Life Science Combined

Proposal form

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Proposal form

Important notice

1. This is a proposal for a contract of insurance, in which ‘proposer’ or ‘you/your’ means the individual, company, partnership, trust, charity, establishment or association proposing for cover.
2. This proposal must be completed in ink, signed and dated. All questions must be answered to enable a quotation to be given but completion does not bind you or Underwriters to enter into any contract of insurance. If space is insufficient to answer any question fully, please attach a signed continuation sheet. You should retain a copy of the completed proposal (and of any other supporting information) for future reference.
3. 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. The proposed insurance covers only those losses which arise from certain events discovered or claims made against the Assured during the period of insurance, as specified in the policy or certificate.

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General information about you

Name of Proposer	
Address	
Postcode	
Website address	
Year established	

Employment Reference Number for each entity to be included in this agreement.

Entity	ERN
a.	
b.	
c.	

1. Business description

2. Income

(i) Please provide a split in your annual revenue between the following geographical areas:

	Prior 12 months	Current 12 months	Projected next 12 months
a. UK to UK	£	£	£
b. UK to USA	£	£	£
c. UK to elsewhere in the World	£	£	£

(ii) To help us understand your business, please provide a further split in your projected (next 12 months) by percentage of annual revenue, by type of activity and field of specialism.

	Medical devices / Medtech	Medicines	Cosmetics	Vitamins & food supplements	Assistive Healthcare	Other
Own R&D	%	%	%	%	%	%
Producer of own brand product	%	%	%	%	%	%
Distributor	%	%	%	%	%	%
Retailer	%	%	%	%	%	%
Contract Manufacturing Organisation (CMO)	%	%	%	%	%	%

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Contract Research Organisation	%	%	%	%	%	%
Product design services	%	%	%	%	%	%
Service engineer	%	%	%	%	%	%
Software engineer	%	%	%	%	%	%
Laboratory	%	%	%	%	%	%
Own R&D	%	%	%	%	%	%

If you have provided a projected income under the "other" column please provide details of what this activity is.

(iii) What are the three largest contracts you have commenced in the last 3 years.

	Contract value
a.	£
b.	£
c.	£

(iv) Approximately how many contracts will you have in force during the next 12 months.

General information about you

3. Have you been trading continuously for the past 5 years? ☐ Yes ☐ No

If No provide details below.

4. Have you ever been subject to an enforcement notice, warning letter or other punitive action by a relevant regulatory body? ☐ Yes ☐ No

If Yes provide details below.

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5. **In the last 5 years has any customer of yours withdrawn your product, or a product that you have contributed to, from sale due to a safety or performance issue?** ☐ Yes ☐ No

If Yes provide details below.

6. **In the last 5 years has any customer yours:**

a. Disputed fees or charges with you ☐ Yes ☐ No

b. Terminated a contract early ☐ Yes ☐ No

c. Suggested that you are in breach of their contract with them ☐ Yes ☐ No

If Yes provide details below.

7. **Do you use an appropriately qualified lawyer to ensure that any product or service that they offer outside the UK is compliant with local laws and they have the necessary permissions and/or licenses to sell in that territory?** ☐ Yes ☐ No

If No provide details below.

8. **Are you aware of any circumstance where:**

a. Your service is not lawfully allowed to be sold or performed in any of your chosen markets ☐ Yes ☐ No

b. There is any connection between you and/or your business, your product or service and a country or person subject to trade sanctions or embargoes asserted by the United Kingdom (UK), European Union (EU), United Nations (UN) or United States of America (USA) ☐ Yes ☐ No

c. Your back office systems have not prevented or will not prevent sales to these territories? ☐ Yes ☐ No

If Yes provide details below.

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Public Liability

9. Do you require public liability insurance; ☐ Yes ☐ No

If Yes.

a. Do any of your activities include:

a) patient handling ☐ Yes ☐ No

b) working with animals ☐ Yes ☐ No

c) work with Hazard Group 3 or Hazard Group 4 biological agents (COSHH)? ☐ Yes ☐ No

If Yes provide details below.

b. Is your business subject to the Dangerous Substances (Notification and Marking of Sites) Regulations 1990 (NAMOS)? ☐ Yes ☐ No

c. Do any of your activities include working away from your premises? ☐ Yes ☐ No

If Yes.

a) When working away from your premises, do you

– Use heat ☐ Yes ☐ No

– Make alterations to buildings or access points or undertake ground works ☐ Yes ☐ No

– Undertake plumbing or electrical work ☐ Yes ☐ No

If Yes provide details below.

Where required please provide additional information here.

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Products Liability

10. Do you require products liability insurance? ☐ Yes ☐ No

If Yes.

a. Have you ever manufactured, sold or supplied any products which are subject or have ever been, to an unexpected or unintended serious side effect, adverse drug reaction, medical device adverse incident, or serious undesirable effect? ☐ Yes ☐ No

If Yes provide details below.

