

GENERAL DEFINITIONS

Accidental Contamination shall mean any accidental or unintentional contamination, impairment or mislabelling during the production process or distribution with the potential to result in:

- (a) **Bodily Injury** within 120 days of consumption; or
- (b) adverse publicity implying that it would cause **Bodily Injury**, whether this is true or not; or
- (c) **Property Damage**.

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

Asbestos shall mean that mineral in any form including, but not limited to, fibres or dust.

Asbestos Hazard shall mean:

- (a) an actual exposure or threat of exposure to **Asbestos** or the harmful properties of **Asbestos**; or
- (b) the presence of **Asbestos** in any place whether or not within a building or structure.

Bodily Injury shall mean accidental physical or mental injury, sickness or disease to, or death of, a person.

Business shall mean the business of the **Policyholder** described in any proposal and referred to in the **Schedule**, and shall include:

- (a) ownership, repair, maintenance and decoration of the **Policyholder's** own property and premises occupied by the **Policyholder**;
- (b) provision and management of canteen, social, sports, educational and welfare organisations for the benefit of any **Person Employed** and first aid, fire, security and ambulance services;
- (c) participation by the **Insured** in exhibitions anywhere in the world;
- (d) private work undertaken by any **Person Employed** for any director, business partner or employee of the **Policyholder** with the prior written consent of the **Policyholder**.

Claim shall mean a written demand for, or a written assertion of a right to, compensation, money, services, relief or redress in respect of any liability insured by this **Policy** made against and notified to any **Insured**. The date of the first written demand to any **Insured** shall represent the date that the **Claim** is first made against the **Insured**.

For the purposes of Section 8 (Government Instructed Product Withdrawal) only, **Claim** shall include a specific instruction by a relevant government to recall **Products**.

For the purposes of Section 11 (Directors' and Officers' Liability) only, **Claim** shall mean:

- (a) any legal, administrative or regulatory proceeding, including the issuance of a writ, claim form, summons, cross-claim or counter-claim issued or initiated against or served upon an **Insured Person(s)** for a **Wrongful Act**;
- (b) any written communication alleging a **Wrongful Act** communicated to an **Insured Person(s)** or to the **Company** evidencing an intention to seek compensation or hold an **Insured Person(s)** responsible for a **Wrongful Act**;
- (c) any **Employment Practice Claim(s)**.

Company shall mean the **Policyholder** and shall include **Subsidiary Companies**. **Company** shall not mean or include any pension scheme or fund established for the **Company's** own directors, officers and employees.

Conditions of Compensation shall mean the conditions set out under that heading in this **Policy**.

Cross Liabilities shall mean any liability of any one or more **Insured** to any other **Insured(s)**.

Deductible shall mean the sum specified as such in the **Schedule** that the **Insured** shall pay before the **Underwriters** shall be liable to make any payment. **Legal Costs** and other costs and expenses shall be subject to the **Deductible**.

Documents shall mean deeds, wills, agreements, maps, plans, records, books, letters, policies, forms, computer programmes or information stored, written or punched into card or tape or magnetic discs or taped or any other data media and documents of any nature whatsoever, whether written, printed or reproduced by any other method.

Documents shall not mean or include money, cheques, travellers' cheques, registered cheques, postal or money orders, bullion, negotiable or non-negotiable instruments, stamps, bonds, stock, shares, coupons, bank notes and currency.

Employment Practice Claim(s) shall mean a **Claim** made by an employee or former employee of the **Company** based upon:

- (a) unlawful discrimination on the basis of an individual's race, colour, religion, age, sex, national origin, disability, pregnancy, sexual orientation or preference or other status protected under applicable law;
- (b) sexual harassment;
- (c) defamation which relates to a person's job skills, job performance, qualifications for employment, professional reputation, disciplinary history or termination of employment;
- (d) wrongful or unfair termination of employment or refusal to employ; or
- (e) an adverse change in the terms and conditions of a person's employment in retaliation for that person's exercise of his or her rights under law or his or her support of the employment rights of another.

Financial Loss shall mean a pecuniary loss, cost or expense not occasioned by **Bodily Injury** or **Property Damage** that is sustained by any party other than the **Insured** and which arises directly from the defective or harmful condition of the **Products**.

Human Clinical Trial shall mean any clinical trial or healthy volunteer study which complies with the statutory requirements or guidelines of the relevant person, authority, department or public or private body in the country in which the trial takes place.

Independent Lawyer shall mean a judge, retired judge, barrister or solicitor who is selected to adjudicate a claim for compensation under the **Conditions of Compensation** within Section 4 (No Fault Compensation for Human Clinical Trials) of this **Policy**.

Insured shall mean the **Policyholder** and shall also include:

- (a) any director or business partner of the **Policyholder**, but only whilst acting in their respective capacities for the **Policyholder**;
- (b) any **Person Employed**, including medical doctors, medical nurses and dentists, but only whilst acting within the scope of their duties for the **Policyholder**;
- (c) the **Subsidiary Companies**,

but, in each case, only in respect of legal liability for which the **Policyholder** would have been entitled to indemnity under this **Policy** if the claim for which indemnity is sought had been made against the **Policyholder**. In addition the **Insured** shall also include:

- (d) the officers, committees and members of the **Policyholder's** canteen, social, sports, educational and welfare organisations and first aid, fire, security and ambulance services in their respective capacities as such;
- (e) any director, business partner or employee of the **Policyholder** in respect of private work undertaken by any **Person Employed** for such director, business partner or employee with the prior written consent of the **Policyholder**;
- (f) any member of a Scientific Advisory Board or Medical Advisory Board of the **Policyholder** in such capacity;
- (g) any Institutional Review Board or Ethics Committee of the **Policyholder** (or any member of such board or committee) that has approved a **Human Clinical Trial** which is the subject of this **Policy**.

Each **Insured** shall, as if he were the **Policyholder**, be subject to the terms, conditions, limitations, exclusions and any endorsement(s) of this **Policy**.

Insured Person(s) shall mean:

- (a) in respect of all **Claims** other than **Employment Practice Claims**, any natural person who was, is or during the **Period of Insurance** becomes a director or officer of the **Company**, an employee of the **Company** acting in a managerial or supervisory capacity, an employee of the **Company** who is named as a co-defendant with a director or officer of the **Company** in respect of a **Claim** or any other natural person who may at any material time be deemed to be such a director, officer or employee of the **Company** acting in a managerial or supervisory capacity;
- (b) in respect of **Employment Practice Claims**, any natural person who was, is or during the **Period of Insurance** becomes a director, officer or employee of the **Company** and any other natural person who may at any material

time be deemed to be such a director, officer or employee of the **Company** within the meaning of any applicable law or regulation;

- (c) in the event of the death, incompetency or bankruptcy of any **Insured Person** as defined in sub-paragraphs (a) or (b) above, such **Insured Person's** estate, heirs, legal representatives or assigns;
- (d) the lawful spouse or civil partner of any **Insured Person** as defined in sub-paragraphs (a) or (b) above, but only to the extent that such spouse or civil partner is a party to any **Claim** solely in his or her capacity as the spouse or civil partner of any **Insured Person(s)** and only for the purposes of any **Claim** in which a proprietary or restitutionary right or remedy is sought over or in respect of property jointly owned by the **Insured Person** and the spouse or civil partner or property transferred from the **Insured Person** to the spouse or civil partner, and only to the extent that such **Insured Person** is or, but for such transfer, would have been covered for such **Claim**;
- (e) any natural person who is deemed a shadow director (as defined in Section 251 of the Companies Act 2006 or any equivalent legislation in the jurisdiction in which the **Company** is domiciled) or a de-facto director of the **Company**; or
- (f) an approved person who performs the controlled functions (as specified by the Financial Conduct Authority in its Table of Controlled Functions in its Supervision Manual at 10A.4.4 of its Handbook and as specified by the Prudential Regulation Authority in its Table of Controlled Functions in its Supervision Manual at 10B.4.3 of its Handbook, each as may be amended from time to time) for the **Company**.

Insured Person(s) shall not mean or include any external auditor or any insolvency practitioner.

Investigation shall mean any formal hearing, investigation or inquiry by any official body in relation to possible misconduct by any **Insured Person** in their capacity as such. **Investigation** shall not mean or include routine regulatory supervision, enquiry, inspection or compliance review, internal investigation or any investigation into the activities or practices of the **Insured Person's** industry which is not related solely to the **Insured Person's** conduct in their capacity as such.

Legal Costs shall mean:

- (a) costs of legal representation at:
 - (i) any coroner's inquest (or, in Scotland, any Fatal Accident Inquiry) in respect of any death;
 - (ii) proceedings in any court arising from any alleged breach of statutory duty resulting in any **Occurrence**;
- (b) all other costs and expenses reasonably and necessarily incurred in the investigation, adjustment, defence, negotiation or appeal of any **Claim** or in relation to any **Occurrence** which may form the subject of a claim for indemnity under this **Policy** (including costs of representing the **Insured** in civil proceedings); and
- (c) legal costs and legal expenses reasonably and necessarily incurred in the defence of a **Claim** which is indemnified under this **Policy**,

provided, in each case, that such costs and expenses are incurred with the prior written consent of the **Underwriters**. **Legal Costs** shall not mean or include any business, internal or overhead expenses of the **Insured**, including any wages, salaries, commission, expenses, benefits, bonuses or other remuneration, or the cost of the **Insured's** time.

Legal Representation Expenses shall mean reasonable and necessary legal costs and legal expenses incurred by or on behalf of an **Insured Person** with the **Underwriters'** prior written consent in their representation at an **Investigation**.

Limit of Liability shall mean the monetary limit of the **Underwriters'** liability as stated in the **Schedule**, which shall not be increased by any circumstance other than a written endorsement signed by the **Underwriters**.

Loss shall mean:

- (a) items insured under any extensions to Section 11 (Directors' and Officers' Liability) of this **Policy**;
- (b) compensatory damages, judgments and / or costs awarded against an **Insured Person** by a court or tribunal empowered to do so;
- (c) settlements in respect of any **Claim** for compensatory damages, interest and / or costs, provided such settlement has been entered into with the **Underwriters'** prior written consent;
- (d) **Legal Costs**; and
- (e) legal fees, costs and expenses which, by order of a court or tribunal, the **Company** is required to pay to any shareholder of the **Company** or to any claimant or complainant (other than the **Company** or an **Insured Person**).

Loss shall not mean or include taxes, fines, penalties, disgorgement, restitution, constructive trusts, aggravated, exemplary, punitive, vindictive, liquidated damages or any other damages resulting from the multiplication of damages and any liability deemed uninsurable by law in the jurisdiction in which the payment is to be made.

In respect of any **Employment Practice Claim**, **Loss** shall not mean or include:

- (a) any obligation pursuant to any law or any regulation in any jurisdiction in respect of workers' compensation, disability benefits, redundancy or unemployment benefits or compensation, unemployment insurance, retirement benefits, social security benefits or any similar law or regulation whatsoever;
- (b) in respect of any **Employment Practice Claim** brought in the United States of America, any obligation pursuant to the following laws of the United States of America:
 - (i) The Workers Adjustment and Retraining Notification Act Public Law 100-379 (1988) and any amendments thereto;
 - (ii) The Consolidated Omnibus Budget Reconciliation Act of 1985 and any amendments thereto;
 - (iii) The Occupational Safety and Health Act and any amendments thereto; or
 - (iv) any similar provision of any law, regulation, decree or ordinance of any country, state or municipality;
- (c) any salary, wages or employment-related benefits to which the claimant became entitled while in the employment of the **Company**;
- (d) any salary, wages or employment-related benefits to which the claimant would have been entitled as an employee of the **Company**, but for the **Wrongful Act** giving rise to a **Claim**;
- (e) any damages or compensation for or in respect of breach of any express contractual term whereby the **Company** was or would have been liable to compensate the claimant for the **Wrongful Act** giving rise to the **Claim** or in any other circumstances; or
- (f) any liability or costs incurred by any **Insured Person** to modify any building, property or working arrangement in order to make such building, property or working arrangement more accessible or accommodating to any disabled persons.

Malpractice shall mean a negligent act, negligent error or negligent omission committed by the **Insured** or by any person or organisation acting on behalf of the **Insured** in the provision of medical services in the conduct of the **Business** to a patient or patients. This definition is extended to include treatment administered at the scene of a medical emergency, accident or disaster by any **Insured** who is present, either by chance or in response to an emergency call following such medical emergency, accident or disaster, commonly known as a "Good Samaritan Act".

Medical Devices shall mean health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or an abnormal physical condition.

Occurrence shall mean an event (including, but not limited to, continuous or repeated exposures to the same conditions or substance). All such exposure to substantially the same conditions or substance shall be deemed to be one **Occurrence**.

Other Contingencies shall mean accidental nuisance, accidental trespass or accidental interference with any easement, right of air, light, water or way.

Outside Company shall mean an entity:

- (a) in which the **Company** holds any issued share(s); or
- (b) which is a tax-exempt non-profit organisation, tax-exempt trade association or registered charity.

Outside Company shall not mean or include an entity which:

- (a) is a **Subsidiary Company**; and / or
- (b) has any of its debt securities or equity securities publicly traded in the United States of America, unless expressly included by endorsement(s).

