

Thank you

FOR BEING OUR POLICYHOLDER

2019 Policy







BUSINESS INSURANCE.
BEST PLACES TO WORK 2018
2014 | 2015 | 2016 | 2017

Navigators



[Named Insured]

[Policy Number]

[Policy Term]

[Broker]

SAMPLE

Navigators
LIFE SCIENCES



COMPLIMENTARY CONSULTATION

Navigators has partnered with national law firm Wilson Elser to provide eligible policyholders* with a one-hour consultation with an experienced attorney on a topic of their choice. As a Navigators Insurance Company Life Sciences policyholder, you have access to this complimentary service conducted by an experienced life sciences defense attorney.

LIFE SCIENCES

- MedWatch reports (especially any causation analyses or manufacturer comments) prior to submission to the FDA.
- Labeling changes prior to submission to the FDA.
- Demand letters from potential litigants.
- Periodic safety report obligations prior to submission to the FDA.
- Correspondence received from the FDA and company obligations regarding response.
- Published peer-reviewed medical articles discussing off-label use of the insured's product and associated implications.
- Draft letters prior to submission to the FDA.
- Webinars related to e-Discovery.

ALLIED HEALTHCARE

- Quality control and risk management.
- Operational issues such as reimbursement.
- Preparation of responses to subpoenas, records requests and government investigations.
- Provision and retention of medical records.
- Healthcare compliance and regulatory such as HIPAA.
- Protection from third-party liability/contractual indemnification.
- Use of arbitration as an alternate means of dispute resolution.
- Employment related and human resource issues such as EEOC claims and credentialing.

*Per policy term of 12 months or longer

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Daniel Tranen

Daniel Tranen has been practicing law for more than 20 years, with a significant focus on the defense of Life Sciences companies in individual claims and in mass torts. Daniel has represented clients in mass torts involving the national pain pump litigation, the heparin contamination crisis, dozens of cases involving allegedly contaminated flush syringes, the defense (as local counsel) of NECC in the national meningitis outbreak, and most recently cases involving the loosening of knee implants. He has served as national coordinating counsel for medical device manufacturers
on several of these mass torts. He also has defended Life Sciences companies in cases involving spinal implants, catheters, infusers, stents, IVC filters, cold therapy devices, dental implants, orthopedic screws and allegedly contaminated allografts.

Daniel is licensed to practice in the state and federal courts of Missouri, Illinois, Georgia and Massachusetts. In addition, he has defended Life Sciences companies in Arizona, California, Florida, Louisiana, Nebraska, Ohio, Pennsylvania, Rhode Island, Texas, and Virginia. Daniel brings extensive experience and strategic thought to each engagement, with the goal of resolving disputes efficiently and in the best interests of his clients.

http://www.wilsonelser.com/attorneys/daniel_e_tranen



Kathleen Warin

Kathleen Warin concentrates her practice on complex civil litigation, with a primary focus on medical device product liability claims. Kathleen has handled high-profile product liability cases in state and federal courts nationwide, including consolidated and multidistrict litigation. She has served as national coordinating counsel in defense of medical device cases in numerous jurisdictions. Kathleen also serves as monitoring counsel for international insurers to advise them on nationwide mass tort cases that involve medical devices and pharmaceuticals.

Among Kathleen's stellar results was securing summary judgment in multiple cases – venued in state and federal courts – on behalf of a domestic medical device distributor. Kathleen also successfully obtained dismissal on behalf of a European medical device manufacturer based on lack of jurisdiction in multiple venues. These rulings were critical in helping to resolve similar claims against our clients.

Kathleen likewise has defended class action cases in federal and state court. She also has extensive professional liability experience, including the defense of medical and legal negligence cases, in addition to other claims of professional negligence.

http://www.wilsonelser.com/attorneys/kathleen_h_warin

To initiate your complimentary consultation, please call: 844 SCI-LIFE (844-724-5433)

ABOUT WILSON ELSER

More than 800 attorneys strong, our firm serves clients of all sizes, across multiple industries and around the world. Wilson Elser has 37 strategically located offices in the United States and one in London. This depth and scale has made us one of the nation's most influential law firms, ranked in the *Am Law* 200 and 53 in the *National Law Journal* 500. Please visit us on the web at **www.wilsonelser.com.**

The material in this document does not bind Navigators Insurance Company in any manner. This document is provided for informational purposes only, and is not intended to be a representation or summary of any coverage that may exist in any particular situation under a policy issued by Navigators Insurance Company, or its wholly-owned subsidiary, Navigators Specialty Insurance Company. Insurance programs or insurance products may not be available to all insureds in all states and policy features may vary by state. Please consult your insurance broker and review the applicable policy for specific terms, conditions, limitations, restrictions and exclusions.

Wilson Elser has agreed to provide this consultation as a service to Navigators Insurance Company. By using this service, Navigators Life Sciences policyholders acknowledge that Wilson Elser is not their attorney and that no attorney-client relationship is created between Wilson Elser and the Navigators Life Sciences policyholders. By participating in a one-hour consultation with Wilson Elser, you understand that Wilson Elser is only offering pragmatic guidance and you agree that this forum is not intended to provide legal advice for a specific situation. If you require legal advice with respect to a specific legal matter, Wilson Elser reserves the right to enter into an attorney-client relationship with you. This consultation is not a substitute for reporting a claim. To be eligible for coverage, claims must be reported using the procedures set forth in your insurance policy.

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NAVIGATORS SPECIALTY INSURANCE COMPANY

THIS POLICY PROVIDES COVERAGE ON A CLAIMS MADE BASIS.
PLEASE READ THE ENTIRE POLICY CAREFULLY.

DECLARATIONS

Attaching to and forming part of

NAVIGATORS LIFE SCIENCES
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

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

Policy Number: [PolicyNumber]

Producer Number: [AgentNumber]

Renewal of Policy Number: [PolicyNumber]

Insuring Company: Navigators Specialty Insurance Company
One Penn Plaza
New York, NY 10119

Producer: [ProducerName]
[ProducerStreet]
[City], [State] [ZipCode]

1. First Named Insured: [First Named Insured]
   Address: [NamedInsuredStreet]
   [City], [State] [ZipCode]

2. Policy Period: From [EffectiveDate] to [ExpirationDate]
   12:01AM STANDARD TIME AT THE ADDRESS SHOWN IN NUMBER 1 ABOVE.

3. Limits of Liability: <u>Coverage – Products-Completed Operations and Professional Liability</u>
   A. $[Limit] Each Claim - including Claims Expenses
   B. $[Limit] Aggregate – including Claims Expenses

4. Retroactive Date: [RetroactiveDate]
   THIS INSURANCE DOES NOT APPLY TO OCCURRENCES WHICH OCCUR BEFORE THE RETROACTIVE DATE.

5. Sublimits: <u>Coverage - Mitigation Expenses Sub-limit – (included within the Limit of Liability):</u>
   A. $[Limit] Each Claim or Circumstance - including Claims Expenses
   B. $[Limit] Aggregate – including Claims Expenses

   <u>Coverage - Class 1 Product- Recall Expenses Sub-limit – (included within the Limit of Liability):</u>
   A. $[Limit] Each Recall - including Claims Expenses
   B. $[Limit] Aggregate – including Claims Expenses

   <u>Coverage - Medical Expenses Sub-limit – (in addition to the Limit of Liability):</u>
   A. $[Limit] Each Person - including Claims Expenses
   B. $[Limit] Aggregate – including Claims Expenses

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Coverage – CyberOne Network Security Liability Sub-limit – (in addition to the Limit of Liability):
A. $[Limit] Each Suit - including Claims Expenses
B. $[Limit] Aggregate – including Claims Expenses

6. Deductible or Retention:

Coverage – Products-Completed Operations and Professional Liability
A. $[Claim] Each Claim - including Claims Expenses
B. $[Claim] Aggregate – including Claims Expenses

Coverage - Class 1 Product- Recall Expenses Sub-limit
A. $[Claim] Each Claim - including Claims Expenses
B. $[Claim] Aggregate – including Claims Expenses

Coverage – CyberOne Network Security Liability Sub-limit
A. $[Claim] Each Suit - including Claims Expenses
B. $[Claim] Aggregate – including Claims Expenses

7. Premium:

$[Premium] Policy Term Premium, subject to Minimum Policy Premium

$[Premium] Minimum Policy Premium - Greater of $0,000 or 25% of the premium above. (This applies even in the event of amendment of policy term)

Audit Rate: $0.00 per $1,000 of revenues in excess of audit basis
Audit Basis: $0,000,000 (Any acquisitions during the policy period may be subject to additional underwriting consideration and additional premium)

8. Endorsements Attached At Issuance: SEE ATTACHED SCHEDULE

By Acceptance of this policy the Insured agrees that the statements in the Declarations and the Application and any attachments hereto are the Insured's agreements and representations and that this policy embodies all agreements existing between the Insured and the Company or any of its representatives relating to this insurance.

IN WITNESS WHEREOF, we have caused this policy to be signed by our President and Secretary.

Vincent C. Tizzio, President

Emily B. Miner, Secretary

SAMPLE

GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE FORM

THIS POLICY PROVIDES COVERAGE ON A CLAIMS MADE BASIS.
PLEASE READ THE ENTIRE POLICY CAREFULLY.

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POLICY NUMBER:

SCHEDULE OF FORMS AND ENDORSEMENTS
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

THE FOLLOWING ARE THE FORMS ATTACHED TO AND FORMING PART OF THE POLICY AT INCEPTION:

Form Number	Edition	Title
NAV LSP PPL DEC	07 18	Declaration
NAV LSP 201	01 16	Schedule of Forms and Endorsements
NAV LSP 200	01 16	GLS Elite Products-Completed Operations and Professional Liability Coverage Form
NAV LSP 225	08 17	GLS Elite Plus Coverage Endorsement
NAV LSP 202	02 19	Designated Products Exclusion
NAV LSP 235	11 18	Amend When Coverage Applies Endorsement
NAV LSC 020	11 16	Cyberone Coverage Endorsement
NAV LSC 026	12 17	Policy Amendment – Claims Notification Address ChangeEndorsement
NAV LSC 030	02 19	Amendatory Endorsement Extended Reporting Periods
NAV LSP 232	01 19	Absolute Opioid(s)/Opiate(s), Narcotic(s), Narcotic(s) Controlled Substances and Naloxone Exclusion Endorsement

ALL OTHER TERMS AND CONDITIONS OF THE POLICY REMAIN UNCHANGED.

