroactive date** is shown in the Declarations of this insurance; or
- The other insurance has a policy period which continues after the **retroactive date** shown in the Declarations of this insurance.

(3) All Coverage Parts

For all Coverage Parts of this Policy, this insurance is excess over:

(a) Any of the other insurance, whether primary, excess, contingent or on any other basis:

- i.** That is Fire, Extended Coverage, Builders' Risk, Installation Risk or similar coverage for **your work**;
- ii.** That is Fire insurance for premises rented to you or temporarily occupied by you with permission of the owner;
- iii.** That is insurance purchased by you to cover your liability as a tenant for **property damage** to premises rented to you or temporarily occupied by you with permission of the owner; or
- iv.** If the loss arises out of the maintenance or use of aircraft, **autos** or watercraft to the extent not subject to Exclusion **b.**, **Aircraft, Auto or Watercraft**, of **SECTION IV – EXCLUSIONS, Common Policy Exclusions.**

(b) Any other primary insurance available to you covering liability for **damages** or **loss** arising out of the premises or operations, or the products and completed operations, for which you are an insured under this Policy or have been added as an insured by attachment of an endorsement.

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

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

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

e. We will share the remaining such **loss**, if any, with any other insurance that is not described in this Excess Insurance provision and was not bought specifically to apply in excess of the limits of insurance shown in the Declarations of this Policy.

f. Method Of Sharing

If all of the other insurance permits contribution by equal shares, we will follow this method also. Under this approach each insurer contributes equal amounts until it has paid its applicable limit of insurance or none of the applicable **loss** remains, whichever comes first. If any of the other insurance does not permit contribution by equal shares, we will contribute by limits. Under this method, each insurer's share is based on the ratio of its applicable limit of insurance to the total applicable limits of insurance of all insurers.

6. Premium Audit

- a. We will compute all premiums for this Policy in accordance with our rules and rates.
- b. Premium shown in this Policy as advance premium is a deposit premium only. At the close of each audit period we will compute the earned premium for that period and send notice to the **First Named Insured**. The due date for audit and retrospective premiums is the date shown as the due date on the bill. If the sum of the advance and audit premiums paid for the policy period is greater than the earned premium, we will return the excess to the **First Named Insured**.
- c. The **First Named Insured** must keep records of the information we need for premium computation, and send us copies at such times as we may request.

7. Representations

At the time this insurance is entered into, the Insured shall make truthful representations in response to the written inquiries of the Insurer.

If the Insured has made any wilful concealment, negligent non-disclosure, or misrepresentation, and such concealment, nondisclosure, or misrepresentation is sufficient to alter or diminish the Insurer's estimation of the risk to be undertaken, the Insurer may rescind the insurance; the same shall apply after the risk has occurred.

However, this provision shall not apply where the Insured proves that the occurrence of the risk was not based upon any fact that it did or did not represent.

The right to rescind as stated in the preceding paragraph shall be extinguished if not exercised within one month of the time the Insurer knows of the cause for rescission. Once two years have elapsed after the insurance is entered into, the insurance shall not be rescinded even if cause for rescission exists.

8. 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:

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

9. Transfer of Rights of Recovery Against Others to Us

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

SECTION VI – DEFINITIONS

1. **Adverse Event** means any incident where the use of a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food is suspected to have resulted in an adverse outcome in a person or animal, whether or not such incident must be reported to any applicable governmental authority in accordance with applicable law.

