Medical devices

Application form

United Kingdom

INTRODUCTION

The purpose of this application form is for us to find out more about you. Completion of this application form does not oblige either you or us to enter into a contract of insurance.

Following a reasonable search you must provide us with all information which may be material to the cover we offer in a clear and accessible manner. Information is material if it would influence our decision whether to insure you, what cover we offer you or what premium we charge you. If you are in any doubt whether a fact or circumstance is material you should disclose it.

HOW TO COMPLETE THIS FORM

Whoever fills out the form must be a principal, director or partner of the applicant company. They should make all the necessary enquiries of their fellow senior management, employees and persons responsible for arranging the insurance to enable our questions to be answered.

If you require extra space to answer the questions or provide any other material information, please use the additional information section at the back of the form. Once you have completed the form please return it directly to your insurance broker.

SECTION 1: COMPANY DETAILS

1.1 Please provide the following details:

Insured company:

Contact name:

Address:

Postcode:

Telephone: Email address:

Fax: Website:

1.2 Please state when your company was established: DD / MM / YY

Please answer question 1.3 only if you require Employer's Liability cover.

1.3 a) Please state your Employer Reference No. (ERN):

b) Do you have any subsidiaries in the UK? ☐ Yes ☐ No

If 'yes', please complete the Supplementary Information section at the back of this proposal form.

1.4 Please briefly describe below the nature of your business activities:
If you have a brochure, or company literature, please attach to this form.

1.5 Please outline below your business development plans for the next 12 months, including the number of products under development and the stage of development for each:

If you have a copy of an up to date business plan, please attach to this form

1.6 Please state the number of employees:

1.7 Please provide estimates of your wageroll for the next 12 months, broken down as follows:

a) Administrative and managerial:

b) Laboratory based staff:

c) Other:

If 'other', please provide full details:

1.8 Do you directly work with, or store, radioactive or biohazardous materials at your premises? ☐ Yes ☐ No

If 'yes', please provide further details below including types of materials, quantities used and how you manage the process of using, storing and disposal:

SECTION 2: PREMISES DETAILS

2.1 Please provide below details of your premises:

PREMISES 1

Address:

Postcode:

Details of usage (e.g. manufacturing, storage, offices etc.):

PREMISES 2

Address:

Postcode:

Details of usage:

Please continue on a separate sheet if more than two premises are to be insured.

2.2 Please provide details of the premises of your supply chain partners that carry out significant work on your behalf, including those where you require cover for damage to your property and those where you have a significant reliance on them for your business activities:

SUPPLY CHAIN PARTNER 1

Address:

Postcode:

Details of usage:

SUPPLY CHAIN PARTNER 2

Address:

Postcode:

Details of usage:

Please continue on a separate sheet if more than two premises are to be insured.

2.3 Are all of the premises:

a) Constructed with external walls of brick, stone or concrete and roofed with slate, tiles, concrete, metal, asbestos or any other non-combustible material? ☐ Yes ☐ No

b) Free from cracks or other signs of damage that may be due to subsidence, landslip or heave and have not previously suffered damage by any of these causes? ☐ Yes ☐ No

c) In an area free from flooding and not near the vicinity of any rivers, streams or tidal waters? ☐ Yes ☐ No

d) In a good state of repair? ☐ Yes ☐ No

e) Self contained with a lockable entrance door? ☐ Yes ☐ No

f) Protected by fire and intruder alarms that are subject to an annual maintenance contract? ☐ Yes ☐ No

NOTE: We may refuse to pay a claim if all of the devices for the protection of your premises (including locks and alarms) are not put into full and effective operation whenever the premises are closed for business or left unattended.

g) Heated by a conventional electric, gas, oil or solid fuel heating system? ☐ Yes ☐ No

h) Fitted with electrical installations which are inspected at least every 5 years by a qualified electrician and any defect remedied? ☐ Yes ☐ No

i) Lifts, boilers, steam and pressure vessels inspected and approved to comply with all of the statutory requirements? ☐ Yes ☐ No

NOTE: Assuming you have answered 'yes' to questions h) and i) above, it is important to keep records of all relevant inspections as we may ask for evidence for these before paying a claim.

If you have answered 'no' to any of the above questions, please provide further details:

2.4 If any of the premises listed in 2.1 and 2.2 contain composite or sandwich panels, please provide details:

Address	Are panels exterior or interior?	Type of panel (Make, model, core material)	Are products LPS1181: 2003 or FMRC4880 (1994) approved?