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Navigators Life Sciences
GLS Elite Products-Completed Operations And Professional Liability Coverage

THIS INSURANCE PROVIDES CLAIMS MADE COVERAGE
PLEASE READ THE ENTIRE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES AND WHAT IS AND IS NOT COVERED

Company means the insurer named in the Declarations. Other key words and phrases that appear in **bold** type have special meanings. Refer to Section **IV. DEFINITIONS**.

In consideration of the payment of the premium, and in reliance upon the information and statements provided in the **application** and **submission materials**, which are made a part of, deemed attached to, and incorporated into this Policy, with the understanding that any intentional material misrepresentation or omission made in the **application** may render this contract of insurance null and void and provide the Company with the right to rescind it, and subject to all the terms and conditions of this Policy, including without limitation, the Limits of Liability and Exclusions, it is agreed as follows:

I. INSURING AGREEMENTS

A. Products-Completed Operations Hazard Coverage and Professional Services Injury Coverage

The Company will pay amounts in excess of the deductible or retention up to the limit of liability for **damages** that an **Insured** becomes legally liable to pay as a result of:

1. a **products-completed operations hazard claim**; or
2. **professional services injury.**

In addition, the Company will pay **claim expenses** in excess of the deductible or retention and up to the limit of liability in connection with a covered **claim**. **Claim expenses** are included within and erode both the limits of liability and the deductible or retention.

B. Professional Liability Coverage

The Company will pay amounts in excess of the deductible or retention up to the limit of liability for **damages** that an **Insured** becomes legally liable to pay as a result of a **professional liability claim.**

In addition, the Company will pay **claim expenses** in excess of the deductible or retention and up to the limit of liability in connection with a covered **claim**. **Claim expenses** are included within and erode both the limits of liability and the deductible or retention.

C. When Coverage Applies

This Policy applies to such **claims** under I. A. and I. B. above only if:

1. such **claim** is both first made against an **Insured** during the **policy period** and reported in a timely manner to the Company in accordance with Section **V. CONDITIONS,** paragraph **A. Your Duties If There Is A Claim**;
2. prior to the effective date of the first Policy in our **coverage relationship**, no **executive officer** of the **Insured** seeking coverage knew of the **wrongful act**, **bodily injury**, **property damage**, or **personal or advertising injury** giving rise to the **claim**;

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3. prior to the effective date of the first Policy in our **coverage relationship**, the **Insured** seeking coverage did not give notice to a prior insurer of any **wrongful act** or **occurrence** giving rise to any such **claim**;
4. **your product**, **your work, professional service** or the **clinical trial** giving rise to such **claim** was first used, ingested, implanted, or applied, or first took place on or after the retroactive date specified in the Declarations; and
5. for **clinical trials**, the **Insured** seeking coverage has obtained all necessary authorizations prior to the **clinical trial(s)** starting, and takes all reasonable steps to ensure each trial is conducted within the scope of applicable protocols.

D. Defense

1. **Duty to defend**
The Company has the right and duty to defend any covered **claim,** against an **Insured,** seeking **damages** that are payable under the terms of this Policy, even if any of the allegations of such **claim** are groundless, false or fraudulent. The Company will designate or, at its option, approve counsel to defend the **claim**.

If the law of the governing jurisdiction permits an **Insured** to select their own counsel to be paid for by the Company, we shall only be liable for the reasonable and necessary defense costs of one law firm per **Insured** at rates customarily paid for the defense of similar **claim**s in the jurisdiction where the **claim** is pending.

2. **Exhaustion of limits**
The Company is not obligated to investigate, defend, pay or settle, or continue to investigate, defend, pay or settle a **claim** after the applicable limit of the Company's liability has been exhausted by payment of **damages** or **claim expenses** or by any combination thereof. In such case, the Company shall have the right to withdraw from the further investigation, defense, payment or settlement of such **claim** by tendering control of said investigation, defense or settlement of the **claim** to the **Insured**.

II. LIMITS OF LIABILITY AND DEDUCTIBLE OR RETENTION

A. Limit of Liability–Each Claim

Subject to the provisions of II.B., below, the limit of liability of the Company for **damages** and **claim expenses** for each **claim** shall not exceed the amount stated in the Declarations for each **claim**.

If the Company, in the exercise of its discretion, pays any amount in excess of the applicable limit of liability, the **Insured** shall reimburse the Company for such amounts.

B. Limit of Liability–Aggregate

The limit of liability of the Company for **damages** and **claim expenses** for all **claims** shall not exceed the aggregate limit as set forth in the Declarations.

C. Deductible or Retention

1. The each **claim** deductible or retention shown in the Declarations applies to **damages** and **claim expenses** for each **claim**.
2. The aggregate deductible or retention shown in the Declarations applies to **damages** and **claim expenses** for all **claims** in the aggregate.

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The limits of liability shown in the Declaration are in addition to and in excess of the deductible or retention.

If the Company, in the exercise of its discretion, pays any amount within the deductible or retention, the **Insured** shall reimburse the Company for such amounts.

D. Multiple Insureds, Claims and Claimants

The limits of liability shown in the Declarations are the amounts the Company will pay as **damages** or **claim expenses** regardless of the number of **Insureds**, **claims** made**,** or persons or entities making **claims**.

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

E. Claim Expenses Within the Limits

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

III. EXCLUSIONS

A. Exclusions applicable to Products-Completed Operations Hazard and Professional Services Injury Coverage

The **Products-Completed Operations Hazard and Professional Services Injury Coverage** provided under this Policy does not apply to:

1. **Assumed Liability**

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

   a. for which an **Insured** would have been liable in the absence of the contract or agreement; or
   b. assumed in a contract or agreement that is an **insured contract,** provided the **bodily injury** or **property damage** occurs subsequent to the execution of the contract or agreement. Solely for the purposes of liability assumed in an **insured contract**, reasonable attorney fees and necessary litigation expenses incurred by or for a party other than an **Insured** are deemed to be part of **claim expenses** because of **bodily injury** or **property damage**, provided:
      i. liability to such party for, or for the cost of, that party's defense has also been assumed in the same **insured contract**; and
      ii. such attorney fees and litigation expenses are for defense of that party against a civil action or alternative dispute resolution proceeding in which **damages** to which this insurance applies are alleged.

2. **Banned Materials**

   based on or arising out of **your product** or **your work** that is manufactured, developed, designed, created, tested, sold, leased, licensed, rented, handled, marketed, distributed or disposed of by **you** or others on

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your behalf in known violation of any law, statute, ordinance or regulation. For purposes of determining the applicability of this exclusion:

a. the facts pertaining to and knowledge possessed by any natural person **Insured** shall not be imputed to any other natural person **Insured**; and
b. only facts pertaining to and knowledge possessed by any **Insured** as set forth in paragraph A. of the definition of **Insured** in **IV.**, **DEFINITIONS** shall be imputed to **you**.

3. **Employer's Liability**

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

a. **your employee** arising out of and in the course of:
    i. employment by **you**; or
    ii. performing duties related to the conduct of **your** business; or
b. the spouse, **domestic partner,** child, parent, brother or sister of that **employee** as a consequence of a.i. or ii. above.

This exclusion applies:

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

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

4. **Expected or Intended Injury**

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

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

5. **Property Damage to Impaired Property**

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

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

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

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6. **Property Damage to Property You Own, or in Your Care, Custody or Control**

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

a. property **you** own, rent, 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. premises **you** sell, give away or abandon, if the **property damage** arises out of any part of those premises;
c. property loaned to **you**;
d. personal property in the care, custody or control of any **Insured**; or
e. 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.

7. **Property Damage to Your Products**

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

8. **Property Damage to Your Work**

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

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

based on or arising out of any loss, cost or expense incurred by **you** or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

a. **your product**;
b. **your work**; or
c. **impaired property**;

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

B. Exclusions applicable to Professional Liability Coverage

The **Professional Liability Coverage** under this Policy does not apply to**:**

1. **Bodily Injury** or **Property Damage**

claims alleging or arising from **bodily injury** or **property damage.**

2. **Conversion of Funds**

based on or arising out of any conversion, commingling, defalcation, misappropriation or improper use of funds or other property; or, the gaining of any personal profit or advantage to which an **Insured** is not legally entitled.

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3. **Discrimination, Humiliation, Harassment**

based on or arising out of discrimination, humiliation or harassment, that includes but shall not be limited to **professional liability claims** based on an individual's race, creed, color, age, gender, national origin, religion, disability, marital status or sexual preference.

4. **Insured's Capacity**

based on or arising out of an **Insured's** capacity as:

a. a former, existing or prospective officer, director, shareholder, partner or manager of a business enterprise or charitable organization (if the above are not named in the Declarations);
b. a former, existing or prospective officer, director, shareholder, partner manager, or trustee of a fund or trust which is a pension, welfare, profit-sharing, mutual or investment fund or trust; or
c. a fiduciary under the Employee Retirement Income Security Act of 1974 and its amendments or any regulation or order issued pursuant thereto or any other similar state or local law.

5. **Performance Delay**

based on or arising out of:

a. delay in delivery of, or failure to complete, **your product** or **your work**; or
b. delay in delivery of, or failure to render, **professional services.**

C. Exclusions applicable to both Products-Completed Operations Hazard and Professional Services Injury Coverage and Professional Liability Coverage

This Policy does not apply to:

1. **Asbestos**

based on or arising out of:

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

2. **Breach of Contract**

any **claim** or suit based on or arising directly or indirectly out of the following:

a. breach of express or implied contract;
b. breach of express or implied warranty;
c. fraud or misrepresentation regarding the formation, terms or performance of a contract; or
d. libel, slander or defamation arising out of or within the contractual relationship;

nor do we have any duty to defend any **claim** or suit arising from a. through d. of the above.

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3. **Claims by Associated Entities**

based on or arising out of any **claim**(s) made against **you** by any person, entity or organization which:

a. is owned, managed, or controlled by **you** or in which **you** have an ownership interest in excess of 25%;
b. in which **you** are an officer, partner, or director; or
c. owns, operates, or manages **you**.

4. **Criminal, Dishonest, Fraudulent, Malicious Conduct or Acts of Intentional Wrongdoing**

based on or arising out of criminal, dishonest, fraudulent or malicious conduct or acts of intentional wrongdoing by the **Insured**; provided, however, that the Company shall provide the **Insured** with a defense of such **claim** unless or until the dishonest, fraudulent, malicious or act of intentional wrongdoing has been determined by a trial verdict, court ruling, regulatory ruling or legal admission, but such a defense will only be provided in a civil action or regulatory proceeding for **claims** asserted by a **bodily injury**, **property damage** or **wrongful act** claimant in his or her individual capacity. The defense of a **claim** will not waive the rights of the Company to deny indemnity under the applicable Policy.