- 2. Approved clinical trial** means a **clinical trial** performed upon or within human beings, provided that the sponsor of the trial makes all filings that are required to be made under all applicable laws and regulations and receives all necessary authorizations in connection therewith, including the approval of the applicable institutional review board, ethics committee or other similar body.
- 3. Auto** means:
- a. A land motor vehicle, trailer or semitrailer designed for travel on public roads, including any attached machinery or equipment; or
 - b. Any other land vehicle that is subject to a compulsory or financial responsibility law or other motor vehicle insurance law in the jurisdiction where it is licensed.
- However, **auto** does not include **mobile equipment**.
- 4. Basic extended reporting period** means the period of time commencing immediately following the policy period and lasting for sixty (60) days.
- 5. Biological Agents** means any
- a. (1) bacteria;
 - (2) mildew, mold or other fungi;
 - (3) other microorganisms; or
 - (4) mycotoxins, spores or other by-products of any of the foregoing;
 - b. viruses or other pathogens (whether or not a microorganism); or
 - c. colony or group of any of the foregoing.
- 6. Bodily injury** means:
- physical:
- Injury;
 - Sickness; or
 - Disease sustained by a person, including the following where resulting from such injury, sickness or disease at any time:
 - Death; or
 - Mental anguish, shock or humiliation.
- 7. Claim** means a demand for **damages**.
- 8. Class I Product Recall** means:
- a. A Class I Product Recall as defined by the applicable governmental authority in Taiwan; or
 - b. The equivalent recall provision outside Taiwan, which provision addresses the removal of **your product**, or a product in which **your product** is a component or on which **your work** was performed, from the market, or a correction of such product, because there is a reasonable probability that the continued use of, or exposure to, such product, without correction, will cause serious adverse health consequences or death.
- Such recall or removal may be taken voluntarily by or on behalf of the insured, or required by a government entity acting in accordance with applicable federal, state, regional or local law.
- 9. Clinical Trial** means the testing of material to establish the effectiveness or safety of such material as a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food, including the taking of all steps to obtain the informed consent of any human beings participating in such tests, and the performance of all other activities taken in connection with such testing.
- 10. Clinical trial contractor** means any person other than your **employees**, or any organization other than your subsidiary, engaged to provide service, advice or instruction in connection with:
- a. Clinical, laboratory or research testing activities, within the scope of and in accordance with the applicable written protocol; or
 - b. The planning monitoring or review; of an **approved clinical trial**.

11. Clinical trial participant means a human being participating as a test subject in an approved clinical trial.

12. Critical fact means the following as it applies to the Coverage Parts stated below:

a. ALL COVERAGE PARTS

A verbal or written demand for any **damages** which would be covered under this Policy;

**b. COVERAGE PART A – PRODUCTS-COMPLETED OPERATIONS LIABILITY
COVERAGE PART C – CLINICAL TRIAL COVERAGE**

For any **loss** covered under any of the Coverage Parts referenced above, **critical fact** means the following:

(1) The suspension of a **clinical trial** for:

(a) Safety reasons; or

(b) Non-compliance with the trial protocol, where there is a reasonable probability that non-compliance would place a person at increased risk of **bodily injury**;

(2) Any of the following actions:

(a) A **Class I Product Recall** regarding, or any banning or seizure of:

i. Your product;

ii. Any product containing your product; or

iii. Any product where your work was performed in connection with such product;

(b) The addition of or change to a black box warning regarding any product referenced in **(2)(a)(i)-(iii)** above; or

(c) The issuance of a “Dear Healthcare Professional” letter regarding any product referenced

in **(2)(a)(i)-(iii)** above advising that a **severe adverse event** could occur;

(3) Any criminal investigation of the insured related to **your product** or **your work**;

(4) An **adverse event** concerning **your product** or **your work** provided that all of the following three criteria below **((a), (b) and (c))** have been satisfied:

(a) The **adverse event** has been reported to, or was required to be reported to, the Taiwan Food and Drug Administration or other appropriate governmental authority;

(b) The **adverse event** is a **severe adverse event**; and

(c) In response to the **severe adverse event**, the **safety surveillance manager** for the insured has recommended to an **Insured Representative** or the appropriate governmental authority that a product label should be changed or a product be redesigned or reconstituted; or

(5) A defect or malfunction in **your product** or error in **your work** set forth in a document in the possession of, or otherwise known by an **Insured Representative** of the **Named Insured**, where the continued use of, or exposure to, **your product** or **your work**, without correction, would potentially cause a **severe adverse event**.

c. COVERAGE PART B – PREMISES OPERATIONS LIABILITY

For any **loss** covered under any of the Coverage Parts referenced above, where such **loss** is covered under the Policy on an **occurrence** basis, **critical fact** means the following which has occurred prior to the inception date of this Policy:

(1) The discovery of a dangerous condition on any premises owned or occupied by or loaned or rented to an insured, or any work improperly performed by the insured, where the dangerous condition or work, if not addressed, would place a person or organization at imminent risk of **loss**;

(2) Any safety or violation notice issued by a governmental body, or any known violation of an applicable regulation, regarding premises owned or occupied by or loaned or rented to an insured, or any work performed by an insured, which requires immediate

corrective measures or which places a person or organization at imminent risk of harm;
or