Period of Insurance shall mean the period from the inception to the expiration of this **Policy** as stated in the **Schedule** or its earlier termination date, if any.

Person Employed shall mean any:

- (a) employee of the **Policyholder**;

- (b) labour master or person supplied by a labour master;
- (c) person employed by labour only sub-contractors;
- (d) self-employed person;
- (e) person hired or borrowed by the **Policyholder**;
- (f) person undertaking study or work experience;
- (g) person supplied under any Youth Training or similar government scheme;
- (h) volunteers,

in each case, while such person is working for the **Policyholder** in connection with the **Business**.

Pharmaceutical shall mean any placebo, or any substance taken by mouth, injected into a muscle, the skin, a blood vessel or a cavity of the body or applied to the skin to treat or prevent a disease, condition or symptom.

Placed Personnel shall mean any person placed by the **Insured** with a client with whom the **Policyholder** has entered into a written contract in return for fees or remuneration in connection with the **Business** (irrespective of any intermediary through which they undertake work or their employment status) except any **Person Employed**.

Policy shall mean collectively:

- (a) this document, including its terms, conditions, limitations, exclusions and all other provisions;
- (b) the **Schedule**;
- (c) any endorsement(s);
- (d) any proposal form(s); and
- (e) all other information provided by or on behalf of the **Policyholder** in connection with this insurance.

Policyholder shall mean the person or entity identified as such in the **Schedule**.

Policy Territory shall mean the territory specified as such in the **Schedule**.

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

Pollution or Contamination shall mean:

- (a) any pollution or contamination of buildings or other structures or of water, land or the atmosphere; and / or
- (b) any loss, damage or injury directly or indirectly caused by such pollution or contamination.

Products shall mean any goods or products, including labelling and instructions, made, sold, handled or distributed by or for the **Insured** in connection with the **Business** after the **Insured** has relinquished possession of such goods or products.

Property Damage shall mean accidental physical damage to, loss of or destruction of material property of a third party. It shall not include loss of computer data.

Research Subject shall mean any person participating in a **Human Clinical Trial**.

Retroactive Date shall mean the date specified as such in the **Schedule**.

Schedule shall mean the form, labelled as such and attached to this **Policy**, which forms a part thereof and contains contract details referred to in the wording.

Subsidiary Company(ies) shall mean any company in respect of which the **Policyholder** (either directly or indirectly through one or more subsidiary companies) at or before the commencement of the **Period of Insurance** and at the time the act, error, omission, **Malpractice**, circumstance, fact, incident, event, occurrence or **Wrongful Act** giving rise to a **Claim** is alleged to have occurred:

- (a) controls the composition of the board of directors;
- (b) holds or controls as a member more than half the voting power; or

(c) holds or has subscribed to more than half of the issued share capital.

If, during the **Period of Insurance**, the **Policyholder** acquires or creates an entity and:

- (a) the **Policyholder** holds or has subscribed to more than half of the issued share capital of the entity; and
- (b) the entity has total assets of less than twenty five percent (25%) of the total assets of the **Policyholder**, as recorded in the latest annual audited report and accounts; and
- (c) the entity has no securities listed in the United States of America,

this **Policy** shall automatically extend to include such entity as a **Subsidiary Company** without notice to the **Underwriters** or additional premium being payable, but only in respect of acts, errors, omissions, circumstances, facts, incidents, events or occurrences arising after the entity becomes a **Subsidiary Company**.

Underwriters shall mean certain underwriters, as stated in the **Schedule**.

Wrongful Act(s) shall mean any actual or alleged wrongful act or wrongful omission (or, in respect of derivative claims, any proposed wrongful act or wrongful omission) on the part of an **Insured Person** in their capacity as such. Related or continuous or repeated or causally related **Wrongful Acts** shall be deemed, for the purposes of this **Policy**, to be a single **Wrongful Act** occurring on the date of the first of any such series or, if continuous, when such **Wrongful Act** first occurred.

SECTION 1 - PUBLIC LIABILITY

(LEGAL COSTS IN ADDITION)

"OCCURRENCE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of **Bodily Injury, Property Damage** or **Other Contingencies** caused by an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** in connection with the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a claim for which there is cover under paragraph (1) above.

LIMIT OF LIABILITY

Regardless of the number of: (1) persons or entities insured under this **Policy**; (2) persons or entities claiming damages for **Bodily Injury, Property Damage** or **Other Contingencies**; and (3) **Claims** made on account of **Bodily Injury, Property Damage** or **Other Contingencies**, the liability of the **Underwriters** shall be limited as follows:

- (a) the limit of the **Underwriters'** total liability to indemnify the **Insured** for damages and claimants' costs and expenses under paragraphs (1) and (2) above in respect of any one **Occurrence** shall not exceed the **Limit of Liability** for this Section 1.
- (b) for the purpose of applying the **Limit of Liability** for this Section 1, any series of **Occurrences** attributable to one source or original cause shall be deemed to be one **Occurrence**.
- (c) for the purpose of applying the **Limit of Liability** for this Section 1, all **Pollution or Contamination** which arises out of one incident shall be deemed to have occurred at the time such incident takes place.
- (d) the liability of the **Underwriters** to indemnify the **Insured** for damages and claimants' costs and expenses in respect of all **Pollution or Contamination** shall not exceed the **Limit of Liability** for this Section 1 in the aggregate for the **Period of Insurance**.

For the purposes of this Section 1, **Legal Costs** are not subject to the **Limit of Liability** and are payable in addition to the **Limit of Liability**.

EXTENSIONS TO SECTION 1

Unless otherwise stated, the following extensions are subject to the terms, conditions, **Limit of Liability** for this Section 1 and exclusions of this **Policy**.

(1) OVERSEAS PERSONAL LIABILITY EXTENSION

The **Underwriters** shall indemnify the **Insured** and any director, business partner or employee of the **Insured**, against:

- (1) legal liability incurred in a personal capacity for damages in respect of **Bodily Injury, Property Damage** or **Other Contingencies** caused by an **Occurrence** happening during the **Period of Insurance** where such liability is incurred in a personal capacity while the **Insured** or, if applicable, the director, business partner or employee of the **Insured**, is temporarily outside the **Policy Territory** in connection with the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above.

The **Underwriters** shall not be liable to indemnify the **Insured**, or any director, business partner or employee of the **Insured**, under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (a) any ownership or occupation of land or buildings.
- (b) any liability for which the **Insured**, or any director, business partner or employee of the **Insured**, is entitled to indemnity under any other insurance, or would be so entitled but for the existence of this **Policy**.

(2) **RESIDUAL EMPLOYERS' LIABILITY EXTENSION**

Notwithstanding anything to the contrary contained in General Exclusions (3) and (4), the **Underwriters** shall indemnify the **Insured** against:

- (1) legal liability for damages in respect of **Bodily Injury** to any **Person Employed** caused by an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** and in the course of employment by the **Insured** in connection with the **Business**;
- (2) legal liability pursuant to any subrogated rights exercised against the **Insured** by any State or Social Security or similar scheme in respect of **Bodily Injury** to any **Person Employed** caused by an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** and in the course of employment by the **Insured** in connection with the **Business**;
- (3) legal liability for claimants' costs and expenses in connection with paragraphs (1) and (2) above;
- (4) **Legal Costs** arising from a **Claim** for which there is cover under paragraphs (1) or (2) above.

The **Underwriters** shall not be liable to indemnify the **Insured** under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any **Bodily Injury** to any **Person Employed**:

- (a) who is employed in Great Britain
- (b) , the Republic of Ireland, Northern Ireland, the Channel Islands or the Isle of Man.
- (c) arising out of and in the course of employment offshore or whilst travelling to or from any offshore installation.
- (d) as is or is normally insured by an Employers' Liability and / or Workman's Compensation Policy in the country in which the **Person Employed** is employed.

(3) **EXCESS EMPLOYERS' LIABILITY EXTENSION**

General Exclusions (3) and (4) shall not apply to any excess beyond the limit of indemnity for Employers' Liability cover provided by a policy effected by or on behalf of the **Insured** locally (hereinafter called the "**Local Policy**"), provided that:

- (1) a valid and collectable **Local Policy** with a minimum limit of indemnity of the local Compulsory Statutory Limits is maintained in force throughout the currency of this **Policy** in each territory in respect of any **Person Employed** in circumstances where the **Insured** is obliged to arrange a compulsory **Local Policy**.
- (2) the indemnity afforded by this extension shall be limited to the scope of cover granted by the **Local Policy** and shall not apply:
 - (a) to any deductible or excess applicable to the **Local Policy**;
 - (b) unless and until the insurers of the **Local Policy** have paid, or have been held liable to pay, the full amount of their limit of indemnity.
- (3) the maximum liability of the **Underwriters** under this extension shall be the difference between the limit of indemnity under the applicable **Local Policy** and the **Limit of Liability** for this Section 1.
- (4) the **Underwriters** shall not be liable to indemnify the **Insured** under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any **Bodily Injury** to any **Person Employed**:
 - (a) who is employed in Great Britain, the Republic of Ireland, Northern Ireland, the Channel Islands or the Isle of Man.
 - (b) arising out of and in the course of employment offshore or whilst travelling to or from any offshore installation.
 - (c) as is or is normally insured by an Employers' Liability and / or Workman's Compensation Policy in the country in which the **Person Employed** is employed.

(4) **CORPORATE MANSLAUGHTER AND CORPORATE HOMICIDE ACT 2007 DEFENCE COSTS EXTENSION**

The **Underwriters** shall indemnify the **Insured** and any director or business partner of the **Insured** or any **Person Employed** against legal costs and legal expenses reasonably and necessarily incurred with the **Underwriters'** prior written consent for:

- (a) the defence of proceedings brought under the Corporate Manslaughter and Corporate Homicide Act 2007 (as may be amended from time to time);
- (b) the appeal against conviction, including appeal against remedial and publicity orders under the Corporate Manslaughter and Corporate Homicide Act 2007 (as may be amended from time to time),

provided that the request for indemnity arises from an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** in connection with the **Business**.

The **Underwriters** shall not be liable to indemnify the **Insured**, or any director or business partner of the **Insured** or any **Person Employed**, under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (i) any legal costs or legal expenses for which the **Insured**, or any director or business partner of the **Insured** or any **Person Employed**, is entitled to indemnity under any other insurance, or would be so entitled but for the existence of this **Policy**.
- (ii) any proceedings brought in relation to any **Person Employed** in the course of employment with the **Insured**.

(5) **EXCESS MOTOR EXTENSION**

Additional Exclusion (1) (d) to this Section 1 shall not apply to any excess beyond the limit of indemnity provided by a local underlying motor policy (hereinafter called the "**Local Motor Policy**") effected by or on behalf of the **Insured** anywhere in the world except in the **Excluded Territories**, provided that:

- (a) a valid and collectable **Local Motor Policy** with a minimum limit of indemnity of the local Compulsory Statutory Limits is maintained in force throughout the currency of this **Policy** in each territory in respect of all of the **Insured's** vehicles.
- (b) the indemnity afforded by this extension shall be limited to the scope of cover granted by the **Local Motor Policy** and shall not apply:
 - (i) to any deductible or excess applicable to the **Local Motor Policy**;
 - (ii) unless and until the insurers of the **Local Motor Policy** have paid, or have been held liable to pay, the full amount of their limit of indemnity.
- (c) the maximum liability of the **Underwriters** under this extension shall be the difference between the limit of indemnity under the applicable **Local Motor Policy** and the **Limit of Liability** for this Section 1.

For the purposes of this extension, "**Excluded Territories**" shall mean and include Republic of Ireland, Great Britain, Northern Ireland, the Channel Islands, the Isle of Man and the United States of America, Canada and any dependencies, protectorates or trust territories within the jurisdiction of any thereof.

(6) **ADDITIONAL INSURED AND WAIVER OF SUBROGATION EXTENSION**

For the purposes of the main Insuring Clause of this Section 1 but not the extensions, the definition of "**Insured**" shall be amended to include as additional insured(s) those persons, entities or organisations that the **Insured** has agreed in a written contract to add as additional insureds on its Public Liability Insurance, provided that such written contract is fully executed and effective prior to the **Occurrence(s)** that gave rise to the liability for which indemnity is sought under this Section 1.

The **Limits of Liability** applicable to such additional insured are sub-limited as follows (which amounts shall be part of, and not in addition to, the **Limits of Liability** for this Section 1):

- (a) EUR 1,000,000 any one **Occurrence**; and
- (b) EUR 1,000,000 in the aggregate.

The **Underwriters** waive any rights of recovery that they may have against such additional insured(s) to the extent required in such written contract.

(7) **LEGAL EXPENSES EXTENSION**

The **Underwriters** shall indemnify the **Insured** against legal expenses reasonably and necessarily incurred by the **Insured** with the prior written consent of the **Underwriters** in the defence of any proceedings for breach of any of the following caused by an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** in connection with the **Business**:

- (a) Food Safety Act 1990, Part II and The Food Safety and Hygiene (England) Regulations 2013;
- (b) Consumer Protection Act 1987 and Consumer Rights Act 2015;
- (c) Equality Act 2010;
- (d) Defective Premises Act 1972 and Defective Premises Order (N.I) 1975;
- (e) Trade Description Act 1968,

(each as may be amended from time to time or the equivalent in any other jurisdiction).