For purposes of determining the applicability of this exclusion:

a. the facts pertaining to and knowledge possessed by any natural person **Insured** shall not be imputed to any other natural person **Insured**; and
b. only facts pertaining to and knowledge possessed by any **Insured** as set forth in paragraph A. of the definition of **Insured** in Section **IV., DEFINITIONS** shall be imputed to **you**.

5. **Failure to Prevent Unauthorized Access**

based on or arising out of any actual or alleged failure to prevent unauthorized access to, or unauthorized use of, **your** client's, or **your** client's customers':

a. confidential or proprietary information; or
b. information systems.

This exclusion applies, but is not limited, to any allegations of loss filed by third-parties based on or arising out any actual or alleged failure in a. or b. above.

6. **Fungi or Bacteria**

based on or arising out of:

a. **bodily injury** or **property damage** which would not have occurred, in whole or in part, but for the actual, alleged or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of, any **fungi** or bacteria on or within a building or structure, including its contents, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such injury or damage; or
b. any loss, cost or expenses 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, **fungi** or bacteria, by any **Insured** or by any other person or entity.

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This exclusion does not apply to any **fungi** or bacteria that are, are on, or are contained in, a good or product intended for bodily consumption.

7. **Intellectual Property Rights**

based on or arising out of a **claim** or **circumstance** of 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:

a. 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);
b. 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;
c. 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
d. 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 against the **Insured** alleging a violation of intellectual property rights, as described above, along with any other allegation, then this exclusion shall apply to preclude coverage for the entire **claim,** even if in the absence of the allegations concerning intellectual property rights any portion of the **claim** would have been covered or a duty to defend the **Insured** would have been owed by us.

8. **Lead**

based on or arising out of:

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

This exclusion does not apply to any **biological products**, **pharmaceutical products**, or **medical devices** intended to treat patients with, or protect patients from, **lead** poisoning.

9. **Medical Services**

based on or arising out of **medical services**. However this exclusion does not apply to:

a. physicians, dentists, nurses, emergency medical technicians or paramedics employed by **you** to the extent that they are rendering first aid; or
b. to any **products-completed operations hazard claim** made against a **clinical trial investigator**.

10. **Misuse of Confidential Information**

based on or arising out of any actual or alleged use or misuse of confidential or proprietary information.

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11. **Nuclear**

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

b. under any Medical Payments coverage, to expenses incurred with respect to **bodily injury** resulting from the **hazardous properties** of **nuclear material** and arising out of the operation of a **nuclear facility** by any person or organization.

c. under any Liability Coverage, to **bodily injury** or **property damage** resulting from **hazardous properties** of **nuclear material**, if:
   i. the **nuclear material** (a) is at any **nuclear facility** owned by, or operated by or on behalf of, an **Insured** or (b) has been discharged or dispersed there from;
   ii. the **nuclear material** is contained in **spent fuel** or **nuclear waste** at any time possessed, handled, used, processed, stored, transported or disposed of, by or on behalf of an **Insured**; or
   iii. the **bodily injury** or **property damage** arises out of the furnishing by an **Insured** of services, materials, parts or equipment in connection with the planning, construction, maintenance, operation or use of any **nuclear facility**, but if such facility is located within the United States of America, its territories or possessions or Canada, this exclusion c. applies only to **property damage** to such **nuclear facility** and any property thereat.

12. **Pollutants**

based on or arising out of:

a. **bodily injury** or **property damage** which would not have occurred in whole or part but for the actual, alleged or threatened discharge, dispersal, seepage, migration, release or escape of **pollutants** at any time; or

b. any loss, cost or expense arising out of any:
   i. 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
   ii. **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**.

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13. **Sexual Abuse**

based on or arising out of the actual, alleged, attempted, proposed or threatened:

a. sexual abuse,
b. molestation,
c. assault, or
d. battery

of any person by an **Insured**.

This exclusion applies regardless of the legal theory or basis upon which an **Insured** is alleged to be liable for any **damages** or injury arising out of the activity described above, including but not limited to assertions of improper or negligent employment, continued employment, investigation, failure to investigate, supervision or failure to supervise.

14. **Silica**

based on or arising out of:

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

15. **War or Civil Insurrection**

based on or arising out of any actual or alleged war, whether or not declared, or any act or condition incident to war. War includes civil war, insurrection, rebellion or revolution.

IV. DEFINITIONS

The following defined words shall have the same meaning throughout this Policy, whether expressed in the singular or the plural and wherever appearing in bold print in this Policy:

Advisory memorandum
means a written communication issued by **you** or on **your** behalf to healthcare professionals, customers, product users, suppliers, vendors or the public at large informing them of an actual or alleged defect or deficiency in **your product** or in its labeling.

Application
means all signed **applications** for this Policy and for any Policy in an uninterrupted series of Policies issued by the Company, or any of its affiliates, of which this Policy is a renewal or replacement, and any materials submitted or required to be submitted therewith.

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

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

Biological product
means any virus, therapeutic serum, toxin, antitoxin, or analogous product that is:

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

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

Bodily injury
means physical harm, sickness or disease sustained by a person including resulting mental injury, mental anguish, shock or death. It also includes physical harm, sickness, disease, mental injury, mental anguish, shock or death sustained by a spouse, **domestic partner** or any relative of that person as a result of that person's injury.

Boxed warning
means any notice required by the Food and Drug Administration pursuant to 21 CFR 201. 57(a) (4) and (c) (1), by any update to the aforesaid sections of the Code of Federal Regulations, or by any foreign equivalent of such.

Circumstance
means an event, act, error or omission reported during the **policy period** from which **you** reasonably expect that a **claim** could be made.

Claim
means:

A. a written demand upon an **Insured** for money or services; or
B. a civil proceeding in a court of law or equity, or arbitration, for money or services, or any appeal therefrom,

against an **Insured**. A **claim** does not include a **circumstance**.

Claim expenses
mean:

A. fees charged by attorneys designated by the Company or by an **Insured** with the Company's prior written consent;
B. all other reasonable and necessary fees, costs and expenses resulting from:
    1. the investigation of a **circumstance**, or
    2. the investigation, adjustment, defense and appeal of a covered **claim**

    if incurred by the Company, or by an **Insured** with the Company's prior written consent, including, but not limited to, premiums for any appeal bond, attachment bond or similar bond but without any obligation of the Company to apply for or furnish any such bond;
C. prejudgment interest awarded against **you** on that part of a judgment the Company pays. If the Company makes an offer to pay the applicable limit of liability, the Company will not pay any prejudgment interest based on that period of time after such offer; or
D. interest on the full amount of a judgment that accrues after entry of the judgment and before the Company has paid, offered to pay or deposited in court the part of the judgment that is within the applicable limit of liability.

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However, **claim expenses** do not include:

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

Class 1 product recall
means that **you** or the United States Food and Drug Administration, or any foreign equivalent, have determined **your product** poses a situation in which there is a reasonable probability that the use of or exposure to **your product** will cause serious adverse health consequences or death.

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

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

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

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

Clinical research organization
means any entity that provides services in connection with organizing, administering or running **clinical trials**.

Coverage relationship
means that period of time between the effective date of the first Policy issued by the Company to the **First Named Insured** and the cancellation or expiration date of that Policy or, if renewed, the last renewal Policy in a consecutive series of renewals issued by the Company to the **First Named Insured**, where there has been no gap in coverage.

Damages
mean judgments; awards; and settlements, but only if made with the Company's prior written consent. **Damages** do not include:

A. restitution and disgorgement of profits, fees, costs and expenses paid or incurred or charged by an **Insured**, no matter whether claimed as restitution of specific funds, forfeiture, financial loss, set-off or otherwise; nor economic injuries that are a consequence of any of the foregoing;
B. civil or criminal fines, sanctions, penalties or forfeitures, whether pursuant to law, statute, regulation or court rule;
C. the multiplied portion of multiplied awards imposed pursuant to any statute or regulation requiring such awards;
D. injunctive or declaratory relief;
E. any amount that is not insurable under any applicable statute or regulation;
F. any amounts for which an **Insured** is liable due to an act or omission in knowing violation of any written contract or agreement; or
G. plaintiff's attorney fees associated with any of the above.

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

Domestic partner
means any person qualifying as such under any federal, state or local laws or under **your employee** benefit plans.

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

Executive officer
means:

A. a person holding any of the officer positions created by **your** charter, constitution, by-laws or any other similar governing document;
B. **your** corporate risk manager; or
C. any **employee** who is responsible for **your** insurance or **claim** reporting.

First Named Insured
means the first entity listed in the Declarations.

Fungi
means any type or form of fungus, including mold or mildew and any mycotoxins, spores, scents or byproducts produced or released by **fungi**.

Hazardous properties
means including radioactive, toxic or explosive properties.

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:

A. the repair, replacement, adjustment or removal of **your product** or **your work**; or
B. **your** fulfilling of the terms of the contract or agreement.