- (3) Any criminal investigation of an insured or an insured's officers or agents related to: (a) any premises owned or occupied by or loaned or rented to an insured; or (b) an insured's work.

d. COVERAGE PART D – ERRORS AND OMISSIONS LIABILITY FOR ECONOMIC DAMAGES

For any **loss** covered under the Coverage Part referenced above, **critical fact** means the following which has occurred prior to the inception date of this Policy:

- (1) A client of an insured has cancelled a contract with the insured, or has requested a refund or withheld payment from the insured due to the insured's alleged:
- (a) non-performance;
 - (b) missed milestone or project deadline; or
 - (c) product or work defect;
- (2) An insured's client has invoked, or sent written notice of its intention to invoke, a liquidated damages or any penalty clause in a contract;
- (3) Payment from a client of the insured is more than 120 days past due, or an insured has initiated collection or other proceedings or a **suit** against a client for delinquent payment;
- (4) A product recall has been initiated by an insured's client or others for products produced or worked on by the insured, or that incorporate the insured's product or work; or
- (5) An insured has received written notice of a contract dispute, alleging non-performance of an insured's product or work in whole or in part.

13. Damages means a monetary judgment, award or settlement of compensatory damages.

But does not include:

- Punitive, exemplary and multiplied damages;
- Fines, taxes or penalties;
- Injunctive or equitable relief except in the form of **medical monitoring expense** otherwise covered under this Policy;
- The return of fees or charges for services rendered or the return of the cost of **your product** or **your work**;
- Expenses incurred by the insured for redesign, changes, additions or remedies to **your product** or **your work** necessitated by a **claim**; or
- The time and expense incurred by the insured in assisting in resolving a **claim**.

14. Deductible means the amount specified in the Declaration for which the insured will first bear for the amount of **loss** and **defense costs** covered by the Policy.

15. Defense costs means:

All reasonable and necessary litigation expenses incurred by us, and by the insured at our request, to investigate or settle any **claim** or **suit** against an insured including the following:

- a. Expenses paid to lawyers, their staff and any necessary consultants or experts to defend the **claim**; provided, however, that if we are required by law to allow the insured to select his, her or its own counsel, such expenses shall be no greater than that generally charged for such services by our panel counsel in the jurisdiction where the lawsuit is being litigated;
- b. Up to NT\$7,500 for the cost of bail bonds required because of accidents or traffic law violations arising out of the use of any vehicle to which this Policy applies, however, we do not have to furnish these bonds;
- c. The cost of bonds to release attachments, but only for bond amounts within the applicable limit of insurance; however, we do not have to furnish these bonds;
- d. All reasonable expenses incurred by the insured at our request to assist us in the investigation or defense of the **claim** or **suit**, including actual loss of earnings up to

NT\$7,500 a day because of time off from work;