The **Underwriters'** total liability to indemnify the **Insured** for legal expenses under this extension shall be sub-limited to EUR1,000,000 in the aggregate for the **Period of Insurance** which sum shall be part of, and not in addition to, the **Limit of Liability** for this Section 1 of the **Policy**.

(8) **POLLUTION CLEAN-UP COSTS EXTENSION**

In the event of an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** in connection with the **Business** which gives rise to **Pollution or Contamination** which is covered by this **Policy**, the **Underwriters** shall indemnify the **Insured** for its legal liability for costs and expenses reasonably and necessarily incurred by statutory bodies in the clean-up of property owned by parties other than the **Insured**.

Notwithstanding anything to the contrary contained in this **Policy**, the liability of the **Underwriters** for all clean-up costs and expenses payable in respect of all **Pollution or Contamination** shall be sub-limited to EUR1,000,000 in the aggregate for the **Period of Insurance** which sum shall be part of, and not in addition to, the **Limit of Liability** for this Section 1.

(9) **MOTOR CONTINGENT LIABILITY EXTENSION**

The **Underwriters** shall indemnify the **Insured** against legal liability for damages in respect of **Bodily Injury** or **Property Damage** caused by an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** arising from the use of a motor vehicle in connection with the **Business**.

The **Underwriters** shall not be liable to indemnify the **Insured** under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (a) any motor vehicle owned or provided by the **Insured**, any principal for whom the **Insured** is working or any sub-contractor acting for or on the behalf of the **Insured**.
- (b) any loss of or damage to such motor vehicle or to goods conveyed therein or thereon.
- (c) any motor vehicle being driven by the **Insured** or by any person who to the knowledge of the **Insured's** representative does not hold a license to drive such motor vehicle, unless such person has held and is not disqualified for holding or obtaining such a license.
- (d) any motor vehicle inside Republic of Ireland, Great Britain, Northern Ireland, the Channel Islands or the Isle of Man.

ADDITIONAL EXCLUSIONS TO SECTION 1

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 1 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any ownership, possession, maintenance, use or operation by or on behalf of the **Insured** of any:
 - (a) aircraft or other aerial device.
 - (b) water-borne vessel or craft, other than those used for business entertainment.
 - (c) hovercraft.
 - (d) mechanically propelled vehicle in respect of which insurance or security is necessary to meet the requirements of road traffic legislation. This additional exclusion (1) (d) to Section 1 shall not apply to any liability, claim or loss arising from any of the following:
 - (i) the use of plant as a tool of trade; or
 - (ii) the loading or unloading of any vehicle,except where indemnity is provided by any motor insurance policy (or would be provided by such policy if this **Policy** did not exist) or where insurance or security is required by law.
- (2) any **Property Damage** to property owned by, leased or rented to or in the care, custody or control of the **Insured**, other than:
 - (a) damage to the property of any directors, business partners, employees and / or visitors of the **Insured**.
 - (b) damage to premises not owned by, leased or rented to the **Insured** at which the **Insured** is undertaking work in connection with the **Business**.
- (3) any **Products** (other than food or drink for consumption on the **Insured's** premises).
- (4) any advice, design, specification or professional services provided for a fee (or provided in circumstances where a fee would normally be charged).
- (5) any disease, disease carrying pollutants, water droplets or water vapour in the atmosphere or water courses from the **Insured's** air conditioning or water or air cooling systems.
- (6) any **Bodily Injury, Property Damage** or **Other Contingencies** that were not caused by an **Occurrence** happening during the **Period of Insurance**.
- (7) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 2 - PRODUCTS' LIABILITY

(LEGAL COSTS IN ADDITION)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for **Bodily Injury** or **Property Damage** arising from **Products** caused by an **Occurrence** within the **Policy Territory** in connection with the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that:

- (i) the **Claim** is first made against the **Insured** during the **Period of Insurance**; and
- (ii) all **Bodily Injury** or **Property Damage** resulting from or alleged to have resulted from the same condition or defect in any of the **Products** shall be considered as resulting from one **Claim** and having occurred during the period of insurance in which the first **Claim** is made against the **Insured**, irrespective of the number of claimants or the period over which **Claims** may thereafter be made against the **Insured** arising from such **Bodily Injury** or **Property Damage**.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; (ii) persons or entities claiming damages for **Bodily Injury** or **Property Damage**; and (iii) **Claims** made on account of **Bodily Injury** or **Property Damage**, the liability of the **Underwriters** shall be limited as follows:

- (a) the limits of the **Underwriters'** total liability to indemnify the **Insured** for damages and claimants' costs and expenses under paragraphs (1) and (2) above shall be:
 - (i) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
 - (ii) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.
- (b) all **Claims** made during the **Period of Insurance** (and any subsequent period for which the **Insured** shall pay and the **Underwriters** shall agree to accept a renewal premium) resulting from or alleged to have resulted from the same condition or defect in any of the **Products** shall be deemed to be one **Claim** and as having been first made during the period of insurance in which the first **Claim** is made against the **Insured**.

For the purposes of this Section 2, **Legal Costs** are not subject to the **Limits of Liability** and are payable in addition to the **Limits of Liability**.

EXTENSIONS TO SECTION 2

Unless otherwise stated, the following extensions are subject to the terms, conditions, **Limits of Liability** for this Section 2 and exclusions of this **Policy**.

(1) VENDORS' COVERAGE EXTENSION

For the purposes of this Section 2, the definition of "**Insured**" shall be amended to include any person or organisation (herein referred to as the "**Vendor**") in respect of the distribution or sale in the regular course of the **Vendor's** business of the **Products**.

The **Underwriters** shall not be liable to indemnify the **Insured** or any **Vendor** under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (a) any express warranty not authorised by the **Insured**.

- (b) any physical or chemical change in the **Product** made intentionally by the **Vendor**.
- (c) any repacking, unless unpacked solely for the purpose of inspection, demonstration, testing or the substitution of parts under instruction from the **Insured** and then repacked in the original container.
- (d) any demonstration, installation, servicing or repair operations, except such operations performed at the **Vendor's** premises in connection with the sale of the **Products**.
- (e) any **Products** which, after distribution or sale by the **Insured**, have been labelled or relabelled or used as a container, part or ingredient of any other thing or substance by or for the **Vendor**.
- (f) any fault or negligence of the **Vendor**.
- (g) any person or organisation from whom the **Insured** has acquired such **Products** or any ingredient, part or container entering into, accompanying or containing such **Products**.

(2) **ADDITIONAL INSURED AND WAIVER OF SUBROGATION EXTENSION**

For the purposes of the main Insuring Clause of this Section 2 but not the extensions, the definition of “**Insured**” shall be amended to include as additional insured(s) those persons, entities or organisations that the **Insured** has agreed in a written contract to add as additional insureds on its Products Liability Insurance, provided that such written contract is fully executed and effective prior to the **Occurrence(s)** that gave rise to the liability for which indemnity is sought under this Section 2.

The **Limits of Liability** applicable to such additional insured are sub-limited as follows (which amounts shall be part of, and not in addition to, the **Limits of Liability** for this Section 2):

- (a) EUR 1,000,000 any one **Claim**; and
- (b) EUR 1,000,000 in the aggregate.

The **Underwriters** waive any rights of recovery that they may have against such additional insured(s) to the extent required in such written contract.

ADDITIONAL EXCLUSIONS TO SECTION 2

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 2 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any **Property Damage** to any **Product** or contract work executed by the **Insured** (or any part thereof).
- (2) any costs or expenses incurred for the recall, withdrawal, inspection, removal, repair, alteration, replacement or reinstatement or amounts claimed for loss of use of or reduction in value of any **Product**, workmanship or contract work executed by the **Insured** (or any part thereof).
- (3) any **Product** which, to the **Insured's** knowledge, is intended for use in or incorporation into any spacecraft, aircraft, aerial device, ship, watercraft, offshore installation or nuclear installation.
- (4) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to a **Claim**.
- (5) any advice, design, specification or professional services provided for a fee (or provided in circumstances where a fee would normally be charged) and not in connection with the supply of a **Product**.
- (6) any:
 - (i) (a) Bisphosphonates;
 - (b) Blood Borne Pathogens;
 - (c) (i) Cerivastatin;
 - (ii) the concomitant or combined use of two or more different products which contain:
 - 1 a Statin; and
 - 2 a Fibrate;
 - (iii) Rhabdomyolysis arising out of either (i) or (ii) above;

- (d) contraceptives (including birth control pills), fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy;
- (ii) (e) any product containing silicone which is in any form implanted or injected into the body;
- (a) Diethylstilbestrol or Stilbestrol or DES;
- (b) Ephedrine Ma Huang Pseudoephedrin Chinese Ephedra Mahuang Extract Ephedra Ephedra Sinica Ephedra Extract Ephedra Herb Powder or Epitonin;
- (c) Fentanyl;
- (d) Fluoxetine;
- (e) Hormone Replacement Therapy;
- (f) Isotretinoin or Accutane;
- (g) Kava or Kava Kava;
- (h) Live virus vaccines;
- (i) L-tryptophan;
- (j) Lymerix;
- (k) Metoclopramide;
- (l) Paroxetine;
- (m) Pertussis Vaccine;
- (n) Phenylpropanolamine (PPA);
- (o) Prozac;
- (p) Retinoic Acid;
- (q) Rosiglitazone;
- (r) Thalidomide;
- (s) Thimerosal or Thiomersal;
- (t) Thiazolidinediones;
- (u) Cox-2 inhibitors;
- (v) Bupropion;
- (w) Docetaxel;
- (x) Primodos / Amenorone Forte,

or any other drug which has the same chemical formula, is a derivative of or has a similar chemical formula, structure or function as any of the substances in the above list.

- (7) any N-Nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA) or carcinogenic agent given off during the manufacturing process of any of Azilsartan, Candesartan, Eprosartan, Irbesartan, Losartan, Olmesartan, Telmisartan, Valsartan and any other Angiotensin II Receptor Blockers (ARBs) and any other drug which has the same chemical formula or is a derivative of or has a similar chemical formula, structure or function of any of the foregoing.
- (8) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 3 - LEGAL LIABILITY FOR HUMAN CLINICAL TRIALS

(LEGAL COSTS IN ADDITION)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for **Bodily Injury** to a **Research Subject** caused by an **Occurrence** within the **Policy Territory** in connection with the **Business** arising from the use of any **Pharmaceutical** or **Medical Devices** in **Human Clinical Trials**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that:

- (i) the **Claim** is first made against the **Insured** during the **Period of Insurance**; and
- (ii) all **Bodily Injury** to a **Research Subject** resulting from or alleged to have resulted from the same **Human Clinical Trial** shall be considered as resulting from one **Claim** and having occurred during the period of insurance in which the first **Claim** is made against the **Insured**, irrespective of the number of claimants or the period over which **Claims** may thereafter be made against the **Insured** arising from such **Bodily Injury**.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; (ii) persons who may have suffered **Bodily Injury**; and (iii) **Claims** made on account of **Bodily Injury**, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability to indemnify the **Insured** for damages and claimants' costs and expenses under paragraphs (1) and (2) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 3, **Legal Costs** are not subject to the **Limits of Liability** and are payable in addition to the **Limits of Liability**.

EXTENSION TO SECTION 3

Unless otherwise stated, the following extension is subject to the terms, conditions, **Limits of Liability** for this Section 3 and exclusions of this **Policy**.

MANSLAUGHTER DEFENCE COSTS (ETHICS COMMITTEE) EXTENSION

The **Underwriters** shall indemnify the Ethics Committee of the **Insured**, or any member of the Ethics Committee of the **Insured**, in respect of **Legal Costs** incurred with the prior written consent of the **Underwriters** in the defence of any criminal proceedings brought (or in an appeal against conviction arising from such proceedings) for manslaughter arising from any event which may be the subject of indemnity under the insuring clause of this Section 3 of this **Policy**, provided that:

- (a) the proceedings relate to an offence alleged to have been committed during the **Period of Insurance** and in the course of the **Business**;
- (b) the **Underwriters** shall not be liable to indemnify the Ethics Committee of the **Insured**, or any member of the Ethics Committee of the **Insured**, under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (i) any proceedings consequent upon any **Bodily Injury** sustained by any **Person Employed** in the course of employment by the **Insured**.
- (ii) any ownership, possession or use by or on behalf of the **Insured** or any other person entitled to indemnity of any mechanically propelled vehicle while being used in circumstances where insurance or security is required by law.