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

Insured
means **you** and any of the following but solely with respect to liability arising out of **your product, your work** or **your professional services**:

A. any individual who was, is or becomes **your** officer, director, member or manager (of a limited liability company), or partner but solely with respect to the conduct of **your** business;

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B. **your** stockholders, but only with respect to their liability as stockholders;

C. **your employees**, but:
   1. with respect to **products-completed operations hazard claims**, solely for acts within the scope of their employment by **you** or while performing duties related to the conduct of **your** business; or
   2. with respect to **professional liability claims**, solely for **professional services** rendered to others on **your** behalf;

   however, none of these **employees** is an **Insured** for:
      a. **bodily injury**:
         i. to **you**, to **your** directors, officers, members or managers, partners, or to a co-**employee** while such injured person is either in the course of his or her employment or performing duties related to the conduct of **your** business, but voluntary participation as a human test subject in a **clinical trial** will not be deemed to be within the scope of employment or performance of duties described herein;
         ii. to the spouse, **domestic partner**, child, parent, brother or sister of such injured person as a consequence of paragraph i. above; or
         iii. for which there is any obligation to share **damages** with or repay someone else who must pay **damages** because of the injury described in paragraphs i. or ii. above;
      b. **property damage** to property:
         i. owned, occupied or used; or
         ii. rented to, in the care, custody or control of, or over which physical control is being exercised for any purpose;

      by **you**, any of **your employees,** any partner or member (if **you** are a partnership or joint venture), or any member (if **you** are a limited liability company);

D. any person (other than **you** or **your employee**), or any organization while acting as **your** real estate manager;

E. **clinical research organizations, medical or biotechnology advisors, clinical trial consultants, institutional review boards** and **clinical trial investigators** (other than **you** or **your employees**); however, no such person or entity is an **Insured** with respect to:
   1. any representation or warranty not authorized by **you;** or
   2. any physical or chemical change in **your** product made intentionally by such person without **your** consent;

F. **medical sales consultants**; however, no such person or entity is an **Insured** with respect to:
   1. any representation or warranty not authorized by **you**;
   2. any physical or chemical change in **your product** made intentionally by such person without **your** consent; or
   3. such person or entity's rendering or failing to render advice, unless the injury or damage arises directly out of the use of **your products**;

G. persons or entities who are vendors of **your products**, but they are **Insureds** only with respect to their liability for **damages** resulting from the distribution or sale of **your products** in the regular course of their business; however, no such person or entity is an **Insured** with respect to:
   1. any representation or warranty not authorized by **you**;
   2. any physical or chemical change in **your product** made intentionally by the vendor;
   3. repackaging, unless unpacked solely for the purpose of inspection, demonstration, or testing, or the substitution of parts under instruction from the manufacturer and then repacked in the original container;

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4. failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business in connection with the distribution or sale of **your products**; or
5. demonstration, installation, servicing or repair operations, except such operations performed at the vendor's premises in connection with the sale of **your products**;

further no person or entity from whom **you** have acquired **your products**, or any container, ingredient or part entering into, accompanying or containing **your products**, is an **Insured** under this provision;

H. any person or entity to whom or to which **you** are obligated by virtue of a written contract, agreement or permit to provide such insurance as afforded by this Policy, but only with respect to liability arising out of **your product, your work** or **your professional services** performed by **you** or on **your** behalf for that **Insured**; however, this provision does not apply;
   1. unless the written contract or agreement has been executed, or the permit has been issued, prior to the **bodily injury, property damage, personal or advertising injury** to a **clinical trial** participant, or **wrongful act**. The contract or agreement will be considered executed when an **Insured's** performance begins, or when it is signed, whichever happens first; or
   2. to any person or entity:
      a. for
         i. **bodily injury,**
         ii. **property damage,**
         iii. **personal or advertising injury** to a **clinical trial** participant, or
         iv. a **professional liability claim**

      arising out of its sole negligence; or
      b. included as an **Insured** by an endorsement issued by the Company and made a part of this Policy.

For sub-sections E., F., G. and H., such persons or entities are **Insureds** only to the extent contained in a written contract or agreement and only up to the amount required by such written contract or agreement, but notwithstanding anything contained in a written contract or agreement, the Company shall not be liable for greater coverage or limits of insurance than provided for in this Policy.

For subsections A.-H., all **claim**s for **damages** because of **bodily injury** to the same person, including **damages** alleged by any person or organization for care, loss of services, or death resulting at any time from the **bodily injury**, will be deemed to have been made at the time the first of those **claims** is made against any **Insured**.

For subsections A.-H., all **claims** for **damages** because of **property damage** or **personal or advertising injury** alleged by 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**.

For subsections A.-H., all **professional liability claims** alleged by 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**.

Insured contract
means that part of any written contract or agreement pertaining to **your** operations or facilities under which **you** assume the tort liability of another to pay **damages** because of **bodily injury**, **property damage, personal or advertising injury** to a **clinical trial** participant, or a **professional liability claim** to a third person or organization, provided such contract or agreement is made prior to the **bodily injury, property damage,** the **personal or advertising injury** to a **clinical trial** participant, or the **wrongful act**. Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.

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Lead
means the element in any form.

Loading or unloading
means the handling of property:

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

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 **automobile**.

Local admitted policy
means any Policy required to be issued by a duly authorized insurer in a jurisdiction outside of the United States, Puerto Rico or Canada that provides compulsory coverage in such jurisdiction.

Management control
means:

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

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

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

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

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

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

Medical or biotechnology advisors
means an entity or individuals, other than **you** or **your employees,** who are serving, or have served as **your** advisor or consultant in a review of the design or development of **your products.**

Medical expenses
means reasonable expense for necessary:

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

Medical sales consultant
means an entity or individuals, other than **you** or **your employees**, providing advice or demonstrating procedures in connection with the sale or distribution of **your products** on the condition that such consultant does not render any direct patient care or **medical services** in connection with the sale or distribution of **your products**.

Medical services
means:

A. dental, medical, mental health, nursing, surgical, imaging, clinical testing or other similar service providing direct care to a patient and performed by a medical intern, resident, technician, nurse, physician or other medical professional;
B. the furnishing of food, beverages, medications or appliances in connection with such services; or
C. the postmortem handling of human bodies.

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 A., B., C. or D. above that are not self-propelled and are maintained primarily to provide mobility to permanently attached equipment of the following types:
    1. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment; or
    2. cherry pickers and similar devices used to raise or lower workers;
F. vehicles not described in A., B., C. or D. above maintained primarily for purposes other than the transportation of persons or cargo.

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

1. equipment designed primarily for:
    a. snow removal;
    b. road maintenance, but not construction or resurfacing; or
    c. street cleaning;
2. cherry pickers and similar devices mounted on **automobile** or truck chassis and used to raise or lower workers; and

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3. air compressors, pumps and generators, including spraying, welding, building cleaning, geophysical exploration, lighting and well servicing equipment.

Named Insured
means any entity listed as such in the Declarations or as amended by endorsement to this Policy.

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

Nuclear facility
means:

A. any **nuclear reactor**;
B. any equipment or device designed or used for (a) separating the isotopes of uranium or plutonium, (b) processing or utilizing **spent fuel**, or (c) handling, processing or packaging **nuclear waste**;
C. any equipment or device used for the processing, fabricating or alloying of **special nuclear material** if at any time the total amount of such material in the custody of an **Insured** at the premises where such equipment or device is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof, or more than 250 grams of uranium 235;
D. any structure, basin, excavation, premises or place prepared or used for the storage or disposal of **nuclear waste**; and

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

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

Nuclear reactor
means any apparatus designed or used to sustain nuclear fission in a self supporting chain reaction or to contain a critical mass of fissionable material. **Property damage** includes all forms of radioactive contamination of property.

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

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

Personal or advertising injury
means injury, including emotional distress and mental anguish, arising out of:

A. defamation or other tort related to disparagement or harm to the character, reputation or feelings of any person or organization, including libel, slander, product disparagement, trade libel, negligent or intentional infliction of emotional distress, outrage or outrageous conduct;
B. false arrest, wrongful detention, false imprisonment, wrongful entry or eviction or other invasion of the right of private occupancy, malicious prosecution or violation of an individual's or entity's right of privacy;

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C. invasion, infringement or interference with rights of privacy or publicity, including false light, public disclosure of private facts, intrusion and commercial appropriation of name or likeness;
D. infringement of copyright, title, slogan, trademark, trade name, trade dress, trade secrets, logo, service mark or service name;
E. the use of another's advertising idea; or
F. plagiarism, piracy, misappropriation of ideas under implied contract or other misappropriation of property rights, ideas or information.

Pharmaceutical drug
means a synthetic or natural chemical:

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

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

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

Pollutants
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.

Products-completed operations hazard
means:

A. **bodily injury** or **property damage** arising out of **your product** or **your work**; or
B. **personal or advertising injury** but solely to the extent such **personal or advertising injury** arises out of **clinical trials** sponsored by **you** or **your** customer, and solely to the extent a **clinical trial** participant incurs such **personal or advertising injury**.

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

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

Products-completed operations hazard claim
means a **claim** alleging a **products-completed operations hazard** and arising out of an **occurrence**.

Professional liability claim
means a **claim** arising out of a **wrongful act.**

Professional services
means those services performed by **you**, or by any other **Insured** on **your** behalf, in relation to **your products** or **your work**, provided such services are specified in a written contract or agreement between **you** and **your** client.

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Professional services does not include services by, or on behalf of, the **Insured** while acting or working as any of the following: accountant, architect or surveyor, lawyer, insurance agent, broker company consultant or representative; real estate agent or broker or civil or structural engineer.

Professional services injury
means a **claim** alleging **bodily injury** or **property damage** arising out of a **wrongful act**.

Property damage
means:

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

Related claims
means all **claims** arising out of a single **wrongful act** or **related wrongful acts**, or an **occurrence** or **related occurrences**.

Related occurrence
means an **occurrence** giving rise to **bodily injury**, **property damage, professional services injury** or **personal or advertising injury** to two or more persons or properties which **bodily injuries**, **property damage, professional services injuries** or **personal or advertising injuries** are attributable directly, indirectly or allegedly to the same actual, or alleged, event, condition, cause, defect, hazard, advice or decision in the design, formulation, manufacturing, distribution, sale, testing, use, operation, maintenance, repair or replacement of **your product** or **your work**. Such **related occurrence** exists regardless of:

A. when or where such **bodily injuries**, **property damage, professional services injuries** or **personal or advertising injuries** occur; or
B. the number of such **bodily injuries**, **property damage, professional services injuries** or **personal or advertising injuries**.

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

Silica
means silicon dioxide occurring in crystalline, amorphous or impure forms, **silica** particles, **silica** dust or **silica** compounds. It does not include processed colloidal silicon dioxide

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

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

Submission materials
means any materials provided by **you** or on **your** or any other **Insured's** behalf in connection with the **application** process for this insurance.

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

Takeover
means:

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

Wrongful act
means any actual or alleged negligent act, error or omission in the rendering of or failure to render **professional services** by **you** or by any **Insured** on **your** behalf.

You (or **Your)**
means any **Named Insured** and any **subsidiary** or any **newly acquired subsidiary**.

Your product
means:

A. Any goods or products including, but not limited to, **biological products**, **pharmaceutical drugs** or **medical devices** manufactured, developed, designed, created, tested, sold, leased, licensed, rented, handled, marketed, distributed to others or disposed of, by **you** or others on **your** behalf; and
B. containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.

Your product includes:

A. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of **your product**; and
B. the providing of, or failure to provide, training, warnings or instructions.

Your work
means:

A. work or operations performed by **you** or on **your** behalf, in compliance with all applicable laws, statutes or ordinances; and
B. materials, parts or equipment furnished in connection with such work, operations or services.