2.5 Do you occupy space within your premises &/or premises of supply chain partners which are:

a) Below ground level ☐ Yes ☐ No

b) Ground level ☐ Yes ☐ No

c) First floor ☐ Yes ☐ No

d) Second floor & above ☐ Yes ☐ No

2.6 Please provide details of your contingency plans to continue your business activities, if damage at the premises listed in 2.2 means your supply chain partners are unable to fulfil contractual commitments:

Supplier name	Nature of reliance	Contingency plans

2.7 Is your stock sensitive to changes in environmental conditions? ☐ Yes ☐ No

If 'yes', please answer the following:

a) What proportion of stock is temperature sensitive? ____ %

b) Is all stock stored in fridges / freezers which are less than 3 years old, or subject to maintenance agreements? ☐ Yes ☐ No

c) Is all electrical equipment and switch gear protected by anti-power surge devices? ☐ Yes ☐ No

d) Are all fridges / freezers connected to automatic self starting power generators? ☐ Yes ☐ No

If 'yes', how many hours back up is provided? Hours

e) Do you have an alarm system that activates if the temperature falls outside the prescribed range? ☐ Yes ☐ No

f) Is the alarm system monitored by a third party central station? ☐ Yes ☐ No

g) Is stock duplicated in more than one freezer on the same site? ☐ Yes ☐ No

h) Is stock duplicated in more than one freezer at different sites? ☐ Yes ☐ No

i) Do you have a formal Business Continuity Plan for a power outage or failure in storage arrangements? ☐ Yes ☐ No

j) Are specialist couriers used if stock is moved? ☐ Yes ☐ No

2.8 a) Is cover for stock in transit required? ☐ Yes ☐ No

If 'yes', please state the stock consignement values:

	Annual value	Maximum value of one consignment
Domestic:		
Outside (domestic) country, but within the continent:		
Elsewhere in the world:		

b) Will you transport stock to areas where the government currently advises against travel? ☐ Yes ☐ No

If 'yes', please provide details:

SECTION 3: ACTIVITIES

3.1 Please state your turnover received in respect of the following years:

	Last complete financial year	Estimate for current financial year	Estimate for next financial year
Domestic turnover:			
USA turnover:			
Other territory turnover:			
Total turnover:			
Profit / (Loss):			

Date of financial year end: DD / MM / YY Currency:

3.2 Please state the percentage of your fees received in respect of each device classification:

Class I	Class IIa	Class IIb	Class III

3.3 Please state the percentage of your fees received in respect of each of the following:

Sale of own product (manufacture sub-contracted):	%
Manufacture and distribution of own product (including repair and service):	%
Contract manufacture of product or product components for third parties:	%
Distribution of third party product (no repair, service or training):	%
Distribution of third party product (including repair, service or training):	%
Other:	%

If 'other', please provide details:

3.4 Please state the percentage of your turnover received in respect of each of the following:

Paediatric:	%
Clinical:	%
Ambulatory:	%
Home use:	%
Products with cosmetic applications:	%
Other:	%

%

If 'other', please provide details:

3.5 Please state the percentage of your fees received in respect of each of the following:

Active implantable:	%
Anaesthesia:	%
Analytical instruments:	%
Cardiovascular:	%
Dental:	%
Diagnostic kits:	%
Dialysis:	%
Drug delivery:	%
Durable equipment:	%
Hospital consumables:	%
Lasers:	%
Monitoring equipment:	%
Passive implantable:	%
Rehabilitation:	%
Respiratory:	%
Surgical:	%

SECTION 4: HEALTH AND SAFETY MANAGEMENT

4.1 a) Do you use a full-time risk manager? ☐ Yes ☐ No

If 'no', how do you control and prioritise risk?

b) Do you have, in place, a Medical Device Vigilance System, Safety Surveillance System or similar? ☐ Yes ☐ No

If 'yes', please provide names and status of people responsible:

If 'no', please explain your method for safety oversight and reporting:

4.2 Have you ever had an inspection visit by a regulatory body? ☐ Yes ☐ No

If 'yes':

a) When was the last visit? DD / MM / YY

b) What requirements or recommendations were made and do any remain outstanding?

4.3) a) Have you ever been subject to a written warning, enforcement notice or prosecution by a regulatory body (e.g. MHRA)? ☐ Yes ☐ No

If 'yes', please provide details:

b) Have you ever been subject to a Medical Device Alert (MDA), Safety Alert Broadcast (SAB), Hazard Alert, Medical Device Report (MDR) or similar? ☐ Yes ☐ No

If 'yes', please provide details:

c) Have you ever withdrawn or recalled a product or discontinued product sales for safety reasons? ☐ Yes ☐ No

If 'yes', please provide details:

d) Have you been associated with a serious adverse event that was ultimately shown to be device related? ☐ Yes ☐ No

If 'yes', please provide details:

e) How do you monitor off-label use (use of a product contrary to your own conformity assessment and certification) of your products by customers and medical professionals?

SECTION 5: CONTRACT MANAGEMENT

5.1 Are all rights of recourse retained against all supply chain partners? ☐ Yes ☐ No

If 'no', please explain why:

5.2 Will supply chain partners carry the following insurance: ☐ Yes ☐ No

a) Products liability for contract manufacturers? ☐ Yes ☐ No

b) Professional liability for service providers and other consultants? ☐ Yes ☐ No

5.3 In your written contracts do you ever accept liability for consequential loss or financial damages? ☐ Yes ☐ No

If 'yes', please provide details:

5.4 Do your written contracts ever contain 'Hold Harmless' or 'Indemnification' clauses in which you accept liability for loss of life, injury, property damage, or financial losses in circumstances other than where they are caused by your negligence? ☐ Yes ☐ No

If 'yes', please explain:

SECTION 6: COVER LIMITS & SUMS INSURED

6.1 Would you like cover for damage to your property? ☐ Yes ☐ No

If 'no', please go to question 6.7.