ADDITIONAL EXCLUSIONS TO SECTION 3

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 3 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any **Human Clinical Trial** performed without the informed written consent of each **Research Subject** obtained prior to the participation of such person in such **Human Clinical Trial**.
- (2) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to a **Claim**.
- (3) any act, error or omission which constitutes or involves a breach of, or failure to comply with, the terms of any protocol governing the **Human Clinical Trial**.
- (4) any advice, design, specification or professional services provided for a fee (or provided in circumstances where a fee would normally be charged).
- (5) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 4 - NO FAULT COMPENSATION FOR HUMAN CLINICAL TRIALS

(LEGAL COSTS IN ADDITION)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) liability to pay compensation and claimants' costs and expenses pursuant to the **Conditions of Compensation** in respect of **Bodily Injury** to a **Research Subject**;
- (2) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that:

- (i) such liability is caused by an **Occurrence** within the **Policy Territory** in connection with the **Business** and arises from the use of any **Pharmaceutical** or **Medical Devices** in **Human Clinical Trials**;
- (ii) the **Insured** has offered and the **Research Subject** has agreed to abide by the **Conditions of Compensation** set out below;
- (iii) the **Claim** is first made against the **Insured** during the **Period of Insurance**; and
- (iv) all **Bodily Injury** resulting from or alleged to have resulted from the same **Human Clinical Trial** shall be considered as resulting from one **Claim** and having occurred during the period of insurance in which the first **Claim** is made against the **Insured**, irrespective of the number of claimants or the period over which **Claims** may thereafter be made against the **Insured** arising out of such **Bodily Injury**.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; (ii) persons claiming compensation for **Bodily Injury**; and (iii) **Claims** made on account of **Bodily Injury**, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability to indemnify the **Insured** for compensation and claimants' costs and expenses under paragraph (1) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 4, **Legal Costs** are not subject to the **Limits of Liability** and are payable in addition to the **Limits of Liability**.

EXTENSION TO SECTION 4

Unless otherwise stated, the following extension is subject to the terms, conditions, **Limits of Liability** for this Section 4 and exclusions of this **Policy**.

MANSLAUGHTER DEFENCE COSTS (ETHICS COMMITTEE) EXTENSION

The **Underwriters** shall indemnify the Ethics Committee of the **Insured**, or any member of the Ethics Committee of the **Insured**, in respect of **Legal Costs** incurred with the prior written consent of the **Underwriters** in the defence of any criminal proceedings brought (or in an appeal against conviction arising from such proceedings) for manslaughter arising from any event which may be the subject of indemnity under the insuring clause of this Section 4 of this **Policy**, provided that:

- (a) the proceedings relate to an offence alleged to have been committed during the **Period of Insurance** and in the course of the **Business**;
- (b) the **Underwriters** shall not be liable to indemnify the Ethics Committee of the **Insured**, or any member of the Ethics Committee of the **Insured**, under this extension in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (i) any proceedings consequent upon any **Bodily Injury** sustained by any **Person Employed** in the course of employment by the **Insured**.
- (ii) any ownership, possession or use by or on behalf of the **Insured** or any other person entitled to indemnity of any mechanically propelled vehicle while being used in circumstances where insurance or security is required by law.

ADDITIONAL EXCLUSIONS TO SECTION 4

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 4 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any **Human Clinical Trial** performed without the informed written consent of each **Research Subject** obtained prior to the participation of each **Research Subject** in such **Human Clinical Trial**.
- (2) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to a **Claim**.
- (3) any act, error or omission which constitutes or involves a breach of, or failure to comply with, the terms of the protocol governing the **Human Clinical Trial**.
- (4) any advice, design, specification or professional services provided for a fee (or provided in circumstances where a fee would normally be charged).
- (5) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

CONDITIONS OF COMPENSATION FOR SECTION 4

- (1) At any time prior to the settlement or other determination of any claim of a **Research Subject**, the **Insured** may, subject to the prior written agreement of the **Underwriters**, offer the **Research Subject** the option of having the claim determined in accordance with these **Conditions of Compensation**. If the **Research Subject** agrees to that proposal the **Insured**, having obtained the prior written agreement of the **Underwriters** as to the sum to be offered, shall make an offer of compensation to the **Research Subject**. The **Research Subject** shall then have three months to consider that offer.
- (2) If the **Insured** and the **Research Subject** agree to the claim being determined in accordance with these **Conditions of Compensation**, but there is no agreement between the **Insured** and the **Research Subject** as to the amount of compensation within the three month period referred to above, an **Independent Lawyer** experienced in medical litigation shall be appointed to adjudicate on the amount of compensation due. The choice of **Independent Lawyer** shall be by written agreement between the **Insured**, the **Underwriters** and the **Research Subject**. In the absence of such agreement, the appointment shall be made by the President for the time being of The Law Society of England and Wales.
- (3) Upon the appointment of an **Independent Lawyer** such person shall:
 - (a) allow the parties a reasonable opportunity to present their cases with both oral and written evidence;
 - (b) be entitled to obtain independent expert advice or opinion;
 - (c) otherwise determine the procedure in order to arrive at a just settlement.
- (4) If the **Independent Lawyer** decides that a sum is due to be paid by the **Insured** to the **Research Subject** in compensation, the **Research Subject** shall be entitled to accept that sum, together with reasonable legal costs and legal expenses, in full and final settlement of all causes of action against the **Insured** and / or any other person in connection with the **Human Clinical Trial**. The **Underwriters** shall, subject to the terms, conditions, **Limits of Liability** and exclusions of this **Policy**, indemnify the **Insured** by paying such compensation and reasonable legal costs and legal expenses directly to the **Research Subject**.
- (5) If the **Research Subject** does not accept the decision of the **Independent Lawyer** within three months of that decision being made, the **Research Subject** shall have no further entitlement pursuant to these **Conditions of Compensation** but shall be able to pursue any such rights as the **Research Subject** may otherwise have.
- (6) If the **Research Subject** accepts an offer made under paragraph (1) above or the decision of the **Independent Lawyer**, the **Research Subject** shall be bound by the following terms:
 - (a) the **Research Subject** shall accept the sum offered or awarded, together with reasonable legal costs and legal expenses, in full and final settlement of all causes of action against the **Insured** and any other person in connection with the **Human Clinical Trial**.

- (b) the **Research Subject** shall waive all rights of action against the **Insured** other than under the settlement agreement made by the process described above, as well as against the **Underwriters** and against any third party who might seek a contribution or indemnity against the **Insured** and / or the **Underwriters**.
 - (c) the **Research Subject** shall assign to the **Insured** all rights of recovery that the **Research Subject** may have against any third party arising out of the **Human Clinical Trial**. Upon the **Underwriters** providing indemnity to the **Insured**, the **Underwriters** shall be subrogated to those rights. The **Research Subject** shall provide such help and assistance as the **Insured** or the **Underwriters** may require in enforcing those rights. Any sums recovered by the **Insured** or the **Underwriters** in the exercise of those rights which exceed the compensation paid and / or payable to the **Research Subject** (after deduction of all legal and other costs incurred in effecting such recovery) shall be paid to the **Research Subject**.
 - (d) the **Research Subject** shall sign such release or other documents as the **Insured** or the **Underwriters** may reasonably require to give effect to the terms of this paragraph (6).
- (7) Compensation shall only be payable under these **Conditions of Compensation** if, on the balance of probabilities, the **Bodily Injury** (including any exacerbation of an existing condition) was caused by the administration to, or use by or on, the **Research Subject** of any **Pharmaceutical** or **Medical Device** involved in the **Human Clinical Trial**. Furthermore, compensation shall only be payable in respect of **Bodily Injury** insofar as the injury was directly attributable to participation in the **Human Clinical Trial**.
- (8) Subject to paragraph (11) below, compensation shall not be refused solely on the basis that the **Bodily Injury** arose from a foreseeable adverse reaction or on the basis that the **Research Subject** was warned of the risk but nevertheless signed a consent form agreeing to participate in the **Human Clinical Trial**.
- (9) Compensation shall not be paid for the failure of a **Pharmaceutical** or **Medical Device** under trial to perform its intended purpose.
- (10) Compensation shall not be unreasonably withheld from a **Research Subject** not receiving or using the **Pharmaceutical** or **Medical Device** under **Human Clinical Trial** if treatment or other drugs normally used in relieving any conditions for which the **Research Subject** was undergoing treatment were withheld for the purposes of the **Human Clinical Trial**.
- (11) The amount of compensation payable shall be determined with reference to the amount of compensatory damages awarded in similar cases by the courts of the country where the **Human Clinical Trial** took place and commensurate with the nature, severity, persistence and effects of the **Bodily Injury**.

The amount of compensation may be reduced, denied or affected by the following circumstances:

- (a) negligence of the **Research Subject** or (where the **Research Subject** is under the age of majority), the **Research Subject's** parents or legal guardian;
 - (b) the seriousness of the injury treated in the **Human Clinical Trial** and the degree of probability that adverse reactions would occur and any warning that the **Research Subject** received;
 - (c) the comparison of risk between established treatments and those that are used or researched in a **Human Clinical Trial**;
 - (d) the availability and efficacy of alternative treatments which would have been available to a **Research Subject** had that person not agreed to participate in the **Human Clinical Trial**.
- (12) The amount of compensation shall be paid as a lump sum, irrespective of any legal principles or rules of court which might or would apply if settlement were not reached under these **Conditions of Compensation**.

SECTION 5 - ERRORS' AND OMISSIONS' LIABILITY

(LEGAL COSTS IN ADDITION)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for a negligent act, negligent error or negligent omission of the **Insured** happening within the **Policy Territory** and in the course of the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the **Claim** is first made against the **Insured** during the **Period of Insurance**.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; (ii) persons or entities claiming damages, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability to indemnify the **Insured** for damages, claimants' costs and expenses and **Legal Costs** under paragraphs (1) and (2) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 5, **Legal Costs** are not subject to the **Limits of Liability** and are payable in addition to the **Limits of Liability**.

EXTENSIONS TO SECTION 5

Unless otherwise stated, the following extensions are subject to the terms, conditions, **Limits of Liability** for this Section 5 and exclusions of this **Policy**.

(1) BREACH OF CONFIDENTIALITY EXTENSION

The **Underwriters** shall indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for an unintentional breach of confidentiality happening within the **Policy Territory** and in the course of the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the **Claim** is first made against the **Insured** during the **Period of Insurance**.

(2) DISHONESTY OF PERSON(S) EMPLOYED EXTENSION

Notwithstanding General Exclusion (13), the **Underwriters** shall indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for a dishonest, fraudulent, criminal or malicious act or omission by any **Person Employed** happening within the **Policy Territory** and in the course of the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the **Claim** is first made against the **Insured** during the **Period of Insurance**.

For the purposes of this extension to Section 5:

- (a) the definition of "**Person Employed**" shall not mean or include any director of the **Insured**.
- (b) the **Underwriters** will not indemnify any person whose dishonest, fraudulent, criminal or malicious act, error or omission or whose collusion in such act, error or omission was the cause of or contributed to such liability.

(3) **LIBEL AND SLANDER EXTENSION**

Notwithstanding General Exclusion (7), the **Underwriters** shall indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for an unintentional libel or unintentional slander by reason of words written or spoken by the **Insured** within the **Policy Territory** and in the course of the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the **Claim** is first made against the **Insured** during the **Period of Insurance**.

(4) **INTELLECTUAL PROPERTY RIGHTS EXTENSION**

Notwithstanding General Exclusion (8), the **Underwriters** shall indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for an unintentional infringement of intellectual property rights by the **Insured** happening within the **Policy Territory** and in the course of the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the **Claim** is first made against the **Insured** during the **Period of Insurance**.

(5) **LOSS OF DOCUMENTS EXTENSION**

Notwithstanding Additional Exclusion (5) to this Section 5, the **Underwriters** shall indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for loss of **Documents** happening within the **Policy Territory** and in the course of the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the discovery of such loss of **Documents** occurred during the **Period of Insurance** and provided that:

- (a) the **Documents** were in the care, custody or control of the **Insured** or a third party to whom the **Insured** had, in the ordinary course of the **Business**, entrusted, lodged or deposited the **Documents**;
- (b) the **Documents** have been destroyed, damaged, lost or mislaid and, after diligent search, cannot be found; and
- (c) the **Underwriters** shall not be liable to make any payment for loss of **Documents** brought about by wear, tear, vermin, mould, mildew or any other gradually occurring cause.

The **Underwriters'** total aggregate liability under this extension shall not exceed the **Limit of Liability** under this Section 5 in respect of all **Claims** (which, for the purposes of this extension, shall be deemed to include all costs and expenses incurred in the investigation, defence or settlement of all **Claims**) made against the **Insured** during the **Period of Insurance**.

(6) **PAYMENT OF WITHHELD FEES EXTENSION**

If the **Insured** attempts to recover any withheld fees and is faced with a counter-claim that would be indemnified by this **Policy** in an amount greater than the fees withheld the **Underwriters** may, in their sole discretion, agree

to pay the withheld fees to the **Insured**, provided that the **Insured** obtains a written confirmation from the debtor / counter-claimant that they will not bring a **Claim** against the **Insured** if the **Insured** agrees not to pursue its claim for fees.