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Your work includes:

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

V. CONDITIONS

A. Your Duties if there is a Claim

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

1. notify the Company as soon as reasonably possible of any **claim;**
    a. such notice must be in writing and be sent to the attention of Navigators Specialty Claims:
    by email to: RBClaims@navg.com
    by fax to: (847) 285-9003
    by mail to: 1375 E. Woodfield Rd., Suite 720 Schaumburg, IL 60173
    b. such notice must be given to the Company no later than ninety days (90) after termination or expiration of the **coverage relationship**, or during the Extended Reporting Period, if applicable;
2. specify the names and addresses of the persons making a **claim** against an **Insured** and provide the Company with information on the time, place and nature of the **claim**;
3. promptly forward to the Company all documents that the **Insured** receives in connection with the **claim**;
4. fully cooperate with the Company or its designee in the defense of a **claim**, including but not limited to assisting the Company in the conduct of suits or other proceedings, settlement negotiations, and the enforcement of any right of contribution or indemnity against another who may be liable to an **Insured**;
5. shall attend hearings and trials and assist in securing evidence and obtaining the attendance of witnesses; and
6. will not voluntarily make any payment, admit liability, assume any obligation or incur any expense, other than first aid, without the Company's written approval.

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

B. Your Rights in the Event of a Circumstance

If, during the **policy period**, **you** report a **circumstance** for which there may be coverage under this Policy, and **you** give the Company written notice containing:

1. what happened, and the details of **your work, your product** or activities **you** performed that might give rise to a **claim**;
2. the nature of any possible injury or **damages**;
3. how **you** first became aware of such **circumstance**;
4. the identity of the specific **Insureds** allegedly responsible for such specific activities; and
5. the nature of the potential demand for money or services that may be sought in consequence of such specific activities,

then any **claim** otherwise covered that may subsequently be made against an **Insured** during the **Coverage Relationship,** during the automatic Extended Reporting Period, or any Supplemental Extended Reporting Period if purchased, arising out of such **circumstance** shall be deemed to have been made against such **Insured** on the date the Company received written notice of the **circumstance**.

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

You must see to it that the Company is advised as soon as reasonably possible of any **advisory memorandums** or **class 1 product recalls** issued during this **policy period**. **You** must also see to it that the Company is advised as soon as reasonably possible of **boxed warnings** added to, or revised for, any of **your** previously approved product labeling during this **policy period**. Timely reporting of such events is required for coverage to be afforded for any future losses or **claims** that may arise as a result of these events.

D. When a Claim shall be Deemed Made

A **claim** is deemed made:

1. in the case of a written demand, on the **executive officer's** receipt of such demand; or
2. in the case of a civil proceeding in a court of law or equity or arbitration, or a regulatory proceeding, on the date of service upon, or other receipt by, **you** of a complaint against **you** in such proceeding or arbitration.

E. Transfer of Rights of Recovery Against Others

If an **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 the Company's request, the **Insured** will bring suit or transfer those rights to the Company and help it enforce them.

However, the Company will waive any right of recovery it may have against any person or entity because of payments it made for injury or damage arising out of **your work** or **your products** under a written contract or agreement with that person or entity. This waiver applies only to persons or entities with whom **you** have a written contract, executed prior to the **occurrence** or **wrongful act,** that requires **you** to waive **your** rights of recovery.

The amount recovered shall be apportioned in the inverse order of payment of **damages** to the extent of actual payment. **Claim expenses** shall be apportioned in the ratio of respective recoveries.

F. Premium

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

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

G. Bankruptcy

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

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H. Changes

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

I. Assignment

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

J. Cancellation

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

If the Company cancels this Policy, a refund due shall be computed on a pro-rata basis and shall be promptly returned to the **First Named Insured**; however, if the **First Named Insured** cancels this Policy, the refund due shall be 90% of the pro-rata unearned paid premium, or 75% of the total policy term premium at inception of this Policy, whichever is less, but subject to the minimum premiums shown in the Declarations. The **First Named Insured** may elect in writing to the Company to have any return premium due applied to the additional premium charged for any Supplemental Extended Reporting Period, if purchased.

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

K. Other Insurance

If the **Insured** is entitled to be indemnified or otherwise covered in whole or in part by any other valid and collectible insurance, self insurance or indemnity agreement for any **claim** which otherwise would have been indemnified in whole or in part by this Policy, the limits of liability specified in the Declarations shall apply in excess of, and shall not contribute to that **claim.** Solely with respect to any **local admitted policy** the company shall only be liable for any **damages** or **claim expenses** that are also covered under the terms and conditions of this Policy to the extent it would have been liable had **you** purchased and maintained such **local admitted policy**. This paragraph does not apply to any other insurance that was bought specifically to apply in excess of the limits of liability shown in the Declarations of this Policy.

The Company will have no duty under this Policy to defend an **Insured** against any **claim** if any other insurer has a duty to defend the **Insured** against that **claim.** If no other insurer defends, the Company will undertake to do so, but it will be entitled to the **Insured's** rights against all those other insurers.

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Solely with respect to any person or organization covered pursuant to Section **IV**. **DEFINITIONS**, the definition of **Insured**, the insurance afforded by this Policy is primary and non-contributory over any other primary insurance available to such **Insured** when required by written contract.

L. Currency

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

M. Action Against the Company

No person or entity has a right under this Policy:

1. to join the Company as a party or otherwise bring it into a suit asking for **damages** from an **Insured**; or
2. to sue the Company on this Policy unless all terms have been fully complied with.

N. Inspection and Audit

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

The Company may examine and audit **your** books and records at any time during the **policy period** and extensions thereof and within three years after the final termination of the Policy.

O. Sole Agent

The **First Named Insured** is authorized to act on behalf of all **Insureds** with respect to giving or receiving notice of cancellation, non-renewal, premium or changes in this Policy or requesting a Supplemental Extended Reporting Period endorsement.

P. Entire Contract

By acceptance of this Policy **you** agree that:

1. all of the information and statements provided to the Company by **you** are true, accurate and complete and shall be deemed to constitute material representations made by all of the **Insureds**;
2. this Policy is issued in reliance upon **your** representations;
3. this Policy, endorsements thereto, together with the completed and signed **application** (which is deemed to be incorporated herein) embody all of the agreements existing between the **Insureds** and the Company and shall constitute the entire contract between the **Insureds** and the Company; and
4. the willful or intentional misrepresentation of any material matter by **you** or **your** agent will render this Policy null and void and relieve the Company from all liability herein.

Q. Territory

This insurance applies anywhere in the world regardless of where the **occurrence** or **wrongful act** takes place or where a **claim** is brought, subject to the following:

1. Solely with respect to any **claim** brought outside of the United States and Canada, this insurance is not a substitute for any **local admitted policy**. The Company assumes no responsibility for the furnishing of

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certificates, evidence of insurance or bonds in any country in which it is not an admitted or authorized insurer. The Company shall not be liable for any fine or penalty imposed upon an **Insured** or any person or entity covered under this Policy, for failing to obtain insurance from an admitted or duly authorized insurer, nor for any other failure to comply with an insurance law of jurisdiction in which it is not an admitted or authorized insurer.

2. Notwithstanding anything to the contrary in this Policy, with respect to any **claim** brought outside of the United States, Puerto Rico or Canada, the **Insured** and not the Company, shall be obligated to assume charge of and pay the costs of the investigation and defense of any such **claims**. The Company, however, has the right to approve in writing the retention of any defense counsel or to participate with the **Insured** in the choice of arbitrators or mediators. The Company also has the right to be kept fully informed, or to have our designated representative kept fully informed, by the **Insured** concerning the conduct of such defense or such arbitration or mediation.
3. Solely with respect to any **claim** brought outside the United States, Puerto Rico or Canada, the Company will reimburse the **Insured** for, or at our sole option, pay on the **Insured's** behalf, those sums that the **Insured** becomes legally obligated to pay as **damages** and **claim expenses** to which this insurance applies.

Any disputes between an **Insured** and the Company as to whether there is coverage under this Policy must be filed in the courts of the United States of America, Puerto Rico or Canada.

R. Extended Reporting Periods

Extended Reporting Periods do not extend the **policy period** or change the scope of coverage provided, nor do they act to reinstate or increase any of the limits of liability. They apply only to **claims** that occur before the end of the **policy period** but not before the retroactive date shown in the Declarations. Extended Reporting Periods begin at the end of the **coverage relationship** and apply to **claims** first made and reported to us during the Extended Reporting Periods. A **claim** first made and reported to us during Extended Reporting Periods will be deemed to have been made on the last day of the **policy period**.

1. Automatic Extended Reporting Period
   The Company will provide an automatic, non-cancelable Extended Reporting Period of 90 days at no additional premium if no other insurance is purchased by **you** to replace this Policy. With respect to any **circumstance** reported to the Company, all **claims** associated with the reported **circumstance** must be reported within 5 years of the end of the **coverage relationship** in accordance with **Section V., CONDITIONS, paragraph B., Your Rights In The Event of a Circumstance.**
2. Supplemental Extended Reporting Period (Optional)
   An optional Supplemental Extended Reporting Period of up to a maximum of 84 months can be purchased to replace the Automatic Extended Reporting Period. To obtain a Supplemental Extended Reporting Period, **you** must make a request to the Company in writing within 90 days after the end of the **policy period,** or the effective date of cancellation. An additional premium of not more than 200% of the adjusted Annual Premium will be charged for this option.

Purchasing a Supplemental Extended Reporting Period does not change the 5 year limit to report **claims** associated with any reported **circumstance.**

Once in effect, a Supplemental Extended Reporting Period may not be canceled unless **you** fail to pay additional premiums or premium audits when due.

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S. Separation of Insureds

Except with respect to the limits of liability, and any rights or duties specifically assigned in this Policy to the **First Named Insured**, this insurance applies:

1. as if each of **you** were the only **you**; and
2. separately to each **Insured** against whom a **claim** is made.

T. Change of Status of Insureds

1. **Takeover** of the **First Named Insured:** In the event of a **takeover** of the **First Named Insured**, this Policy shall automatically and without any notification terminate effective as of the date of such **takeover**, unless the Company is notified in writing of the **takeover** prior to the **takeover** effective date and agrees in writing to continue the Policy beyond the effective date of **takeover** and the **First Named Insured** accepts any special terms, conditions and exclusions and pays any additional premium charge required by the Company.
2. Cessation of **Subsidiary:** if any entity ceases to be a **subsidiary**, such **subsidiary** shall cease to be an **Insured** under this Policy and all coverage for such **subsidiary** under this Policy shall terminate with respect to such **subsidiary** without any notification on the effective date of such cessation, unless the Company is notified in writing of such cessation prior to the effective date thereof and agrees in writing to continue coverage for such **subsidiary**, and the **First Named Insured** accepts any special terms, conditions and exclusions and pays any additional premium charge required by the Company.