- e. All court costs taxed against the insured in the **suit**; however, these payments do not include attorneys' fees or attorneys' expenses taxed against the insured;
 - f. Prejudgment interest awarded against the insured on that part of the judgment we pay. If we make an offer to pay the applicable limit of insurance, we will not pay any prejudgment interest based on that period of time after the offer; and
 - g. All interest on the full amount of any judgment that accrues after entry of the judgment and before we have paid, offered to pay, or deposited in court the part of the judgment that is within the applicable limit of insurance.
- 16. Economic injury** means monetary loss sustained by a person or organization because the property of such person or organization, including property in the form of software, data and other information in electronic form, is less useful or cannot be used, in whole or in part.
- 17. Employee** includes a **leased worker**. **Employee** does not include a **temporary worker**.
- 18. Executive officer** means a person holding any of the officer positions created by charter, constitution, by-laws or any other similar governing document.
- 19. Extended reporting period** means the period of time commencing immediately following the expiration of the policy period and extending until the expiration date of the **extended reporting period** set forth in the Policy or as amended by endorsement.
- 20. Financial or investment services** means any **professional service** or other advice, instruction or service:
- Related to the design, formation, administration, operation, analysis, valuation or any similar activities associated with any financial or investment product or service;
 - The purpose for which is to handle, protect, invest, manage or preserve money or assets or reduce liability; or
 - Related to credit reporting, lending or other extensions of credit, tax services or any banking, financing, investment or venture capital activity.
- 21. First Named Insured** means the person or organization listed as such in the Declarations.
- 22. Healthcare services** means:
- a. The provision of:
 - (1) Medical, surgical, dental, x-ray or nursing service, treatment, advice or instruction, or the related furnishing of food or beverages, including clinical testing performed in connection with the foregoing services;
 - (2) Any health or therapeutic service, treatment, advice or instruction; or
 - (3) Any service, treatment, advice or instruction for the purpose of appearance or skin enhancement, hair removal or replacement or personal grooming;
 - b. The furnishing or dispensing of drugs or medical, dental or surgical supplies or appliances;
 - c. Clinical testing performed in connection with the services, treatment, advice or instruction, or the furnishing or dispensing activities described in Paragraph **a.** and **b.** above; and
 - d. The handling or treatment of dead bodies, including autopsies, organ donation or other procedures.
- 23. Impaired property** means tangible property, other than **your product** or **your work**, that cannot be used or is less useful because:
- a. It incorporates **your product** or **your work** that is known or thought to be defective, deficient, inadequate or dangerous; or
 - b. You have failed to fulfill the terms of a contract or agreement; if such property can be restored to use by the repair, replacement, adjustment or removal of **your product** or **your work** or your fulfilling the terms of the contract or agreement.
- 24. Initial coverage date** means the date stated in the **Declarations**.
- 25. Insured client** means your client or the client of a person or organization acting on your behalf.

- 26. Insured contract** means that part of any written contract or agreement entered into by you in the usual course of your Business under which you assume the tort liability of another to pay **damages** because of **bodily injury, property damage** or **economic injury** to a third person or organization, provided such contract or agreement is made prior to the **bodily injury, property damage** or **economic injury**. Tort liability means a liability which would be imposed by law in the absence of any contract or agreement.
- 27. Insured representative** means the insured's **executive officers**; the members of the legal department and risk management departments of the insured; and any person(s) designated by the insured as responsible for **claims** reporting or insurance matters.
- 28. Leased worker** means a person leased to you by a labor leasing firm under an agreement between you and the labor leasing firm, to perform duties related to the conduct of your business. **Leased worker** does not include a **temporary worker**.
- 29. Life science contractor** means a **clinical trial contractor, product sales contractor** or **product service contractor**.
- 30. 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 **auto**; 1.
 - b. While it is in or on an aircraft, watercraft or **auto**; or
 - c. While it is being moved from an aircraft, watercraft or **auto** to the place where it is finally delivered;
- but **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 **auto**.
- 31. Loss** means, wherever applicable, **bodily injury, property damage, medical monitoring expense, economic injury**, or any other loss, injury, damage or expense covered by this Policy or any endorsement attached thereto.
- 32. Medical monitoring expense** means expenses incurred to conduct medical testing on or medical monitoring of a claimant in the absence of physical injury, illness or disease:
- a. Where the claimant has been exposed to **your product** or a product on which **your work** was performed;
 - b. Such exposure creates a substantial, increased risk that the claimant will sustain **bodily injury** in the future;
 - c. Medical testing or monitoring expenses are medically warranted because the prospect of early diagnosis of such **bodily injury** will improve the chance of beneficial medical intervention; and
 - d. The expense provides no other material benefit to the claimant.
- 33. 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 you own or rent;
 - 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 Paragraph **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 Paragraph 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 **autos**:

(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 land vehicles that are subject to a compulsory or financial responsibility law or other motor vehicle insurance law in the jurisdiction where it is licensed. Land vehicles subject to a compulsory or financial responsibility law or other motor vehicle insurance law are considered **autos**.

34. Occurrence means an accident, including continuous or repeated exposure to substantially the same general harmful conditions.

35. Pollutant means 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.

36. Products-completed operations hazard:

a. Means all **loss** occurring away from premises owned or occupied by or loaned or rented to you and arising out of **your product** or **your work** except:

(1) Products that are still in your physical possession; or

(2) Work that has not yet been completed or abandoned. However, **your work** will be deemed completed at the earliest of the following times:

(a) When all of the work called for in your contract has been completed.

(b) When all of the work to be done at the job site has been completed if your contract calls for work at more than one job site.