ADDITIONAL EXCLUSIONS TO SECTION 5

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 5 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to a **Claim**.
- (2) any negligent act, error or omission by the **Insured** to effect or maintain insurance or to provide finance or advice on financial matters.
- (3) any insolvency of the **Insured**.
- (4) any negligent act, error or omission by the **Insured** in the preparation of estimates of cost.
- (5) any costs of replacing and / or restoring documents which have been lost, mislaid, damaged or destroyed.
- (6) any costs or expenses incurred for the recall, withdrawal, inspection, removal, repair, alteration, replacement or reinstatement or amounts claimed for loss of use of or reduction in value of any **Product, Pharmaceutical, Medical Device**, workmanship or contract work executed by or for the **Insured** or of any property of which such form a part.
- (7) any short delivery, non-delivery or late delivery of **Products** or non-completion of works or operations.
- (8) any **Cross Liabilities**.
- (9) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 6 - PRODUCTS FINANCIAL LOSS

(LEGAL COSTS IN ADDITION)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for **Financial Loss** arising from **Products** caused by an **Occurrence** within the **Policy Territory** in connection with the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that:

- (i) the **Claim** is first made against the **Insured** during the **Period of Insurance**; and
- (ii) all **Financial Loss** resulting from or alleged to have resulted from the same condition or defect in any of the **Products** shall be considered as resulting from one **Claim** and having occurred during the period of insurance in which the first **Claim** is made against the **Insured**, irrespective of the number of claimants or the period over which **Claims** may thereafter be made against the **Insured** arising from such **Financial Loss**.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; (ii) persons or entities claiming damages for **Financial Loss**; and (iii) **Claims** made on account of **Financial Loss**, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters**' total liability to indemnify the **Insured** for damages and claimants' costs and expenses under paragraphs (1) and (2) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 6, **Legal Costs** are not subject to the **Limits of Liability** and are payable in addition to the **Limits of Liability**.

ADDITIONAL EXCLUSIONS TO SECTION 6

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 6 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to a **Claim**.
- (2) any **Bodily Injury** or **Property Damage**.
- (3) any insolvency of the **Insured**.
- (4) any **Financial Loss** sustained by shareholders or stockholders of the **Insured** in their capacities as such.
- (5) any deliberate, conscious or intentional disregard by the **Insured's** directors or technical or administrative management of the need to take all reasonable steps to prevent **Financial Loss**.
- (6) any liability assumed by the **Insured** by agreement (other than liability arising from a condition or warranty of goods implied by law) and which would not have attached in the absence of such agreement unless, prior to the commencement thereof, full details have been notified to the **Underwriters** and the **Underwriters** have agreed in writing to provide an indemnity.

- (7) any costs or expenses incurred for the recall, withdrawal, inspection, removal, repair, alteration, replacement or reinstatement or amounts claimed for loss of use of or reduction in value of any **Product** supplied, structure erected or contract work executed by or for the **Insured** or of any commodity, article or thing in which such **Product**, structure or work is incorporated.
- (8) any **Financial Loss** suffered as a result of short delivery, non-delivery or late delivery of **Products** or non-completion or late completion of works or operations by or on behalf of the **Insured**.
- (9) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 7 - PRODUCT CONTAMINATION

(INCLUSIVE OF LEGAL COSTS)

"OCCURRENCE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) costs and expenses (including third party recall costs) reasonably and necessarily incurred in recalling, inspecting, destroying, replacing and re-distributing contaminated **Products**;
- (2) lost gross profit resulting directly from a decline in sales of the contaminated **Products** due to the contamination and additional expenses reasonably and necessarily incurred in minimising such loss;
- (3) other costs and expenses (including those of consultants) reasonably and necessarily incurred in respect of contaminated **Products**;
- (4) **Legal Costs** incurred in connection with contaminated **Products**,

provided that such is caused by an **Occurrence** of **Accidental Contamination** happening during the **Period of Insurance** within the **Policy Territory** in connection with the **Business** and is notified to the **Underwriters** in writing during the **Period of Insurance**.

LIMITS OF LIABILITY

Regardless of the number of persons or entities insured under this **Policy**, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability to indemnify the **Insured** under paragraphs (1), (2) (3) and (4) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Occurrence**" for all costs, expenses, losses and **Legal Costs** arising from any one **Occurrence**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Occurrences** of **Accidental Contamination** happening during the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 7, **Legal Costs** are included within the **Limits of Liability**.

ADDITIONAL EXCLUSIONS TO SECTION 7

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 7 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to **Accidental Contamination**.
- (2) any **Accidental Contamination** that did not happen during the **Period of Insurance**.
- (3) any **Accidental Contamination** that was not notified to the **Underwriters** during the **Period of Insurance**.
- (4) any costs, expenses or loss incurred later than twelve (12) months after the **Accidental Contamination** became known to the **Insured**.
- (5) any liability, claim, loss, costs or expenses more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 8 - GOVERNMENT INSTRUCTED PRODUCT WITHDRAWAL

(INCLUSIVE OF LEGAL COSTS)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) expenses reasonably and necessarily incurred for:
 - (a) media communication and correspondence;
 - (b) transportation arising directly from the return of a **Product** or any part thereof; or
 - (c) examination, sorting and / or destruction,in respect of a specific instruction by a relevant government to recall **Products** which are likely to cause **Bodily Injury or Property Damage** for which the **Insured** may be legally liable; and
- (2) **Legal Costs** arising from a specific instruction by a relevant government to recall **Products** which are likely to cause **Bodily Injury or Property Damage** for which the **Insured** may be legally liable,

provided that the specific instruction takes place during the **Period of Insurance** within the **Policy Territory** in connection with the **Business**.

LIMITS OF LIABILITY

Regardless of the number of persons or entities insured under this **Policy**, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability to indemnify the **Insured** under paragraph (1) and (2) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for all expenses arising from any one specific instruction by a relevant government; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for all expenses arising from all specific instructions by relevant governments in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 8, **Legal Costs** are included within the **Limits of Liability**.

ADDITIONAL EXCLUSIONS TO SECTION 8

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 8 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving:

- (1) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to a **Claim** or to a specific instruction by a relevant government to recall **Products**.
- (2) any repair, reconditioning, modification or replacement of any **Product** or any part thereof.
- (3) any liability, claim, loss, costs or expenses more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 9 - BARCODE COVERAGE

(INCLUSIVE OF LEGAL COSTS)

“OCCURRENCE” BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) costs and expenses reasonably and necessarily incurred and arising directly from an error in printing or illegible printing of the barcode used to code the **Products**;
- (2) costs and expenses reasonably and necessarily incurred in informing the retailers to whom incorrectly printed or illegibly printed barcoded **Product(s)** have been delivered;
- (3) the **Insured's** legal liability in respect of a **Claim** for costs and expenses incurred by a retailer in respect of:
 - (a) removing such incorrectly printed or illegibly printed barcoded **Product(s)** from its stock and returning them to the **Insured**; or
 - (b) re-labelling such incorrectly printed or illegibly printed barcoded **Product(s)**;
- (4) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (3) above,

provided that the **Occurrence** of the error in printing or illegible printing happened during the **Period of Insurance** within the **Policy Territory** in connection with the **Business** and is notified to the **Underwriters** in writing during the **Period of Insurance**.

LIMITS OF LIABILITY

Regardless of the number of persons or entities insured under this **Policy**, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters' total liability** to indemnify the **Insured** under paragraphs (1), (2), (3) and (4) above shall be:

- (a) the amount stated in the **Schedule** as “any one **Occurrence**” for all liability, claims, loss, costs and expenses arising from any one **Occurrence**; and
- (b) the amount stated in the **Schedule** as “in the aggregate” for all **Occurrences** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 9, **Legal Costs** are included within the **Limits of Liability**.

ADDITIONAL EXCLUSIONS TO SECTION 9

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 9 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving:

- (1) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to an error in printing or illegible printing of the barcode used to code its **Products**.
- (2) any error in printing or illegible printing that did not happen during the **Period of Insurance**.
- (3) any error in printing or illegible printing that was not notified to **Underwriters** in writing during the **Period of Insurance**.
- (4) any liability, claim, loss, costs or expenses more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 10 - MANUFACTURERS' ERRORS AND OMISSIONS LIABILITY

(LEGAL COSTS IN ADDITION)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for a negligent act, negligent error or negligent omission of the **Insured** happening within the **Policy Territory** and in the course of the contract manufacturing of **Products** by the **Insured** for third parties;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the **Claim** is first made against the **Insured** during the **Period of Insurance**.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; and (ii) persons or entities claiming damages, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability to indemnify the **Insured** for damages and claimants' costs and expenses under paragraphs (1) and (2) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 10, **Legal Costs** are not subject to the **Limits of Liability** and are payable in addition to the **Limits of Liability**.

ADDITIONAL EXCLUSIONS TO SECTION 10

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 10 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any circumstances which the **Insured** was, or ought to have been, aware prior to the commencement of the **Period of Insurance** might give rise to a **Claim**.
- (2) any **Bodily Injury**.
- (3) any advertising injury.
- (4) any cost guarantees, cost estimates or estimates of probable costs being exceeded.
- (5) any return of all or any part of payments made to the **Insured**.
- (6) any costs or expenses incurred by the **Insured** to comply with any warranties, representations or promises.
- (7) any costs or expenses incurred for the recall, withdrawal, inspection, removal, repair, alteration, replacement or reinstatement or amounts claimed for loss of use of or reduction in value of any **Product**, workmanship or contract work executed (or any part thereof).
- (8) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 11 - DIRECTORS' AND OFFICERS' LIABILITY

(INCLUSIVE OF LEGAL COSTS)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, pay:

- (1) **Loss** on behalf of an **Insured Person** in respect of a **Claim** first made against an **Insured Person** during the **Period of Insurance** which is not indemnified by the **Company**;
- (2) **Loss** on behalf of the **Company** in respect of a **Claim** first made against an **Insured Person** during the **Period of Insurance** which is indemnified by the **Company**;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; and (ii) persons or entities claiming damages, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability under paragraphs (1), (2) and (3) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured Persons** and the **Company** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 11, **Legal Costs** are included within the **Limits of Liability**.

EXTENSION TO SECTION 11

Unless otherwise stated, the following extensions are subject to the terms, conditions, **Limits of Liability** for this Section 11 and exclusions of this **Policy**.

LEGAL REPRESENTATION EXPENSES EXTENSION

The **Underwriters** shall pay **Legal Representation Expenses** on behalf of an **Insured Person** incurred in relation to an **Investigation**, provided that the **Insured Person**:

- (a) is first notified in writing during the **Period of Insurance** that he or she is legally compelled to attend the **Investigation**; or
- (b) is first identified in writing by an investigating authority during the **Period of Insurance** as a subject of the **Investigation**.

ADDITIONAL EXCLUSIONS TO SECTION 11

The **Underwriters** shall not be liable to pay any **Loss** under this Section 11 in respect of any liability, claim or loss for:

- (1) any actual or alleged bodily injury, mental illness or emotional distress (except emotional distress with respect to an **Employment Practice Claim**), sickness, disease or death of any person.
- (2) any actual or alleged damage to or destruction of any tangible property, including loss of use thereof.
- (3) any act, error or omission by an **Insured Person** as a trustee, fiduciary or administrator of a company's pension, profit sharing or employee benefits programme, including any actual or alleged violation of the responsibilities, obligations or duties imposed by the Employee Retirement Income Security Act of 1974 (USA) or the Pensions Act 1995 (UK) or any similar provisions of the law, common or statutory, of any state, territory, jurisdiction or political sub-division thereof.

The **Underwriters** shall not be liable to pay any **Loss** under this Section 11 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (4) any **Pollutants, Pollution or Contamination** or any rectification or clean-up costs relating to any **Pollutants or Pollution or Contamination**.
- (5) any dishonest, deceitful, fraudulent, reckless, wrongful, criminal or malicious act, error or omission of any **Insured Person** or the **Company** or collusion in or direction of any dishonest, deceitful, fraudulent, reckless, wrongful, criminal or malicious act, error or omission by any **Insured Person** or the **Company** or any intentional breach of the law by any **Insured Person** or the **Company**. This exclusion shall only apply if it is found through a judgment or any other final adjudication (including appeals) or any written admission that such conduct occurred.
- (6) any **Insured Person** or the **Company** gaining any profit or advantage or receiving any remuneration to which they were not legally entitled or may not lawfully retain. This exclusion shall only apply if it is found through a judgment or any other final adjudication (including appeals) or any written admission that such conduct occurred.
- (7) any actual or alleged act, error, omission, circumstance, fact, incident, event, situation, transaction, occurrence, misrepresentation, neglect, breach of duty or **Wrongful Act** which any **Insured Person** was, or ought to have been aware of, prior to the **Period of Insurance** may give rise to a **Claim**.
- (8) any **Wrongful Act** or series of related **Wrongful Acts** alleged in any **Claim** or circumstances of which notice has been given under any policy existing or expired before or on the commencement of the **Period of Insurance**.
- (9) any **Claim** or application brought or maintained in the United States of America by an **Insured Person** and / or the **Company** or an **Outside Company**. This exclusion shall not apply to any **Claim** or application:
 - (a) instigated by a shareholder or group of shareholders without the active solicitation, participation or assistance of:
 - (i) the **Company**;
 - (ii) any director of the **Company**; or
 - (iii) any **Insured Person** in connection with or party to any **Wrongful Act**.
 - (b) made by or on behalf of any **Insured Person** in respect of an **Employment Practice Claim**.
 - (c) brought or maintained by any **Insured Person** for contribution or indemnity if the **Claim** results directly from any other **Claim** to which this **Policy** responds.
 - (d) brought or maintained by a liquidator, administrative receiver or receiver either directly or derivatively on behalf of the **Company** without the solicitation, participation or assistance of any **Insured Person** or the **Company**.
 - (e) brought or maintained by any former director or officer of the **Company**.
 - (f) brought or maintained by an **Insured Person** or any director or officer (or equivalent in any other country) of an **Outside Company** in their capacity as a "whistleblower" (as defined by governmental, federal, state, local or foreign law) alleging a **Wrongful Act** by any **Insured Person** in connection with a protected activity categorised by any governmental, federal, state, local or foreign law as a "whistleblower" activity.
- (10) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

SECTION 12 - MEDICAL MALPRACTICE LIABILITY

(INCLUSIVE OF LEGAL COSTS)

"CLAIMS MADE" BASIS

COVER

The **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for **Bodily Injury** arising from **Malpractice** within the **Policy Territory**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a **Claim** for which there is cover under paragraph (1) above,

provided that the **Claim** is first made against the **Insured** during the **Period of Insurance**.