U. U.S. Economic and Trade Sanctions Limitations Clause

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 the trade or economic sanctions, laws or regulations of the United States of America.

The United States of America trade or economic sanctions, laws or regulations shall include, but not be limited to, those sanctions administered and enforced by the U.S. Treasury Department's Office of Foreign Assets Control (OFAC).

V. Estates, Legal Representatives and Spouses

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

W. Service of Suit

In the event the Company fails to pay an amount alleged to be due hereunder, the Company, at the request of the **First Named Insured**, will not dispute personal jurisdiction in any state within the United States. Nothing herein constitutes or should be understood to constitute a waiver of the Company's rights to commence an action in any court of competent jurisdiction in the United States, to remove an action to United States District Court, to seek a transfer of an action to another court as permitted by law, or to seek the dismissal of an action based upon the doctrine of forum non conveniens.

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Service of process in such suit shall be made upon:

Name: Navigators Management Company
Attn: General Counsel
Address: 400 Atlantic Street, 8th Floor, Stamford, CT 06901

and in any suit instituted against such person upon this Policy, the Company will abide by the final decision of such court or of any appellate court in the event of an appeal.

The General Counsel is authorized and directed to accept service of process on behalf of the Company in any such suit and, upon the request of the **First Named Insured**, to give a written undertaking to the **First Named Insured** that he or she will enter a general appearance upon the Company's behalf in the event such suit shall be instituted.

Further, pursuant to any statute of any state, territory or district of the United States that makes provision therefor, the Company hereby designates the Superintendent, Commissioner or Director of Insurance or other officer specified for that purpose in the statute, or his successor or successors in office, as its true and lawful attorney upon whom may be served any lawful process in any action, suit or proceeding instituted by or on behalf of any **Named Insured** or any beneficiary hereunder arising out of this contract of insurance, and hereby designates the above-named as the person to whom the said officer is authorized to mail such process or true copy thereof.

X. Headings

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

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THIS ENDORSEMENT CHANGES THE POLICY
PLEASE READ IT CAREFULLY

NAVIGATORS LIFE SCIENCES
GLS ELITE PLUS COVERAGE ENDORSEMENT

This endorsement modifies insurance provided under the following:
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

I) The following is added to Section **I. INSURING AGREEMENTS** of this policy**:**

E. **Supplementary Benefits**

Subject to paragraph **C. When Coverage Applies** of Section **I. INSURING AGREEMENTS**:

1. **Mitigation Expenses**

a. The Company will reimburse **you** for 90% of the **mitigation expenses** subject to the **mitigation expenses** sublimit of liability set forth in the Declarations provided that prior to incurring any **mitigation expenses**:

i. **you** report the **claim** or **circumstance** for which **you** intend to incur such **mitigation expenses** in accordance with Section **V., CONDITIONS**, paragraphs **A.** and **B.**;
i. **you** provide the Company with details of the action being contemplated by **you** to minimize any potential **damages** arising out of such **claim** or **circumstance** and the amount of **mitigation expenses** that are contemplated in connection with such action;
ii. the Company provides written approval of any **mitigation expenses** prior to such **mitigation expenses** being incurred. No **mitigation expenses** will be approved by the Company that are requested less than five business days prior to the planned incurrence of such **mitigation expenses**; and
iii. **you** cooperate with the Company in addressing the **claim** or **circumstance** for which **you** are incurring **mitigation expenses.**

b. **Your** participation on the **mitigation expenses** are borne entirely by **you** and **you** will not obtain insurance to cover it.

2. **Class 1 Product Recall Expenses Reimbursement**

The Company will reimburse **you** for **class 1 product recall expenses** in excess of the **class 1 product recall expenses** deductible and subject to the **class 1 product recall expenses** sublimit of liability set forth in the Declarations provided that the **class 1 product recall**:

a. takes place in the coverage territory;
b. is initiated during the **policy period**;
c. prior to the **policy period**, no **executive officer** had prior knowledge of any potential need for such **class 1 product recall;** and
d. the Company provides written approval of any **class 1 product recall expenses** prior to such **class 1 product recall expenses** being incurred.

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3. **Medical Expenses**

The Company will reimburse **you** for **medical expenses**, subject to the **medical expenses** limit of liability set forth in the Declarations, for **bodily injury** caused by an accident that happens to a human subject in connection with the conduct of a **clinical trial**, provided that:

a. the accident takes place during the **policy period**;
b. the **medical expenses** are incurred by a **Named Insured** and reported to the Company within one year of the date of the accident;
c. the injured human subject submits to examination, at the Company's expense, by physicians of the Company's choice as often as the Company reasonably requires; and
d. such **bodily injury** is not otherwise excluded under the policy.

The Company will make these payments regardless of fault.

II) Section **II. LIMITS OF LIABILITY AND DEDUCTIBLE OR RETENTION, D. Multiple Insureds, Claims and Claimants** is deleted and replaced by:

D. Multiple Insureds, Claims and Claimants

The limits of liability shown in the Declarations are the amounts the Company will pay as **damages**, **claim expenses, mitigation expenses**, or **class 1 product recall expenses** regardless of the number of **Insureds**, **claims** made**, circumstances** reported, **class 1 product recalls,** or persons or entities making **claims**.

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

III) The following is added to Section **II. LIMITS OF LIABILITY AND DEDUCTIBLE OR RETENTION** of this policy**:**

F. **Supplementary Benefits Limits**

1. **Mitigation expenses Sublimit of Liability**

a. **Sublimit of Liability–each claim or circumstance**
Subject to paragraph b**.** below, the amount paid by the Company for **mitigation expenses** for each **claim** or **circumstance** shall not exceed the **mitigation expenses** sublimit for Each Claim or Circumstance set forth in the Declarations.

b. **Sublimit of Liability–in the aggregate**
The sublimit of liability of the Company for **mitigation expenses** for all **claims** or **circumstances** shall not exceed the amount set forth in the Declarations as the **mitigation expenses** Aggregate.

The **mitigation expenses** sublimits set forth in the Declarations are included within and are not in addition to the Products-Completed Operations and Professional Liability Each Claim and Aggregate Liability limits as shown in the Declarations. As such, the **mitigation expenses** sublimits erode the

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Each Claim Products-Completed Operations and Professional Liability limit and the Products-Completed Operations and Professional Liability Aggregate limit of liability set forth in the Declarations. All **mitigation expenses** arising out of the same **occurrence** or **wrongful act** are subject to the applicable limits of liability of the policy where the first request for **mitigation expenses** is made.

2. **Class 1 product recall expenses Sublimit of Liability**

   a. **Sublimit of Liability–each recall**
   Subject to paragraph b**.** below, the amount paid by the Company for expenses for each **class 1 product recall** shall not exceed the **class 1 product recall expenses** sublimit for Each Recall set forth in the Declarations.

   b. **Sublimit of Liability–in the aggregate**
   The amount paid by the Company for expenses for all **class 1 product recalls** shall not exceed the amount set forth in the Declarations as the **class 1 product recall expenses** Aggregate.

   The **class 1 product recall expenses** sublimits set forth in the Declarations are included within and are not in addition to the Products-Completed Operations Each Claim and Aggregate Liability limits as shown in the Declarations. As such, the **class 1 product recall expenses** sublimits erode the Each Claim Products-Completed Operations Liability limit and the Products-Completed Operations Liability Aggregate limit of liability set forth in the Declarations. All **class 1 product recall expenses** arising out of the same **occurrence** are subject to the applicable limits of liability of the policy where the first request for **class 1 product recall expenses** is made.

3. **Medical Expenses Sublimit of Liability**

   a. **Limit of Liability–each person**
   Subject to paragraph b. below, the limit of liability of the Company for all **medical expenses** for each injured human subject shall not exceed the **medical expenses** sublimit set forth in the Declarations.

   b. **Limit of Liability–in the aggregate**
   The limit of liability of the Company for all **medical expenses** in the aggregate shall not exceed the amount stated in the Declarations as the aggregate.

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

IV) The following is added to Section **III. EXCLUSIONS C. Exclusions applicable to both Products-Completed Operations Hazard and Professional Services Injury Coverage and Professional Liability Coverage** of this policy:

Class 1 Product Recall Expenses Exclusion:

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

1. **Caprice**

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caprice or whim of any **Insured**;

2. **Chemical change**

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

3. **Faulty formula**

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

4. **Intended purpose**

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

5. **Loss of reputation**

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

6. **Prior circumstances**

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

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

7. **Redistribution or replacement**

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

8. **Shelf life**

your product exceeding its designated shelf life;

9. **Withdrawal of similar products**

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

V) The following is added to Section **IV. DEFINITIONS, Claim expenses:**

Claim expenses do not include **mitigation expenses.**

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VI) In regards to **Class 1 product recall expense** coverage only, Section **IV. DEFINITIONS, Class 1 product recall** is deleted and replaced by:

Class 1 product recall
means that **you** or the United States Food and Drug Administration, or any foreign equivalent, have determined **your product** poses a situation in which there is a reasonable probability that the use of or exposure to **your product** will cause serious adverse health consequences or death, and as a result of that determination, you issue a recall for **your products** that had been manufactured, processed, packaged, handled, distributed, or sold by **you,** and physically relinquished to others. A **class 1 product recall** is deemed to be a **circumstance** and is subject to the reporting requirements of Section **V., CONDITIONS,** paragraph **B. Your Rights In The Event Of A Circumstance.**

VII) The following is added to Section **IV. DEFINITIONS**:

Class 1 product recall expenses
means reasonable and necessary expenses, incurred with the Company's prior written consent as a result of a **class 1 product recall**, for:

A. any communication costs incurred to announce the withdrawal, including but not limited to:

    1. telephone, radio, television, and internet announcements; and
    2. production costs of the announcements, such as printing costs, stationary, envelopes and postage;

B. transporting **your product** from any purchaser, distributor or user, to locations designated by **you**;

C. transporting your **employees** to any purchaser, distributor or user in order to effectuate reasonable and necessary on-site repairs due to a **class 1 product recall**;

D. remunerating **your employees** for overtime to perform the actions in 1. 2., or 3. above, and, if necessary, the cost to hire and pay additional persons other than **your** regular employees to perform these actions;

E. properly disposing of **your product**, including packaging that cannot be reused; or

F. renting temporary locations used to store **your product**.

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

Mitigation expenses
means reasonable and necessary fees, costs and expenses incurred by **you** in **your** efforts to mitigate potential **damages** for which **you** might become liable due to a **claim** or a **circumstance**. **Mitigation expenses** do not include fees, costs or expenses incurred to comply with any governmental or regulatory requirement, **class 1 product recall expenses** or **medical payments**. **Mitigation expenses** do not include **damages** or **claim expenses**.