*If 'yes', **please attach information** regarding the value of the following property, including estimated maximum values at risk at any one time where applicable, at the premises listed in question 2.1 and 2.2:*
a) Buildings
b) Tenants improvements, fixtures & fittings
c) Machinery and laboratory equipment
d) Fixed electronic equipment
e) Portable electronic equipment
f) Own stock
g) Third party stock in your custody and control
h) Any other property not listed above

6.2 Would you like the policy to cover any of the following:

a) Spoilage of perishable stock? ☐ Yes ☐ No

b) Pollution or contamination? ☐ Yes ☐ No

c) Machinery breakdown? ☐ Yes ☐ No

d) Property in transit? ☐ Yes ☐ No

e) Terrorism? ☐ Yes ☐ No

f) Ideologically motivated attack (that is not delared an act of terrorism by the goverment)? ☐ Yes ☐ No

6.3 Would you like Business Interruption cover? ☐ Yes ☐ No

If 'yes', please state the 'First Loss' sum insured required:

6.4 Please state the sublimits required for Business Interruption following damage at the premises of your supply chain partners listed in question 2.2:

Supply Chain Partner Name	Business Interruption Sublimit

6.5 Please state the Indemnity Period required (6 - 24 months): Months

6.6 Would you like cover for Employers' Liability? ☐ Yes ☐ No

6.7 Would you like cover for Public Liability? ☐ Yes ☐ No

If 'yes', please state the Limit of Liability required:

6.8 Would you like cover for Products and Services Liability? ☐ Yes ☐ No

If 'yes', please state the Limit of Liability required:

6.9 Would you like cover for Professional Indemnity? ☐ Yes ☐ No

6.10 Would you like cover for Clinical Trials? ☐ Yes ☐ No

If yes, please complete our Clinical Trials proposal form.

6.11 Would you like cover for D&O? ☐ Yes ☐ No

If yes, please complete our D&O proposal form.

SECTION 7: CLAIMS EXPERIENCE & INSURANCE HISTORY

7.1 Please provide details of your current insurance

Type	Expiry date	Retroactive date	Insurer
Property & Business Interruption:	DD / MM / YY	N/A	
Employers' & Public Liability:	DD / MM / YY	N/A	
Products Liability:	DD / MM / YY	DD / MM / YY	
Professional Liability:	DD / MM / YY	DD / MM / YY	
Clinical Trials:	DD / MM / YY	DD / MM / YY	
Directors & Officers Liability:	DD / MM / YY	DD / MM / YY	

7.2 Regarding all of the types of insurance to which this proposal form relates, AFTER ENQUIRY:

a) are you aware of any loss or damage, whether insured or not, that has occurred to any of the Companies to be insured (or to any existing or previous business of the partners or directors of any of the Companies to be insured) within the last 5 years, or

b) are you aware of any circumstances which may give rise to a claim against any of the Companies to be insured or any partners or directors thereof, or

c) have any claims or cease and desist orders been made against any of the Companies to be insured, or partners or directors thereof, or

d) have any partners or directors of the Companies to be insured been found guilty of any criminal, dishonest or fraudulent activity or been investigated by any regulatory body?

With reference to questions a, b, c and d above: ☐ Yes ☐ No

If the answer to the above is 'yes', then please attach full details including an explanation of the background of events, the maximum amount involved / claimed, the status of the claim(s) or circumstance(s) and any reserve(s) or payment(s) made by you and / or by Insurers, and the dates of all developments and payments.

SECTION 8: DECLARATION

I declare that:

- after full enquiry the answers to the questions contained in this application form, and any other information supplied by me, are substantially true, accurate and correct;
- I will inform underwriters before cover incepts of any change to the information supplied by me; and
- I understand that if any of the information contained in this application form or provided elsewhere is substantially untrue, inaccurate or incorrect, or I have not disclosed any other information that is material, the Policy may be avoided without any return of premium, the terms and conditions may change, a higher premium may become payable or we may reduce the amount of any claim payment.

Signed:		Full name:	
Position held at insured:		Date:	DD./ MM / YY

SUBSIDIARY 1

Company name: ERN:

Address:

Postcode:

SUBSIDIARY 2

Company name: ERN:

Address:

Postcode:

SUBSIDIARY 3

Company name: ERN:

Address:

Postcode:

SUBSIDIARY 4

Company name: ERN:

Address:

Postcode:

If you have more than 4 subsidiaries please continue your response in the Additional Information section.

ADDITIONAL INFORMATION: