



Quote form

Medical device manufacturers

To be eligible for cover you must comply with the criteria in section C and the declaration in section D. If this isn't possible our biomedical and life sciences product may suit your needs.

PART A – CHOOSE YOUR COVER

	Step 1: Select your mandatory cover option				Step 2: Select optional cover	
	Standalone options		Package options			
	A	B	C	D	1	2
Public liability / products liability	£2,000,000	£5,000,000	£2,000,000	£5,000,000		
Professional liability			£1,000,000			
Employers' liability			£10,000,000			
Property and business interruption			Up to £50,000 combined sum insured and £100,000 flexible first loss business interruption			
Cyber and data risks					£100,000	
Directors' and officers' liability						£1,000,000
Premium	£300	£450	£750	£900	£60	£200
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Premiums exclude IPT which should be added at the prevailing rate. Cover will be underwritten by Markel (UK) Limited on behalf of Markel International Insurance Company Limited.

PART B – PROPOSER INFORMATION

Name	<input type="text"/>
Address of registered or principal office	<input type="text"/>
Postcode	<input type="text"/>
Telephone number	<input type="text"/>
Email address	<input type="text"/>
Website address	<input type="text"/>
Are you Employment Reference Number (ERN) exempt? If not please provide your ERN:	YES <input type="checkbox"/> NO <input type="checkbox"/>

PART C – ELIGIBILITY

We can only provide cover under this offering if you are able to comply with the criteria below. If this isn't possible our **biomedical and life sciences** product may suit your needs.

Mandatory cover: Public and products liability (standalone and package options)

Cover is available for UK businesses undertaking the manufacture of an approved medical device classified under Directive 93/42/EEC or 98/79/EC, or manufacture of laboratory equipment, instruments or apparatus who can confirm the following:

- None of the products are or include:
 - Class 3 medical devices
 - Invasive surgical devices for long term use (30 days or more including concurrent periods)
 - Infusion systems or infusion pumps
 - Specifically designed for pregnant women or minors
 - Impotence products
 - Weight loss products
 - Latex gloves
 - Birth control or fertility products
 - Annex IIb or IIa in vitro diagnostic (IVD) product
 - Specifically designed for Human Immunodeficiency Virus (HIV)
 - Acquired Immunodeficiency Syndrome (AIDS)
 - Transmissible Spongiform Encephalopathies (TSEs) or viral hepatitis
 - Di-(2-ethylhexyl) Phthalate (DEHP)
 - Mercury
- You comply with the following regulatory and inspection requirements:
 - All products where required by European legislation carry a CE mark
 - All products are manufactured to ISO 13485
 - You have procedures in place to comply with the most recent Medical Device Vigilance System (MEDDEV) guidelines
 - No past or present products have been subject to a Field Safety Corrective Action (FSCA) or been subject to a voluntary or enforced recall due to risk to health
 - You have procedures in place to notify your customers and recall affected products
- You are unaware of any off-label use or misuse of your product
- You have 10 employees or fewer
- Your projected annual income for the forthcoming twelve months does not exceed £500,000 turnover
- Work is neither undertaken at height or with animals

Can you confirm that you comply with these criteria?

YES

Optional cover: Cyber & data risks (not available in isolation)

Cover is available for UK businesses who undertake the following on ALL computers:

- Utilise and maintain updated ant-virus, anti-spyware and firewall protections in accordance with the software providers recommendations
- Undertake a backup of data at least monthly
- All employees are automatically prompted to change their passwords at least every 90 days
- Do not operate any websites that process payment online

Can you confirm that you comply with these criteria?

YES

Optional cover: Directors and officers liability (not available in isolation)

Cover is available for UK businesses who can comply with the following:

- You have funding in place to continue your business for at least the forthcoming 12 months
- You are able to pay your debts as they fall due
- You are a UK registered private limited company with no traded shares

Can you confirm that you comply with these criteria?

YES

PART D - DECLARATION

By accepting this insurance you confirm that the facts stated below are, to the best of your knowledge and belief, true. Failure to do so may make the contract of insurance voidable, severely prejudice your rights or reduce the amount we pay you in the event of a claim.

This form together with any other information provided by you or on your behalf before inception of cover is incorporated in and forms the basis of the contract of insurance.

You are recommended to request a specimen copy of the proposed policy or certificate from your insurance broker and to consider carefully the terms, conditions, limitations and exclusions applicable to the cover. You are also recommended to retain a copy of this proposal for your records.