LIMITS OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; and (ii) persons or entities claiming damages for **Bodily Injury**; and (iii) **Claims** made on account of **Bodily Injury**, the liability of the **Underwriters** shall be limited as follows:

the limits of the **Underwriters'** total liability to indemnify the **Insured** for damages, claimants' costs and expenses and **Legal Costs** under paragraphs (1), (2) and (3) above shall be:

- (a) the amount stated in the **Schedule** as "any one **Claim**" for liability arising from any one **Claim**; and
- (b) the amount stated in the **Schedule** as "in the aggregate" for liability arising from all **Claims** in the **Period of Insurance**,

irrespective of the number of policies issued on behalf of the **Insured** by the **Underwriters**, their subsidiaries or affiliates which are in force and otherwise provide liability insurance coverage anywhere in the world.

For the purposes of this Section 12, **Legal Costs** are included within the **Limits of Liability**.

EXTENSION TO SECTION 12

Unless otherwise stated, the following extension is subject to the terms, conditions, **Limits of Liability** for this Section 12 and exclusions of this **Policy**.

LEGAL COSTS EXTENSION

The **Underwriters** shall indemnify the **Insured** against **Legal Costs** incurred with the prior written consent of the **Underwriters** in respect of:

- (a) any official investigation, examination, inquiry or other proceeding ordered or commissioned by an official body;
- (b) any coroner's inquest arising from the death of any patient of the **Insured**;
- (c) the prosecution (criminal or otherwise) of the **Insured**;
- (d) any disciplinary proceedings against the **Insured**,

arising from actual or alleged **Malpractice**, provided:

- (i) the investigation, examination, inquiry, prosecution or other proceeding relates to, or is connected with, the **Business** and the **Insured** is legally compelled to attend;
- (ii) the investigation, examination, inquiry, prosecution or other proceeding is opened within the **Period of Insurance**;
- (iii) the **Insured** notified the **Underwriters** in writing within the **Period of Insurance** and within 28 days of having received notice of the investigation, examination, inquiry, prosecution or other proceeding; and
- (iv) the **Underwriters** shall, in any event, be entitled to nominate lawyers to represent the **Insured**.

ADDITIONAL EXCLUSIONS TO SECTION 12

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 12 in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any circumstances which the **Insured** was, or ought to have been, aware might give rise to a **Claim** prior to the commencement of the **Period of Insurance**.
- (2) any **Bodily Injury** to any person or loss of or damage to tangible property of any person, save where such **Bodily Injury** or property damage results, or is alleged to result, directly from **Malpractice**.
- (3) any act in violation of a law or ordinance.
- (4) any clinical waste that has not been disposed of by an appropriately qualified waste disposal contractor.
- (5) any clinical trial or research project.
- (6) any performance of a service while under the influence of intoxicants or narcotics.
- (7) any:
 - (a) failure of any programme, instruction or data for use in any computer or other electronic processing device, equipment or system to function in the way expected or intended.
 - (b) failure of any plant and / or machinery.
 - (c) transmission or receipt of any virus, programme or code that causes loss or damage to any computer system and / or prevents or impairs its proper function or performance.
 - (d) defect or defective workmanship in the installation, repair or maintenance of any computer or other electronic equipment or system or computer hardware or software.
- (8) any use of instruments in contact with skin tissue to penetrate skin tissue or used in contact with bodily fluid that:
 - (a) are not stored, handled and used in accordance with the manufacturer(s) instructions.
 - (b) where approved by the manufacturer(s) and the Department of Health or equivalent to be used more than once, are not sterilised prior to such use using sterilising apparatus specifically approved by the manufacturer(s) in accordance with such manufacturer(s) instructions, recommendations and / or guidelines and in accordance with the guidelines of the Department of Health or equivalent.
- (9) any non-employee doctor of medicine providing medical services for or using the facilities of the **Insured** that is not a member of a recognised medical defence union or recognised medical defence association or recognised medical defence protection society or otherwise does not carry his or her own malpractice liability insurance policy.
- (10) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

ADDITIONAL CONDITIONS TO SECTION 12

REPLACEMENT DEFINITION OF "INSURED"

For the purposes of this Section 12 only, the definition of "**Insured**" shall be amended to read:

"**Insured** shall mean the **Policyholder** and shall include the **Policyholder's** directors, members, managers, employees and committee members working on its behalf or at its direction".

RECORDS OF PROFESSIONAL SERVICES AND EQUIPMENT

The **Insured** shall, at all times, maintain accurate and descriptive records of all professional services and equipment used in procedures which shall be available for inspection and use by the **Underwriters** or their duly appointed representatives. These records shall be retained for a period of at least ten (10) years from the date of treatment and, in the case of a minor, for a period of at least ten (10) years after that minor attains majority.

SECTION 13 - EMPLOYERS' LIABILITY

(LEGAL COSTS IN ADDITION)

"OCCURRENCE" BASIS

COVER

Notwithstanding the General Exclusions the **Underwriters** shall, subject to the terms, conditions, limitations and exclusions of this **Policy**, indemnify the **Insured** against:

- (1) legal liability for damages in respect of a **Claim** for **Bodily Injury** to a **Person Employed** or **Bodily Injury** to **Placed Personnel** caused by an **Occurrence** happening during the **Period of Insurance** within the **Policy Territory** in the course of employment by the **Insured** in connection with the **Business**;
- (2) legal liability for claimants' costs and expenses in connection with paragraph (1) above;
- (3) **Legal Costs** arising from a claim for which there is cover under paragraph (1) above.

LIMIT OF LIABILITY

Regardless of the number of: (i) persons or entities insured under this **Policy**; (ii) persons claiming damages for **Bodily Injury**; and (iii) **Claims** made on account of **Bodily Injury**, the limits of the **Underwriters'** total liability to indemnify the **Insured** for damages and claimants' costs and expenses under paragraphs (1) and (2) above in respect of any one **Occurrence** shall not exceed the **Limit of Liability** for this Section 13.

For the purposes of this Section 13, **Legal Costs** are not subject to the **Limit of Liability** and are payable in addition to the **Limit of Liability**.

ADDITIONAL EXCLUSIONS TO SECTION 13

The **Underwriters** shall not be liable to indemnify the **Insured** under this Section 13 in respect of any liability, claim or loss arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any **Bodily Injury** to any **Person Employed** or **Bodily Injury** to any **Placed Personnel** caused whilst working offshore or whilst travelling to or from any offshore installation. This exclusion shall not apply to the first **TBA** 5,000,000 of the liability of the **Insured** in respect of any one **Occurrence**.
- (2) any **Person Employed** or **Placed Personnel**:
 - (a) being carried in or upon any vehicle;
 - (b) entering, getting on to or alighting from a vehicle, in circumstances where any road traffic legislation requires insurance or security.
- (3) any dispute concerning employment practices, including disputes concerning wrongful or unfair dismissal, discrimination, harassment or victimisation.
- (4) any workers' compensation, unemployment compensation or disability benefits law or under any similar law.
- (5) any **Asbestos** or any materials containing **Asbestos**.
- (6) any:
 - (a) ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel;
 - (b) radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof, where such liability or loss is:
 - (i) that of any principal;
 - (ii) accepted under contract or agreement and would not have attached in the absence of such contract or agreement.
- (7) any:
 - (a) war, invasion, acts of foreign enemies, hostilities or warlike operations (whether war be declared or not), civil war, rebellion, revolution, insurrection, martial law, military or usurped power or civil commotion assuming the proportion of or amounting to an uprising.
 - (b) **Act of Terrorism**.
 - (c) action taken in controlling, preventing, suppressing or in any way relating to (a) and / or (b) above.

If the **Underwriters** allege that by reason of this exclusion any liability, claim or loss is not covered by this **Policy**, the burden of proving the contrary shall be upon the **Insured**.
In the event any portion of this exclusion is found to be invalid or unenforceable, the remainder shall remain in full force and effect.
(8) any fines, penalties, punitive damages, aggravated damages, liquidated damages or exemplary damages.
(9) any liability more specifically insured under any other Section of this **Policy** or any extension or endorsement.

GENERAL EXCLUSIONS

The **Underwriters** shall not be liable to indemnify the **Insured** under this **Policy** in respect of any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any of the following:

- (1) any:
 - (a) war, invasion, acts of foreign enemies, hostilities or warlike operations (whether war be declared or not), civil war, rebellion, revolution, insurrection, martial law, military or usurped power or civil commotion assuming the proportion of or amounting to an uprising.
 - (b) strike, riot, civil commotion or labour disturbance.
 - (c) **Act of Terrorism.**
 - (d) action taken in controlling, preventing, suppressing or in any way relating to (a) and / or (b) and / or (c) above.

- (2) any:
 - (a) ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel.
 - (b) radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof.

For this purposes of Section 12 (Medical Malpractice Liability) only, this exclusion shall not apply to any **Claim** in respect of the use of radio-isotopes, radium or radium compounds when used in or incidental to medical procedures and away from the place where such substances are made.

- (3) any **Bodily Injury** to any **Person Employed**. This exclusion applies:
 - (a) whether or not the **Insured** may be liable as an employer or in any other capacity; and
 - (b) to any liability, including any contribution for which the **Insured** may be liable or any obligation to indemnify any other person in respect of such **Bodily Injury**.
- (4) any obligation for which the **Insured** or his insurer may be held liable under any worker's compensation, disability benefits or unemployment compensation law or any similar law (including a subrogated claim by an insurer of any **Person Employed**).
- (5) any **Pollution or Contamination**:
 - (a) other than caused by a sudden, identifiable, unintended and unexpected incident which takes place in its entirety at a specific time and place during the **Period of Insurance**.
 - (b) occurring in the United States of America and / or Canada and / or their dependencies or trust territories.
- (6) any sexual misconduct of any nature, including sexual relations, sexual contact or intimacy, sexual harassment, sexual molestation, sexual exploitation or sexual discrimination.
- (7) any libel, slander or defamation.
- (8) any violation or alleged violation of any competition, price fixing or restraint of trade law, or any passing off, injurious falsehood or infringement or alleged infringement of any patent, copyright, trade mark, service mark, trade name, trade secret, registered design right or other intellectual property rights.
- (9) any:
 - (a) Chlorofluorocarbons, Chloro Fluoride Carbons (CFCs) or Chlorinated Hydro-Carbons.
 - (b) Chromated Copper Arsenate (CCA).
 - (c) electromagnetic fields (EMFs).
 - (d) Hepatitis.

- (e) Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants, derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome (AIDS) or any syndrome or condition of a similar kind howsoever it may be named.
- (f) latex and / or latex protein and / or latex derivatives and / or latex substances (howsoever these are named, identified, described or classified).
- (g) Lead.
- (h) Methyl Tertiary Butyl Ether (MTBE).
- (i) mould, fungi or bacteria on, within or arising from any building, structure or site.
- (j) Polychlorinated Biphenyls (PCBs), also known as Askarels, including polychlorinated biphenyl generated dibeneofurans and dioxins or any polychlorinated biphenyls-containing product or material or derivative thereof or the presence of or the actual or threatened use, installation, withdrawal or disposal of any such product or material.
- (k) product containing silicon or silicone which is in any form implanted or injected in the body.
- (l) tobacco or any tobacco products (or ingredients thereof).
- (m) Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).
- (n) Formaldehyde.