If Yes.

b. Do you ever subcontract the design, manufacture, assembly, packaging or installation of their product to a third party organisation? ☐ Yes ☐ No

If Yes.

a) Do you maintain full rights of recourse against them via a written contract ☐ Yes ☐ No

c. Are any of your past, present or planned future products

a) specifically designed for minors ☐ Yes ☐ No

b) specifically designed for pregnant people ☐ Yes ☐ No

If Yes provide details below.

d. Do you import any product from outside the United Kingdom ☐ Yes ☐ No

If Yes.

a) Are you indemnified by written contract with your supplier for damages incurred by you arising from a defective product? ☐ Yes ☐ No

e. Do you require your customer to be referred to a prescribing professional in order to purchase a product directly from you? ☐ Yes ☐ No

If Yes provide details below.

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f. Do you have any past, present or planned future products classified as or include:

a) E-cigarettes ☐ Yes ☐ No

b) Smoking cessation devices ☐ Yes ☐ No

g. Do you have any past, present or planned future products classified as or include:

a) Products containing perfluoroalkyl and/or polyfluoroalkyl substances (PFAS) ☐ Yes ☐ No

If Yes provide details below.

h. Do you import any products from outside the UK? ☐ Yes ☐ No

If Yes.

a) Are you indemnified under contract by your supplier for liability for damages arising from a defect in the product you sourced from them? ☐ Yes ☐ No

Medical Devices

i. Are any of your past, present or planned future products classified as a medical device? ☐ Yes ☐ No

If Yes.

a) Can you agree to the statement in Appendix 1.1 “Medical Devices ☐ Yes ☐ No

If No provide details below.

b) Have you ever sold a medical device that is not approved for use (other than in clinical trials)? ☐ Yes ☐ No

If Yes provide details below.

c) Have you ever sold, or plan to sell, a medical device that is able to connect to the internet? ☐ Yes ☐ No

If Yes.

– Can you agree to the statement in Appendix 1.2 “Medical Devices - IOT” ☐ Yes ☐ No

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If No provide details below.

Medicines

j. Are any of your past, present or planned future products classified as a medicine? ☐ Yes ☐ No

If Yes.

a) Can you agree to the statements in Appendix 1.3 “Medicines” ☐ Yes ☐ No

If No provide details below.

b) Have you ever sold, or plan to sell a medicine subject to the ‘black triangle scheme’ or local equivalent ☐ Yes ☐ No

If Yes provide details below.

Cosmetics and cosmetic devices

k. Are any of your past, present or planned future products classified as a cosmetic or cosmetic device? ☐ Yes ☐ No

If Yes.

a) Can you agree to the statements in Appendix 1.4 “Cosmetics” ☐ Yes ☐ No

If No provide details below.

Vitamins and Food Supplements

l. Are any of your past, present or planned future products classified as a vitamin or food supplement? ☐ Yes ☐ No

If Yes.

a) Can you agree to the statements in Appendix 1.5 “Vitamins and food supplements” ☐ Yes ☐ No

If No provide details below.

b) Have you ever sold, or plan to sell Cannabidiol (CBD)? ☐ Yes ☐ No

If Yes.

– Can you agree to the statements in Appendix 1.6 “Cannabidiol” ☐ Yes ☐ No

If No provide details below.

Contract Manufacturing Organisation

m. Do your activities include being a Contract Manufacturing Organisation (CMO)? ☐ Yes ☐ No

If Yes.

a) deviate from specifications provided by your customer including, but not limited to, the use of approved raw materials, ingredients, parts and methods? ☐ Yes ☐ No

If Yes provide details below.

Professional liability and products liability (financial loss)

11. Do you require professional liability and products liability (financial loss) insurance? ☐ Yes ☐ No

a. Do you ensure all contracts and/or terms and conditions agreed with your customers, vendors, partner companies and suppliers employ the following clauses? ☐ Yes ☐ No

1. A force majeure clause
2. A consequential loss exclusion
3. A reasonable limitation of your liability
4. A detailed description of the obligations of each party
5. A description of the standard of care that the Proposer will provide
6. A termination clause
7. A dispute resolution / mediation procedure
8. A clause making the contract subject to the exclusive jurisdiction of English and Welsh or Scottish courts?

If No provide details below.

b. Are all your contracts reviewed by a lawyer who is qualified to review such contracts and/or terms and conditions? ☐ Yes ☐ No

If No provide details below.

c. Would you ever accept changes to contracts which are not documented and signed off by all parties? ☐ Yes ☐ No

If Yes provide details below.

d. Do you act as a UK Responsible Person (UKRP) for a non UK-based entity? ☐ Yes ☐ No

If Yes provide details below.

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e. Do you employ or enter into a contract for service with any doctor, surgeon or physician, midwife, prescribing nurse, dentist or anaesthetist ☐ Yes ☐ No

If Yes.