The proposed insurance covers only those losses which arise from certain events discovered or claims made against you during the period of insurance, as specified in the policy document.

RISK SPECIFICATION

Where property and business interruption are selected –

- (i) The buildings at the premises are in a good state of repair and are constructed of brick, stone or other non-combustible materials and roofer with slates, tiles, metal, concrete, asphalt, asbestos or other non-combustible materials
- (ii) The premises are not in an area troubled by flooding
- (iii) You have not sustained any loss, damage or claim
- (iv) The following minimum level of security must be in full and proper use at all times when the Premises are closed for business or left unattended and are maintained in proper working order throughout the currency of the insurance
 - (a) all external doors (and any internal doors leading to any part of the Buildings not in Your sole occupation) are secured with either
 - 1. if an aluminium door: a cylinder mortice deadlock to EN1303, or
 - 2. if an armoured plate door: the door manufacturer's locks as supplied, or
 - 3. if a UPVC door: a multi-point locking system incorporating a minimum of 3 deadbolts
 - 4. if any other type of single leaf door
 - a. where the door thickness is at least 4.5 cm: a five lever mortice deadlock to at least British Standard 3621 together with a 17.5 cm boxed steel striking plate
 - b. where the door is less than 4.5 cm thick: a deadlocking rim latch keyed into the deadlock position or a mortice deadlock and two key operated security bolts engaging with the door frame and with internal operation only
- (v) if double leaf doors
 - (a) the standing leaf secured with internal surface mounted key operated security bolts or concealed flush bolts sited top and bottom engaging with the door frame and the floor, and
 - (b) the final closing leaf secured with either a lock fitted as above dependent on door type or both leaves fitted with a coach-bolted locking bar secured with a close shackle padlock (or, if the locking bar is sited internally, either a close or open shackle padlock) having at least five levers
- (vi) if a designated fire door: either
 - (a) a panic bar locking system incorporating bolts which engage both the head and sill of the door frame, or
 - (b) a mortice lock having specific application for emergency exit doors and which is operated from the inside by means of a conventional handle and/or thumb turn mechanism.
- (vii) all external ground floor windows, accessible windows and/or skylights, originally designed to open are secured by
 - (a) key operated window locks, or
 - (b) adequately secured metal bars or grilles, external or internal metal shutters or internal collapsible metal security grill, or
 - (c) screwed shut.
- (viii) Neither You, nor any director, manager, partner or trustee of Yours, nor any person insured or proposing for insurance has been convicted, or charged but not yet tried, of any criminal offence other than a motoring offence

- (a) You have never had an application for this type of insurance declined by an insurer, had a renewal of such insurance declined, nor had similar insurance cancelled or made subject to special conditions.
- (b) No claims, prosecutions, proceedings or investigations (successful or otherwise) have been made or instigated against You and/or any person insured or proposing for insurance to which this proposal relates.
- (c) Neither You nor any person insured or proposing for insurance is aware, AFTER ENQUIRY, of any circumstance or incident which they have reason to suppose might afford grounds for any future claim such as would fall within the scope of the expiring insurance or the proposed insurance which has not already been advised to Underwriters.

I hereby declare that I am authorised to complete this proposal on behalf of the proposer and that to the best of my knowledge and belief, the statements and particulars in this proposal are true and complete and no material facts have been mis-stated or suppressed.

I undertake to inform underwriters of any material alteration or addition to these statements or particulars which occurs before any contract of insurance based on this proposal is effected and acknowledge that this proposal (together with any other information supplied to underwriters) shall be the basis of such contract.

***Signed**

Name:

***Capacity**

Date:

Please return to lifesciences@markelintl.com

We shall incept cover with effect from the date we receive the completed form. If cover is required from a specific date in the future, please let us know. Unfortunately we are unable to back date cover.

Markel (UK) Limited

Verity House, 6 Canal Wharf, Leeds LS11 5AS Tel: +44 (0)345 351 2600 Fax: +44 (0)345 351 2601
www.markelinternational.com/uk

Offices at Birmingham, Bristol, Leeds, London, Manchester and Reigate
Registered office: 20 Fenchurch Street, London, EC3M 3AZ Registered in England number 2430992

Markel (UK) Limited is an Appointed Representative of Markel International Insurance Company Limited who are authorised by the Prudential Regulation Authority and regulated by the Financial Conduct Authority and the Prudential Regulation Authority.