For the purposes of Section 12 (Medical Malpractice Liability) only, sub-paragraphs (d), (e) and (m) of this exclusion shall not apply to any **Claim** for **Malpractice** committed in the course of medical care and / or medical treatment and / or medical testing of any person for:

- (a) Hepatitis;
 - (b) HTLV iii or LAV or the mutants, derivatives or variations thereof or AIDS or any syndrome or condition of a similar kind howsoever it may be named; or
 - (c) TSE, CJD, vCJD or nvCJD.
- (10) (a) any actual or threatened injury or damage of any nature or kind to persons or property which arises out of any **Asbestos Hazard** or would not have occurred but for any **Asbestos Hazard**.
- (b) any liability to make any payment or contribution, or indemnify any person in respect of liability for an occurrence, injury or damage which arises out of any **Asbestos Hazard** or would not have occurred but for any **Asbestos Hazard**.
- (c) any obligation, request, demand, order or statutory or regulatory requirement that any **Insured** or others test for, monitor, clean-up, remove, contain, treat, neutralize, protect against or in any other way respond to the actual, alleged or threatened presence of **Asbestos** or any material or product containing, or alleged to contain, **Asbestos**.
- (11) any use of, reliance upon, sale, lease, license or supply of any computer hardware or related information technology or communication system, any computer software, internet, intranet, website or similar facility, system or network and / or any electronic data or related information, provided that this exclusion shall not exclude **Claims** for **Bodily Injury** caused by an accident involving physical contact with computer hardware.
- (12) any **Bodily Injury**, **Property Damage** or **Other Contingencies** expected or intended from the standpoint of the **Insured**, except when such **Bodily Injury**, **Property Damage** or **Other Contingencies** arise solely from the use of reasonable force for the purpose of protecting persons or property.
- (13) any dishonest, deceitful, fraudulent, reckless, wrongful, criminal or malicious act, error or omission of any **Insured** or collusion in or direction of any dishonest, deceitful, fraudulent, reckless, wrongful, criminal or malicious act, error or omission by any **Insured**. This exclusion shall not apply to the cover provided by Section 11 (Directors' and Officers' Liability) of the **Policy**.
- (14) any failure by the **Insured** to take all reasonable steps and precautions to prevent any circumstance or event which may give rise to a **Claim**.
- (15) any liability assumed by the **Insured** by agreement (other than liability arising from a condition or warranty of goods implied by law) and which would not have attached in the absence of such agreement unless, prior to the commencement thereof, full details have been notified to the **Underwriters** and the **Underwriters** have agreed in

writing to provide an indemnity. This exclusion shall not operate to exclude any liability under Section 4 (No fault Compensation for Human Clinical Trials) in respect of sums payable under the **Conditions of Compensation**.

- (16) any **Product, Pharmaceutical or Medical Device** manufactured, handled, sold or distributed in violation of any statutory or regulatory requirement.
- (17) any **Product, Pharmaceutical or Medical Device** that does not have the appropriate regulatory approval, unless such:
 - (a) is the subject of a licence under the provisions of legislation and complies with good manufacturing practice and good laboratory practice; and
 - (b) is the subject of approval for marketing by the provisions of legislation; and
 - (c) has not been the subject of any adverse decision requiring its withdrawal from the market.
- (18) any dispute concerning employment practices, including disputes concerning wrongful or unfair dismissal, discrimination, harassment or victimisation. This exclusion shall not apply to the cover for **Employment Practice Claims** provided by Section 11 (Directors' and Officers' Liability) of the **Policy**.
- (19) any actual or alleged breach of any data protection laws or regulations.
- (20) any loss sustained by shareholders or stockholders of the **Insured** in their capacities as such.
- (21) any trading debts of the **Insured**.
- (22) any fines, penalties, punitive damages, aggravated damages, liquidated damages or exemplary damages.
- (23) any act, error, omission, circumstance, incident, event, occurrence, **Claim, Human Clinical Trial, Wrongful Act** or series of related **Wrongful Acts** or **Malpractice** happening, or alleged to have occurred, prior to the **Retroactive Date**. This General Exclusion (23) shall not apply to Section 1 (Public Liability), Section 7 (Product Contamination), Section 9 (Barcode Coverage) or Section 13 (UK Employers' Liability).
- (24) any breach of any human rights.
- (25) any failure of any **Product** to cure or alleviate any **Bodily Injury**.
- (26) any use or operation, as a means for inflicting harm, of any computer, computer system, computer software programme, malicious code, computer virus or process or any other electronic system.
- (27) any business conducted and / or transacted via the internet, intranet, extranet and / or via the **Insured's** own website, internet site, web address and / or via the transmission of electronic mail or documents by electronic means.

This exclusion shall not apply where the liability of the **Insured** would have existed in the absence of the business being conducted and / or transacted via the internet, intranet, extranet and / or via the **Insured's** own website, internet site, web address and / or via the transmission of electronic mail or documents by electronic means. The onus of proof in this regard rests with the **Insured** and not with the **Underwriters**.

General Exclusions (1) to (27) above shall not apply to Section 13 (UK Employers' Liability) of the **Policy**.

The **Underwriters** shall not be liable to indemnify the **Insured** against any claim or provide any cover or benefit hereunder to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose the **Underwriters** to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, United Kingdom or United States of America.

GENERAL CONDITIONS

(1) THE CONTRACT

This **Policy** and the **Schedule** shall be read together as one document and any word or expression to which a specific meaning has been attached in any part of this **Policy** or of the **Schedule** shall bear such specific meaning wherever it may appear.

The **Insured** confirms that it is aware of and has complied with the duty of fair presentation under the Insurance Act 2015.

(2) NOTICE OF CLAIM

The **Insured** shall, as soon as possible:

- (a) give notice in writing to the **Underwriters** of any circumstances or **Occurrences** which may give rise to a **Claim** and provide all information and documents available to the **Insured**; and
- (b) on receipt by it or its servants or agents forward to the **Underwriters** any **Claim** or notice of proceedings in respect of which the **Underwriters** may be required to indemnify the **Insured**.

(3) EXTENSION BY NOTICE (APPLICABLE TO SECTIONS HEADED "CLAIMS MADE" BASIS)

This condition shall only apply to those sections of the **Policy** headed "Claims Made" Basis".

If, during the **Period of Insurance**, the **Insured** shall give written notice to the **Underwriters**, duly in accordance with General Condition (2) (a) above, of any circumstances or **Occurrences** which the **Underwriters** accept may give rise to a **Claim**, any **Claim** subsequently made against the **Insured** arising out of that circumstance or **Occurrence** shall be deemed to have been first made against the **Insured** during the **Period of Insurance**, regardless of when such **Claim** is actually made.

(4) CLAIMS CO-OPERATION AND CONDUCT OF PROCEEDINGS

The **Insured** shall, at its own expense, co-operate fully with the **Underwriters** and provide such assistance, information, documents and access to premises as the **Underwriters** shall request. The **Insured** shall give all such assistance to deal with **Claims** and the conduct of legal proceedings as the **Underwriters** and / or their legal advisers and consultants may require. The **Insured** shall immediately on receipt by it or its servants or agents forward to the **Underwriters** any correspondence or information regarding any **Claim** or proceedings in respect of which the **Underwriters** may be required to indemnify the **Insured**. The **Insured** agrees to waive any claim to legal professional privilege to the extent that the privilege would otherwise prevent any legal adviser or consultant of the **Underwriters** from disclosing information to the **Underwriters**.

The **Underwriters** shall be entitled to conduct in the name of the **Insured** the defence or settlement of any **Claim** or to prosecute in the name of the **Insured** for its own benefit any claim. In any such matter, the **Underwriters** shall have sole discretion in the conduct of any proceedings and in the settlement of any claim.

(5) ASSUMPTION OF LIABILITY

No admission, offer, promise, arrangement, payment or indemnity shall be made or given by or on behalf of the **Insured** without the prior written consent of the **Underwriters**. The **Underwriters** shall not be liable for any settlement, **Legal Costs**, admission, offer, promise, arrangement, payment or indemnity to which it has not consented.

(6) ACTION AGAINST UNDERWRITERS

No action shall lie against the **Underwriters** unless and until the amount of the **Insured's** obligation to pay shall have been finally determined either by judgment against the **Insured** after trial or by written agreement of the **Insured**, the claimant and the **Underwriters**. Nothing contained in this **Policy** shall give any person or entity any right to join the **Underwriters** as a co-defendant in any action against the **Insured** to determine the **Insured's** liability.

(7) INSPECTION

The **Underwriters** shall be permitted to inspect the **Insured's** premises, records and operations and the **Insured** shall provide any relevant information and documentation as may be requested by the **Underwriters** at any time. The **Underwriters** waive no right and undertake no responsibility by reason of such inspection or the omission thereof.

(8) **OTHER INSURANCE**

If the **Insured** has other insurance that is applicable to the **Occurrence, Claim**, loss, liability, costs or expenses (or which would be applicable if this **Policy** did not exist), such other insurance shall be primary to the cover afforded by this **Policy** and the **Underwriters** shall not be liable to indemnify the **Insured** until such other insurance is exhausted. If such other insurance were exhausted, the **Limit of Liability** (or, if applicable, the sub-limit of liability) would apply in excess of the limit of indemnity applying under the other insurance.

(9) **SUBROGATION**

- (a) In the event of any payment or indemnity being made or provided under this **Policy**, the **Underwriters** shall be subrogated to the extent of such payment to all the **Insured's** rights of recovery, indemnity or contribution against any third party.
- (b) The **Insured** shall not surrender any right or settle any claim arising from any such right of recovery, indemnity or contribution and shall execute all papers required and do everything necessary within its power to secure such rights. The **Insured** shall do nothing to prejudice such rights.
- (c) The **Insured** shall, at its own expense, co-operate fully with the **Underwriters** in the pursuit of any subrogated claim and shall provide such assistance, documents and access to premises as the **Underwriters** shall request.
- (d) If the **Underwriters** make a recovery in the exercise of rights of subrogation, any sums recovered shall be applied in the following order of priority:
 - (i) firstly, to reimbursement of any outlay or anticipated outlay of the **Underwriters** (including payments made to indemnify the **Insured**, costs and disbursements);
 - (ii) secondly, to reimbursement of uninsured losses of the **Insured**; and
 - (iii) thirdly, to reimbursement of the liability of the **Insured** in respect of the **Deductible**.
- (e) The **Underwriters** shall not exercise any right of subrogation that may exist against any employee or former employee of the **Insured** unless the **Underwriters** shall have made a payment brought about or contributed to by the act, error or omission of the employee or former employee which was dishonest, deceitful, fraudulent, reckless, wrongful, criminal or malicious.

(10) **CANCELLATION**

- (a) This **Policy** may be cancelled at any time at the written request of the **Policyholder**. The **Underwriters** shall, upon surrender of the **Policy**, refund the amount by which paid premium exceeds earned premium (that being computed in accordance with the short rate calculation table attached).
- (b) The **Underwriters** shall, except in the case of non-payment of premium, give the Corporate Risk Department (or its equivalent) of the **Policyholder** thirty (30) days written registered mail notice of cancellation and, in the case of non-payment of premium, the **Underwriters** shall give fifteen (15) days' notice of cancellation.
- (c) If the premium for the whole or part of this **Policy** is demanded and / or paid on an estimated basis, premium adjustment may be made by the time cancellation is effected or, if not then made, shall be made as soon as practicable after cancellation becomes effective.
- (d) In this condition the expression "paid premium" means premium actually paid by the **Policyholder** to the **Underwriters** or their authorized agent and does not include any premium or part thereof paid to the **Underwriters** by an agent, unless actually paid to the agent by the **Policyholder**.

Upon cancellation of this **Policy**, any certificate(s) of insurance shall be cancelled, and shall be returned by the **Policyholder** to the **Underwriters** immediately.

(11) **WAIVER, VARIATION AND ASSIGNMENT**

- (a) No provision of this **Policy** may be waived or varied, except by an endorsement issued and signed by the **Underwriters**. Notice given to any agent of the **Insured** or of the **Underwriters** or knowledge possessed by any such agent or any other person, shall not be held to effect a waiver or change in any part of this **Policy**.
- (b) No change, modification or assignment of any interest under this **Policy** shall be effective without the prior written approval of the **Underwriters**.

(12) **CROSS LIABILITY**

The insurance afforded by Sections 1 to 13 (inclusive) of this **Policy** shall apply in respect of any **Claim** brought against any one **Insured** by any other **Insured**. The coverage shall apply in the same manner and to the same extent as if a separate policy had been issued to each **Insured**. Any breach of a term or condition of this **Policy** by any **Insured** shall not affect the protection given by this **Policy** to any other **Insured**. Nothing in this condition shall operate to increase the **Limits of Liability** under this **Policy**.

(13) **GOVERNING LAW AND JURISDICTION**

Unless otherwise stated on the **Schedule**, this **Policy** shall be governed by and construed in accordance with Irish law and any disputes arising out of or concerning this **Policy** shall be subject to the exclusive jurisdiction of the courts of Republic of Ireland.

(14) **BASIS OF PREMIUM**

If any part of the premium is based on estimates furnished by the **Insured**, the **Insured** shall keep an accurate record containing all relevant particulars and shall allow the **Underwriters** to inspect such record. Within one month of the expiry of the **Period of Insurance**, the **Insured** shall furnish such information as the **Underwriters** may require. The deposit premium shall thereupon be adjusted and the difference paid by or allowed to the **Insured**, subject to the retention by the **Underwriters** of any minimum premium.

(15) **ADMINISTRATION AND THE POLICYHOLDER**

It is agreed that the **Policyholder** has acted and shall continue to act as agent of each and every **Insured** with irrevocable authority with respect to all aspects of this **Policy** including, but not limited to, the following: contract negotiations; renewals and decisions not to renew; amendments and endorsements to cover; premium payment; premium adjustments; receipt of notices regarding this **Policy**; dispute resolution matters; claims management; consent to defence and settlement; claim payments and exercising rights of the **Insured**; allocation; and cancellation.

(16) **EROSION OF DEDUCTIBLE BY LEGAL COSTS**

The **Deductible** shall be eroded by any payment of **Legal Costs** by the **Insured**.