(c) When that part of the work done at a job site has been put to its intended use by any person or organization other than another contractor or subcontractor working on the same project.

Work that may need service, maintenance, correction, repair or replacement, but which is otherwise complete, will be treated as completed.

b. Does not include **loss** arising out of:

(1) The transportation of property, unless the injury or damage arises out of a condition in or on a vehicle not owned or operated by you, and that condition was created by the **loading or unloading** of that vehicle by any insured;

(2) The existence of tools, uninstalled equipment or abandoned or unused materials.

37. Product sales contractor means any person or organization other than your **employees** or subsidiaries engaged to provide service, advice or instruction in connection with the dispensing, distribution, furnishing for sale of a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food, other than in connection with a **clinical trial**.

38. Product service contractor means any person or organization other than your **employees** or subsidiaries engaged to provide clinical; design or development review; laboratory; or research service, advice or instruction in connection with a drug, biologic, medical device,

dietary supplement, cosmetic, cosmetic drug or medical food, other than in connection with a **clinical trial**.

39. Professional service means or refers to any service, advice, or instruction specialized to the insured's vocation and requiring the insured's specialized knowledge, skill, experience or training, regardless of whether the insured needs a license or other formal certification to perform such service, advice or instruction.

40. Property damage means:

- a. Physical injury to tangible property, including all resulting loss of use of that property. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or
- b. Loss of use of tangible property that is not physically injured, provided such loss of use is caused by physical injury to other tangible property. All such loss of use shall be deemed to occur at the time of the **occurrence** that caused it, or in the case of claims-made coverage, the event which precipitated the **claim**.

For the purposes of this insurance, electronic data is not tangible property. As used in this definition, electronic data means information, facts or programs stored as or on, created or used on, or transmitted to or from, computer software, including systems and applications software, hard or floppy disks, CD-ROMS, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

41. Renewal policy means a life science liability policy issued to you by us where we have provided continuous, uninterrupted, substantially similar coverage to you from the **initial coverage date** to the commencement of the policy period.

42. Retroactive date means the date stated in the Declarations.

43. Safety surveillance manager means the person(s) for the insured responsible for monitoring, evaluating and reporting **adverse events** regarding **your work** or **your product**, or recommending label or product changes in response to a **severe adverse event**.

44. Severe adverse event means the following:

- a. Death;
- b. A life-threatening event;
- c. Hospitalization;
- d. Disability or permanent damage;
- e. A congenital anomaly or birth defect; or
- f. Required intervention to prevent permanent impairment or damage.

45. Suit means a civil proceeding in which **damages** because of **loss** to which this insurance applies are alleged.

Suit includes:

- a. An arbitration proceeding in which such **damages** are claimed and to which the insured must submit or does submit with our consent; or
- b. Any other alternative dispute resolution proceeding in which such **damages** are claimed and to which the insured submits with our consent.

46. Supplemental extended reporting period means the period of time commencing upon the expiration of the **basic extended reporting period** and lasting until the end of the **supplemental extended reporting period** as set forth in the Policy or by endorsement.

47. Temporary worker means a person who is furnished to you to substitute for a permanent **employee** on leave or to meet seasonal or short-term workload conditions.

48. Volunteer worker means a person who is not your **employee**, and who donates his or her work and acts at the direction of and within the scope of duties determined by you, and is not paid a fee, salary or other compensation by you or anyone else for their work performed for you.

49. Your product:

Means

- a. Any goods or products manufactured, sold, handled, distributed or disposed of by:
 - (1) You;
 - (2) Others trading under your name; or
 - (3) A person or organization whose business or assets you have acquired;
- b. Containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products;
- c. Vending machines or other property loaned or rented to or located for the use of others by:
 - (1) You;
 - (2) Others trading under your name; or
 - (3) A person or organization whose business or assets you have acquired;
- d. Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of **your product**, including the supervision or failure to supervise persons or organizations with respect to the making of such warranties or representations; and
- e. The providing of or failure to provide warnings or instructions.

50. Your work:

Means:

- a. Work or operations performed by you or on your behalf; and
- b. Materials, parts or equipment furnished in connection with such work or operations;
- c. Warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of **your work**, including the supervision or failure to supervise persons or organizations with respect to the making of such warranties or representations; and
- d. The providing of or failure to provide warnings or instructions.