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DESIGNATED PRODUCTS EXCLUSION

This endorsement modifies insurance provided under the following:
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

The following is added to Section **III. EXCLUSIONS, A. Exclusions applicable to Products-Completed Operations Hazard and Professional Services Injury Coverage:**

Excluded Products

based on or arising out of:

1) manufacturing or sponsoring of:

   - Any product containing mercury, where such product is or is intended to be implanted, ingested, injected, inhaled or absorbed
   - Birth control or fertility goods or products whose primary function is to control or affect fertility, fertilization, conception or contraception
   - Di-(2-Ethylhexyl) Phthalate (DEHP) used in goods or products approved for neonatal patients
   - Diethylstilbestrol (DES)
   - Ephedra
   - Ephedrine, or pseudoephedrine, except where used in over the counter drug products or prescription products
   - Isotretinoin
   - Latex gloves when sensitivity warning is not on the package or other labeling
   - Metoclopramide (including but not limited to Reglan) in regards to side effects of Tardive Dyskinesia, worsening of Parkinson's, and other movement disorders resulting from usage of the drug
   - Oral hormone replacement products approved for menopause treatment
   - Pain pumps when inserted directly into an orthopedic joint and administering pharmaceuticals not approved for joint application
   - Permanent breast implants, except when part of mastectomy reconstruction products and warning of ALCL has been added to the package and other labeling
   - Phentermine used in combination with fenfluramine (including but not limited to Pondimin) or dexfenfluramine (Redux)
   - Propoxyphene (including but not limited to Darvon or Darvocet)

   The exclusions above shall not apply to contract manufacturers who are indemnified and held harmless contractually, or do not have responsibility, for label or warning design, regulatory reporting, safety surveillance, formulation or development.

2) blood banks and blood donation facilities, except biobanks handling and storing samples for research and development, clinical trials and testing.

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AMEND WHEN COVERAGE APPLIES ENDORSEMENT

This endorsement modifies insurance provided under the following:
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

Section **I. INSURING AGREEMENTS, C. When Coverage Applies,** subparagraph 4. is deleted and replaced by the following:

4. a. the claimant first used, first ingested, first had implanted, first applied, first had applied or first consumed **your product**, including in a **clinical trial**, on or after the retroactive date specified in the Declarations;
   b. the claimant first used, first applied, first encountered, or first interacted with **your work** or **your professional services** on or after the retroactive date specified in the Declarations; and

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CYBERONE COVERAGE
NETWORK SECURITY LIABILITY

This endorsement modifies insurance provided under the following:
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

Throughout this Coverage Endorsement (hereinafter referred to as "CyberOne Coverage"), the words "you" and "your" refer to the Named Insured(s) shown in the Declarations of this policy and any other person(s) or organization(s) qualifying as a Named Insured under this CyberOne Coverage. The words "we", "us" and "our" refer to the company providing this insurance.

Words and phrases that appear in "quotations" have special meaning. Refer to DEFINITIONS of this endorsement for those words and phrases. Other words and phrases that appear in **bold** also have special meaning. Refer to DEFINITIONS in the GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE or the GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE for words or phrases in **bold**.

COVERED CAUSE OF LOSS

This Network Security Liability coverage applies only if all of the following conditions are met:

1. You first receive notice of a "network security liability suit" during the **policy period** for which this endorsement is applicable or any Extended Reporting Periods; and
2. Such "network security liability suit" is reported to us as soon as practicable, but in no event more than 60 days after the date it is first received by you.

COVERAGES PROVIDED

If both of the conditions listed above in COVERED CAUSE OF LOSS have been met, then we will provide you the following coverages for loss directly arising from such "network security liability suit".

1. Defense
   We will pay your necessary and reasonable "network security liability defense costs".
2. Settlement Costs
   We will pay your necessary and reasonable "network security liability settlement costs".

LIMITS

Except for post-judgment interest, the most we will pay under Network Security Liability coverage is the Network Security Liability Limit indicated for this endorsement shown in the Declarations of this policy.
The Network Security Liability Limit is an annual aggregate limit. This amount is the most we will pay for the total of all loss covered under this endorsement (other than post-judgment interest) arising out of all "network security liability suits" of which you first receive notice during the present annual **policy period** or any Extended Reporting Periods. This limit applies regardless of the number of "network security liability suits" of which you first receive notice during that period.

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You may first receive notice of a "network security liability suit" in one **policy period** but it may cause covered costs in one or more subsequent **policy period**s. If so, all covered costs arising from such "network security liability suit" (other than post-judgment interest) will be subject to the Network Security Liability Limit applicable to the **policy period** when notice of the "network security liability suit" was first received by you.

The Network Security Liability Limit for the Extended Reporting Periods (if applicable) shall be part of, and not in addition to, the Network Security Liability Limit for the immediately preceding **policy period**.

DEDUCTIBLE

The Network Security Liability coverage is subject to the Network Security Liability Deductible indicated in the Declarations for this policy. You shall be responsible for the applicable deductible amount as respects loss arising from each "network security liability suit" covered under this endorsement.

EXCLUSIONS, ADDITIONAL CONDITIONS AND DEFINITIONS

EXCLUSIONS

The following additional exclusions apply:
We will not pay for costs or loss arising from the following:

1. Loss to the internet, an internet service provider, or any computer or computer system that is not owned or leased by you and operated under your control.
2. Costs to research or correct any deficiency.
3. Any fines or penalties.
4. Any criminal investigations or proceedings.
5. Any threat, extortion or blackmail. This includes, but is not limited to, ransom payments and private security assistance.
6. Your intentional or willful complicity in a covered loss event or your reckless disregard for the security of your computer system or data.
7. Any criminal, fraudulent or dishonest act, error or omission, or any intentional or knowing violation of the law by you.
8. That part of any "network security liability suit" seeking any non-monetary relief.
9. Any "network security liability suit" arising from a propagation of malware, denial of service attack, or if applicable, loss, release or disclosure of business data that occurred prior to the first inception of this CyberOne coverage endorsement or any coverage substantially similar to that described in this endorsement.
10. The propagation or forwarding of malware, including viruses, worms, Trojans, spyware and keyloggers in connection with hardware or software created, produced or modified by you for sale, lease or license to third parties.

ADDITIONAL CONDITIONS

The following additional conditions apply to this endorsement.

A. Due Diligence

You agree to use due diligence to prevent and mitigate costs covered under this endorsement. This includes, but is not limited to, complying with reasonable and industry-accepted protocols for:

1. Providing and maintaining appropriate computer and internet security; and
2. Maintaining and updating at appropriate intervals backups of computer data.

B. Duties in the Event of a "Network Security Liability Suit"

If a "network security liability suit" is brought against you, you must:

1. Immediately record the specifics of the "network security liability suit" and the date received; and
2. Provide us with written notice, as soon as practicable, but in no event more than 60 days after the date the "network security liability suit" is first received by you.

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3. Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the "network security liability suit";
4. Authorize us to obtain records and other information;
5. Cooperate with us in the investigation, settlement or defense of the "network security liability suit";
6. Assist us, upon our request, in the enforcement of any right against any person or organization which may be liable to you because of loss to which this insurance may also apply; and
7. Not take any action, or fail to take any required action, that prejudices your rights or our rights with respect to such "network security liability suit".

C. Extended Reporting Periods

1. You shall have the right to the Extended Reporting Periods described in this section, in the event of a "termination of coverage".
2. If a "termination of coverage" has occurred, you shall have the right to the following:
   a. An Automatic Extended Reporting Period of 30 days after the effective date of "termination of coverage" at no additional premium in which to give us written notice of a "network security liability suit" of which you first receive notice during said Automatic Extended Reporting Period for any propagation of malware, denial of service attack, or if applicable, loss, release or disclosure of business data occurring before the end of the coverage period for this CyberOne coverage and which is otherwise covered by this CyberOne coverage; and
   b. Upon payment of an additional premium of 100% of the full annual premium applicable to this CyberOne coverage, a Supplemental Extended Reporting Period of 1 year immediately following the effective date of "termination of coverage" in which to give to us written notice of a "network security liability suit" of which you first receive notice during said Supplemental Extended Reporting Period for any propagation of malware, denial of service attack, or if applicable, loss, release or disclosure of business data occurring before the end of the coverage period for this CyberOne coverage and which is otherwise covered by this CyberOne coverage.
   To obtain the Supplemental Extended Reporting Period, you must request it in writing and pay the additional premium due, within 30 days of the effective date of "termination of coverage". The additional premium for the Supplemental Extended Reporting Period shall be fully earned at the inception of the Supplemental Extended Reporting Period. If we do not receive the written request as required, you may not exercise this right at a later date.
   This insurance, provided during the Supplemental Extended Reporting Period, is excess over any other valid and collectible insurance that begins or continues in effect after the Supplemental Extended Reporting Period becomes effective, whether the other insurance applies on a primary, excess, contingent, or any other basis.

D. Network Security Liability Defense

1. We shall have the right and the duty to assume the defense of any applicable "network security liability suit" against you. You shall give us such information and cooperation as we may reasonably require.
2. You shall not admit liability for or settle any "network security liability suit" or incur any defense costs without our prior written consent.
3. If you refuse to consent to any settlement recommended by us and acceptable to the claimant, we may then withdraw from your defense by tendering control of the defense to you. From that point forward, you shall, at your own expense, negotiate or defend such "network security liability suit" independently of us. Our liability shall not exceed the amount for which the suit could have been settled if such recommendation was consented to, plus defense costs incurred by us, and defense costs incurred by you with our written consent, prior to the date of such refusal.
4. We shall not be obligated to pay any damages or defense costs, or to defend or continue to defend any "network security liability suit", after the Network Security Liability Limit has been exhausted.
5. We shall pay all interest on that amount of any judgment within the Network Security Liability Limit which accrues:
   a. After entry of judgment; and
   b. Before we pay, offer to pay or deposit in court that part of the judgment within the Network Security Liability Limit or, in any case, before we pay or offer to pay the entire Network Security Liability Limit.

   These interest payments shall be in addition to and not part of the Network Security Liability Limit.