(17) **DISCHARGE BY PAYMENT**

In connection with any **Claim** against the **Insured**, the **Underwriters** may, at any time, pay to the **Insured** a sum equal to the **Limit of Liability** applying to the relevant section of this **Policy**, or any lesser amount for which, in the reasonable opinion of the **Underwriters**, such **Claim** can be settled. Upon payment of such sums, the **Underwriters** shall be entitled to relinquish the control of such **Claim** and be under no further liability in connection therewith, save for such **Legal Costs** as the **Underwriters** have already agreed in writing to pay in respect of matters prior to the date of such payment.

(18) **REASONABLE STEPS AND PRECAUTIONS**

- (a) The **Insured** shall, at its own expense, take all reasonable steps and precautions to prevent any event, circumstance or occurrence which may give rise to liability indemnified under this **Policy** and shall maintain all buildings, furnishings, ways, works, machinery, plant and vehicles in sound condition. As soon as possible after discovery, the **Insured** shall cause any defect or danger to be made good or remedied and, in the meantime, shall cause such additional precautions to be taken as the circumstances may require.
- (b) If any **Insured** becomes aware of any event, circumstance or occurrence which may give rise to a **Claim** or liability against any **Insured** it shall, at its own expense, take all reasonable steps and precautions to avoid or minimise any **Claim** or liability arising from that event, circumstance or occurrence.
- (c) Prior to the commencement of any **Human Clinical Trial**, the **Insured** shall ensure that all applicable statutory and regulatory requirements and professional guidelines and standards have been complied with in respect of that **Human Clinical Trial**.

(19) **CURRENCY**

All amounts shown in this **Policy** are deemed to be expressed in pounds sterling unless clearly stated to the contrary.

(20) **INTERLOCKING CLAUSE**

In the event of any acts, errors, omissions, events, circumstances, **Claims**, occurrences, **Human Clinical Trial**, **Wrongful Act** or **Malpractice** or in respect of which the **Insured** is entitled to indemnity under more than one section, extension or endorsement of this **Policy**, each section, extension or endorsement shall be subject to its applicable **Limit of Liability**, provided that the total amount of the **Underwriters'** liability shall not exceed the lesser of: (a) the greatest **Limit of Liability** available under one of the sections, extensions or endorsements providing indemnity; and (b) the aggregate **Limit of Liability** for sections 2 to 12 and all extensions and endorsements combined, as specified in the **Schedule**.

(21) **CHANGE OF INTEREST / ALTERATION OF RISK**

This **Policy** shall automatically terminate if:

- (a) the interest of the **Insured** ceases other than as a result of death; or
 - (b) the **Business** is wound up, carried on by a liquidator or an administrator or permanently discontinued,
- save where, within 14 days, the **Underwriters** sign a memorandum stating that the **Policy** continues.

If any material change is made to the **Business**, or if any material change of any kind shall occur which affects to any extent the risks insured under this **Policy**, the **Underwriters** shall not be liable in respect of any liability, claim, loss, costs or expenses arising out of such material change, unless the **Underwriters** have previously been notified of such material change and have agreed to it in writing.

(22) **FRAUDULENT CLAIMS**

If any claim under this **Policy** is in any respect fraudulent, the **Underwriters** shall be entitled to:

- (a) refuse to pay the claim;
- (b) recover any sums paid by the **Underwriters** to the **Insured** in respect of the claim from the **Insured**; and
- (c) give notice of termination of the **Policy**, which shall be effective from the date of the fraud.

(23) **UNENFORCEABLE / VOID PROVISIONS**

If any clause of this **Policy** shall be struck down in whole or in part, the remainder of the **Policy** shall continue in full force and effect.

(24) **DEDUCTIBLE**

The **Underwriters** may, at their sole discretion, pay any part or all of the **Deductible** to effect settlement of any **Claim** and, upon notification of the action taken, the **Policyholder** shall promptly reimburse the **Underwriters** for such **Deductible** (or portion thereof) as the **Underwriters** have paid.

(25) **CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999**

Any person or company who is not a party to this **Policy** has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this **Policy**. This condition does not affect any right or remedy which exists or would be available but for the operation of that Act.

(26) **ALLOCATION**

In the event that the **Insured** is the subject of, or party to, a **Claim** or proceedings which are covered only in part by this **Policy**, the **Policyholder** and the **Underwriters** shall use their best efforts to agree upon a fair and proper allocation of liability, loss, costs or expenses or **Legal Costs** and any other sums insured under this **Policy**, taking into account the relative legal and financial exposures attributable to covered matters and matters not covered under this **Policy**.

(27) Stamp duty has been paid or will be paid to the Revenue Commissioners in accordance with the provisions of Section 113 of the Finance Act 1990.

(28) It is noted and agreed that wherever a Law, Act or Legislation is mentioned or referred to in this **Policy** that does not apply to the Republic of Ireland, it is replaced with the equivalent Law, Act or Legislation in Irish Law.

(27) **NOTICES**

Unless stated otherwise, all notices and other correspondence required by this **Policy** to be sent to the **Underwriters** should be sent to Newline Underwriting Management Limited (as agent of the **Underwriters**) at the following address:

Newline Underwriting Management Limited
4th Floor
55 Mark Lane
London
EC3R 7NE

Tel: +44(0)20 7090 1700
Fax: +44(0)20 7090 1701

COMPLAINTS NOTICE - IRELAND

Any complaint should be addressed to:

Service Manager
Operations Team
Lloyd's Insurance Company S.A.
Bastion Tower
Marsveldplein 5
1050 Brussels
Belgium

Tel: +32 (0)2 227 39 39

E-mail: enquiries.lloydsbrussels@lloyds.com

Your complaint will be acknowledged, in writing, within 5 (five) business days of the complaint being made. You will also be informed of the name of one or more individuals that will be your point of contact regarding your complaint until the complaint is resolved or cannot be progressed any further. You will be provided with an update on the progress of the investigation of your complaint, in writing, within twenty business days of the complaint being made.

A decision on your complaint will be provided to you, in writing, within 40 (forty) business days of the complaint being made.

Should you remain dissatisfied with the final response or if you have not received a final response within 40 (forty) business days of the complaint being made, you may be eligible to refer your complaint to the Financial Services and Pensions Ombudsman (FSPO). The contact details are as follows:

Financial Services and Pensions Ombudsman
Lincoln House
Lincoln Place
Dublin 2
D02 VH29
Republic of Ireland

Tel: +353 1 567 7000

E-mail: info@fspo.ie

Website: www.fspo.ie

If you have purchased your contract online you may also make a complaint via the EU's online dispute resolution (ODR) platform. The website for the ODR platform is www.ec.europa.eu/odr.

The complaints handling arrangements above are without prejudice to your right to commence a legal action or an alternative dispute resolution proceeding in accordance with your contractual rights.

**DATA PROTECTION SHORT FORM INFORMATION NOTICE
YOUR PERSONAL INFORMATION NOTICE**

WHO WE ARE

We are Lloyd's Insurance Company S.A. identified in the contract of insurance and/or in the certificate of insurance.

THE BASICS

We collect and use relevant information about you to provide you with your insurance cover or the insurance cover that benefits you and to meet our legal obligations.

This information includes details such as your name, address and contact details and any other information that we collect about you in connection with the insurance cover from which you benefit. This information may include more sensitive details such as information about your health and any criminal convictions you may have.

In certain circumstances, we will need your consent to process certain categories of information about you (including sensitive details such as information about your health and any criminal convictions you may have). Where we need your consent, we will ask you for it separately. You do not have to give your consent and you may withdraw your consent at any time by sending an e-mail to data.protection@lloyds.com (without however affecting the lawfulness of processing based on consent prior to its withdrawal). However, if you do not give your consent, or you withdraw your consent, this may affect our ability to provide the insurance cover from which you benefit and may prevent us from providing cover for you or handling your claims.

The way insurance works means that your information may be shared with, and used by, a number of third parties in the insurance sector for example, insurers, insurance agents or insurance brokers, reinsurers, loss adjusters, sub-contractors, regulators, law enforcement agencies, fraud and crime prevention and detection agencies and compulsory insurance databases. We will only disclose your personal information in connection with the insurance cover that we provide and to the extent required or permitted by law.

OTHER PEOPLE'S DETAILS YOU PROVIDE TO US

Where you provide us or your insurance agent or insurance broker with details about other people, you must provide this notice to them.

WANT MORE DETAILS?

For more information about how we use your personal information please see our full privacy notice, which is available in the Privacy section of our website www.lloydsbrussels.com or in other formats on request.

CONTACTING US AND YOUR RIGHTS

You have rights in relation to the information we hold about you, including the right to access your information. If you wish to exercise your rights, discuss how we use your information or request a copy of our full privacy notice(s), please contact us. Alternatively, you may contact the Data Protection Officer of our agent, Newline Underwriting Management Limited, at:

Newline Group
4th Floor
55 Mark Lane
London
EC3R 7NE

Tel: +44 (0)20 7090 1700 (request the Data Protection Officer)

Fax: +44 (0)20 7090 1701

E-mail: DPO@newlinegroup.com

You also have the right to lodge a complaint with your competent data protection authority, but we encourage you to contact us before.

SERVICE OF SUIT AND JURISDICTION CLAUSE

It is agreed that this Insurance shall be governed exclusively by the law and practice of Ireland, and any disputes arising under, out of or in connection with this Insurance shall be exclusively subject to the jurisdiction of any competent court in Ireland.

Lloyd's Insurance Company S.A. hereby agrees that all summonses, notices or processes requiring to be served upon it for the purpose of instituting any legal proceedings against them in connection with this Insurance shall be properly served if addressed to it and delivered to its care of

Eamonn Egan
Country Manager for Ireland
Lloyd's Ireland Representative Limited
7/8 Wilton Terrace
Dublin 2
D02 KC57
Ireland
Tel: + 353 (0) 16441000

E-mail: eamonn.egan@lloyds.com or lloydsireland@lloyds.com

who in this instance, has authority to accept service on its behalf.

Lloyd's Insurance Company S.A. by giving the above authority does not renounce its right to any special delays or periods of time to which it may be entitled for the service of any such summonses, notices or processes by reason of its residence or domicile in Belgium.

This Service of Suit and Jurisdiction Clause will not be read to conflict with or override the obligations of the parties to resolve their disputes as provided for in any other clause in this Policy and, to the extent required, shall apply to give effect to that process.

LBS0006A
01/12/2019

PREMIUM PAYMENT CLAUSE

The (Re)Insured undertakes that premium will be paid in full to Underwriters within sixty (60) days of inception of this policy (or, in respect of instalment premiums, when due).

If the premium due under this policy has not been so paid to Underwriters by the {Response} day from the inception of this policy (and, in respect of instalment premiums, by the date they are due) Underwriters shall have the right to cancel this policy by notifying the (Re)Insured via the broker in writing. In the event of cancellation, premium is due to Underwriters on a pro rata basis for the period that Underwriters are on risk but the full policy premium shall be payable to Underwriters in the event of a loss or occurrence prior to the date of termination which gives rise to a valid claim under this policy.

It is agreed that Underwriters shall give not less than 15 days prior notice of cancellation to the (Re)Insured via the broker. If premium due is paid in full to Underwriters before the notice period expires, notice of cancellation shall automatically be revoked. If not, the policy shall automatically terminate at the end of the notice period.

Unless otherwise agreed, the Leading Underwriter (and Agreement Parties if appropriate) are authorised to exercise rights under this clause on their own behalf and on behalf of all Underwriters participating in this contract.

If any provision of this clause is found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, such invalidity or unenforceability will not affect the other provisions of this clause which will remain in full force and effect.

Where the premium is to be paid through a London Market Bureau, payment to Underwriters will be deemed to occur on the day of delivery of a premium advice note to the Bureau.

11/01
LSW3000
11/06/2019

SHORT RATE CALCULATION TABLE

Days Policy in force			% of premium		Days Policy in force			% of premium	
Up to	-	83	33	215	-	218	68
84	-	87	34	219	-	223	69
88	-	91	(3 Months)	35	224	-	228	70
92	-	94	36	229	-	232	71
95	-	98	37	233	-	237	72
99	-	102	38	238	-	241	73
103	-	105	39	242	-	246	(8 Months)	74
106	-	109	40	247	-	250	75
110	-	113	41	251	-	255	76
114	-	116	42	256	-	260	77
117	-	120	43	261	-	264	78
121	-	124	(4 Months)	44	265	-	269	79
125	-	127	45	270	-	273	(9 Months)	80
128	-	131	46	274	-	278	81
132	-	135	47	279	-	282	82
136	-	138	48	283	-	287	83
139	-	142	49	288	-	291	84
143	-	146	50	292	-	396	85
147	-	149	51	297	-	301	86
150	-	153	(5 Months)	52	302	-	305	(10 Months)	87
154	-	156	53	306	-	310	88
157	-	160	54	311	-	314	89
161	-	164	55	315	-	319	90
165	-	167	56	320	-	323	91
168	-	171	57	324	-	328	92
172	-	175	58	329	-	332	93
176	-	178	59	333	-	337	(11 Months)	94
179	-	182	(6 Months)	60	338	-	342	95
183	-	187	61	343	-	346	96
188	-	191	62	347	-	351	97
192	-	196	63	352	-	355	98
197	-	200	64	356	-	360	99
201	-	205	65	361	-	366	(12 Months)	100
206	-	209	66					
210	-	214	(7 Months)	67					