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E. Other Data Coverage in This Policy

Some elements of this CyberOne coverage may also be covered under the policy to which this endorsement is attached. If so, this CyberOne coverage will apply as excess, additional coverage. If loss payment has been made under the policy for the same event, the amount of such payment will count towards the deductible that applies to this CyberOne coverage.

F. Services

The following conditions apply as respects any services provided to you by any service firm provided or paid for in whole or in part under this endorsement:

1. The effectiveness of such services depends on your cooperation and assistance.
2. We do not warrant or guarantee that the services will end or eliminate all problems associated with the covered events.

DEFINITIONS

With respect to the provisions of this endorsement only, the following definitions are added:

1. "Network Security Liability Defense Costs"
   a. "Network security liability defense costs" means reasonable and necessary expenses resulting solely from the investigation, defense and appeal of any "network security liability suit" against you. Such expenses may be incurred by us. Such expenses may include premiums for any appeal bond, attachment bond or similar bond. However, we have no obligation to apply for or furnish such bond.
   b. "Network security liability defense costs" does not mean your salaries or your loss of earnings.
2. "Network Security Liability Settlement Costs"
   a. "Network security liability settlement costs" means the following, when they arise from a "network security liability suit":
      1) Damages, judgments or settlements; and
      2) Defense costs added to that part of any judgment paid by us, when such defense costs are awarded by law or court order; and
      3) Pre-judgment interest on that part of any judgment paid by us.
   b. "Network security liability settlement costs" does not mean:
      1) Civil or criminal fines or penalties imposed by law;
      2) Punitive or exemplary damages;
      3) The multiplied portion of multiplied damages;
      4) Taxes; or
      5) Matters which may be deemed uninsurable under the applicable law.
3. "Network Security Liability Suit"
   a. "Network security liability suit" means a civil proceeding against you in which damages are alleged. Such proceeding must be brought in the United States of America, Puerto Rico or Canada. Such proceeding must be based on an allegation that a negligent security failure or weakness with respect to a computer or other electronic hardware that is owned or leased by you and operated under your control allowed one or more of the following to happen:
      1) The unintended propagation or forwarding of malware, including viruses, worms, Trojans, spyware and keyloggers. Malware does not include shortcomings or mistakes in legitimate electronic code.
      2) The unintended abetting of a denial of service attack against one or more other systems.
   b. "Network security liability suit" also means a civil proceeding against you in which damages are alleged which is brought in the United States of America, Puerto Rico or Canada and which is based on an allegation that a negligent security failure or weakness with respect to a computer or other electronic hardware that is owned or leased by you and operated under your control allowed the loss, release or disclosure of business data that is owned by or proprietary to a third party. This does not include personally identifying information or other information that is sensitive or personal to individuals.
   c. "Network security liability suit" includes the following:
      1) An arbitration or alternative dispute resolution proceeding that you are required to submit to or which we agree you should submit to; or
      2) A written demand for money, when such demand could reasonably result in a civil proceeding as described in this definition.

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d. "Network security liability suit" does not mean any demand or action alleging or arising from property damage or bodily injury.
e. "Network security liability suit" does not mean any demand or action brought by or on behalf of someone who is:
1) Your director or officer;
2) Your owner or part-owner; or
3) A holder of your securities;
in their capacity as such, whether directly, derivatively, or by class action.

4. "Termination of Coverage" means:
a. You or we cancel this CyberOne coverage;
b. You or we refuse to renew this CyberOne coverage; or
c. We renew this CyberOne coverage on an other than claims-made basis or with a retroactive date later than the date of the first inception of this CyberOne coverage endorsement or any coverage substantially similar to that described in this endorsement.

ALL OTHER PROVISIONS OF THIS POLICY APPLY.

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POLICY AMENDATORY ENDORSEMENT
CLAIMS NOTIFICATION ADDRESS CHANGE

This endorsement modifies insurance provided under the following:
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

It is agreed that Section **V. CONDITIONS, A. Your Duties if there is a Claim,** Item 1.a., is deleted and replaced as follows:

A. Your Duties if there is a Claim

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

1. notify the Company as soon as reasonably possible of any **claim;**
    a. such notice must be in writing and be sent to Navigators Insurance, Attn. Claims Department:
        i. by email to: NEWLOSS@navg.com;
        ii. by phone to: (855) 444-4796;
        iii. by fax to: (847) 285-9003; or
        iv. by mail to: Navigators Insurance, Attn: Claims Department, 83 Wooster Heights Rd., Danbury, CT 06810;

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AMENDATORY ENDORSEMENT
EXTENDED REPORTING PERIODS

This endorsement modifies insurance provided under the following:
GLS ELITE PRODUCTS-COMPLETED OPERATIONS LIABILITY COVERAGE
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

Section **V. CONDITIONS, R. Extended Reporting Periods,** deleted in its entirety and replaced by the following:

Extended Reporting Periods do not extend the **policy period** or change the scope of coverage provided, nor do they act to reinstate or increase any of the limits of liability. They apply only to **occurrences** that occur before the end of the **policy period** but not before the retroactive date shown in the Declarations.
Extended Reporting Periods begin at the end of the **coverage relationship** and apply to **claims** first made and reported to us during the Extended Reporting Periods. A **claim** first made and reported to us during Extended Reporting Periods will be deemed to have been made on the last day of the **policy period**.

1. Automatic Extended Reporting Period
   The Company will provide an automatic, non-cancelable Extended Reporting Period of 90 days at no additional premium if no other insurance is purchased by **you** to replace this Policy. With respect to any **circumstance** reported to the Company, all **claims** associated with the reported **circumstance** must be reported within 5 years of the end of the **coverage relationship** in accordance with **Section V., CONDITIONS, paragraph B., Your Rights In The Event of a Circumstance.**
2. Supplemental Extended Reporting Period (Optional)
   An optional Supplemental Extended Reporting Period of up to a maximum of 84 months can be purchased to replace the Automatic Extended Reporting Period. To obtain a Supplemental Extended Reporting Period, **you** must make a request to the Company in writing within 90 days after the end of the **policy period,** or the effective date of cancellation. An additional premium of not more than 200% of the adjusted Annual Premium will be charged for this option.

Purchasing a Supplemental Extended Reporting Period does not change the 5 year limit to report **claims** associated with any reported **circumstance.**

Once in effect, a Supplemental Extended Reporting Period may not be canceled unless **you** fail to pay additional premiums or premium audits when due.

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ABSOLUTE OPIOID(S)/OPIATE(S), NARCOTIC(S), NARCOTIC(S) CONTROLLED SUBSTANCES AND NALOXONE EXCLUSION ENDORSEMENT

This endorsement modifies insurance provided under the following:
GLS ELITE PRODUCTS-COMPLETED OPERATIONS AND PROFESSIONAL LIABILITY COVERAGE

A. The following exclusion is added to paragraph **C**. **Exclusions applicable to both Products-Completed Operations Hazard and Professional Services Injury Coverage and Professional Liability Coverage** in Section **III. EXCLUSIONS**:

This Policy does not apply to:

Opioid(s)/Opiate(s), Narcotic(s), Narcotic(s) Controlled Substances and Naloxone

any **claim** or **circumstance** seeking or alleging relief, remedy or recovery of any kind or description or **damages** based upon, arising out of, relating to, directly or indirectly resulting from, in consequence of, attributable to, or in any way involving, whether via any delivery method, whether by direct or passive exposure, or whether intentional or unintentional, the following:

1. The actual or alleged use of, abuse of, misuse of, overdose of, distribution of, diversion of, risks of, absorption of, and/or addiction to:

    a. Any opioid(s)/opiate(s) drug, opioid(s)/opiate(s) medication, or opioid(s)/opiate(s)-containing substances of any type, nature, or kind, including all derivatives, all compounds or all degradation by-products thereof;
    b. Any **narcotic(s)** drug, **narcotic(s)** medication, or **narcotic(s)**-containing substances of any type, nature, or kind, including all derivatives, all compounds or all degradation by-products thereof;
    c. Any **narcotic(s)** controlled substances, including all derivatives, all compounds or all degradation by-products thereof, defined by or included in the United States Controlled Substances Act [21 U.S.C. § 801, *et seq*. (including its Schedules)] or any other regulatory, statutory, legislative, judicial or other legal action of any nation, state, province, municipality or other governmental division or subdivision; or
    d. Any naloxone medication, naloxone drug, naloxone compound(s) or naloxone-containing substances of any type, nature or kind, including all derivatives or all degradation by-products thereof.

2. The absence, failure or inadequacy of any control required by any regulation, statute, ordinance, law, legislation, judicial or other legal act of any nation, state, province, municipality or other governmental division or subdivision to prevent or report suspicious behavior related to the actual or alleged use of, abuse of, misuse of, overdose of, distribution of, diversion of, risks of, absorption of, and/or addiction to any drug, medication or substance, including all derivatives or all degradation by-products thereof, referenced in 1.a., 1.b., 1.c. and 1.d. above;

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3. The absence, failure or inadequacy of any recordkeeping controls, practices or procedures related to the actual or alleged use of, abuse of, misuse of, overdose of, distribution of, diversion of, risks of, absorption of, and/or addiction to any drug, medication or substance, including all derivatives or all degradation by-products thereof, referenced in 1.a., 1.b., 1.c. and 1.d. above;

4. The failure to warn or inadequacy or absence of any warnings, labels or instructions related to the actual or alleged use of, abuse of, misuse of, overdose of, distribution of, diversion of, risks of, absorption of, and/or addiction to any drug, medication or substance, including all derivatives or all degradation by-products thereof, referenced in 1.a., 1.b., 1.c. and 1.d. above;

5. Advertisements, warranties, representations, misrepresentations, literature, marketing or informational materials related to any drug, medication or substance, including all derivatives or all degradation by-products thereof, referenced in 1.a., 1.b., 1.c. and 1.d. above; or

6. The absence, failure or inadequacy of any controls, practices or procedures related to the marketing, sale, storage, inventory, safeguarding, distribution, or diversion of any drug, medication or substance, including all derivatives or all degradation by-products thereof, referenced in 1.a., 1.b., 1.c. and 1.d. above.

B. The following definition is added to Section **IV. DEFINITIONS**:

Narcotic(s) means, as defined by the United States Food and Drug Administration, 21 C.F.R. § 1300.01, *et seq*., any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

A. Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium;
B. Poppy straw and concentrate of poppy straw;
C. Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed;
D. Cocaine, its salts, optical and geometric isomers, and salts of isomers;
E. Ecgonine, its derivatives, their salts, isomers and salts of isomer; or
F. Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (1) through (5) of this definition.

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