1. Are they a current member of their recognised UK governing professional body or association; and ☐ Yes ☐ No
2. They have in place their own insurance or arrangements of a similar kind to insure against their professional errors, omissions, negligence or malpractice ☐ Yes ☐ No

If No provide details below.

Intellectual property rights

12. Do you require insurance for intellectual property rights cover ☐ Yes ☐ No

If Yes.

a. You understand that there is no cover under this insurance policy for infringement of patent rights. ☐ Yes ☐ No

b. Do you have documented procedures to ensure that you:

i. Are not infringing third parties' intellectual property rights ☐ Yes ☐ No

If No provide details below.

ii. Have renewed your own intellectual property rights where required ☐ Yes ☐ No

If No provide details below.

Clinical trials

13. Do you require clinical trials insurance? ☐ Yes ☐ No

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If Yes.

a. Details of the clinical trials that you sponsor.

Trial reference	Trial description	Period	Number of research subjects	Location

b. Are any of the research subjects of a clinical trial sponsored by you:

a) Under 18 years old ☐ Yes ☐ No

b) Pregnant or females not actively using birth control ☐ Yes ☐ No

c) Employees of yours or any associated company ☐ Yes ☐ No

d) Prisoners ☐ Yes ☐ No

e) Unable to give their consent ☐ Yes ☐ No

If Yes provide details below.

Employer's Liability

14. Do you require employer's liability insurance? ☐ Yes ☐ No

If Yes.

a. Are all your employees domiciled in and work in England, Scotland or Wales ☐ Yes ☐ No

If No provide details below.

b. Do any of your activities include working: ☐ Yes ☐ No

i. At heights where the distance to the ground is greater than 3m

ii. With animals

iii. Directly with patients or research subjects

iv. Offshore

If Yes provide details below.

c. Do you have a health and safety policy which: ☐ Yes ☐ No

i. Is reviewed annually and updated when required

ii. Identifies people in the business responsible for health and safety in the workplace

iii. Details how the policy will be implemented including risk assessments, warning signs and issurance and use of protective equipment

If No provide details below.

d. Are you subject to any of the following regulations? ☐ Yes ☐ No

i. Provision and Use of Work Equipment Regulations, 1998 (PUWER)

ii. Control of Substances Hazardous to Health Regulations, 2002 (COSHH)

iii. UK Registration, Evaluation, Authorisation & restriction of Chemicals (REACH)

If Yes.

1. Have you ever been advised that you have been non-compliant or in breach of the legislations you are subject to? ☐ Yes ☐ No

If Yes provide details below.

Property damage

15. Do you require property damage insurance? ☐ Yes ☐ No

If Yes.

a) Are the buildings used by you for your business

i) in a good state of repair? ☐ Yes ☐ No

ii) constructed of non-combustible materials such as brick, stone or other non-combustible materials and roofed with slates, tiles, metal, concrete, asphalt, asbestos or other non-combustible materials? ☐ Yes ☐ No

If No provide details below.

iii) listed? ☐ Yes ☐ No

If Yes provide details below.

iv) adjoining or within 10 meters of a neighbouring premises? ☐ Yes ☐ No

If Yes please provide details of the activities undertaken in these neighbouring premises below.

v) fitted with solar panels? ☐ Yes ☐ No

b) Do any of the buildings used by You for your business

i) have composite insulated panels on the exterior façade or used in the internal structure of the building? ☐ Yes ☐ No

If Yes.

1. Do the composite insulated panels have a mineral wool core or are they LPCB approved, achieving LPS 1181: Part 1 EXT A30 for external envelopes and LPS 1181: Part 2 INT-2 for internal areas? ☐ Yes ☐ No

If No provide details below.

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ii) include, or do you have a suspicion that they may include, reinforced autoclaved aerated concrete (RAAC)? ☐ Yes ☐ No

If Yes provide details below.

iiii) have a flat roof? ☐ Yes ☐ No

If Yes.

a. The flat roof is less than 10 years old

b. The flat roof has been inspected at least twice a year or after severe weather events?

iv) have business critical property stored in a basement? ☐ Yes ☐ No

If Yes provide details below.

c) Do your activities at any of your premises include ☐ Yes ☐ No

i) Unattended heat processes

ii) Unattended overnight processes

iii) High pile storage (greater the 3m from floor)

iv) Storage which exceeds 12,000sqft (1,115m2) of floor area

v) Work with property which is very sensitive to changes in its environment or contamination, including but not limited to temperature or humidity

vi) Data storage

vii) Work with combustible metals or filling of aerosols

viii) Storage of branded pharmaceuticals, computer hardware, electronic components, nonferrous metals, controlled drugs, branded cosmetics or radioactive materials

ix) Work with animals

If Yes provide details below.

x) Volatile chemicals/combustible materials ☐ Yes ☐ No

If Yes.

1. Were they stored in accordance with The Dangerous Substances and Explosive Atmospheres Regulations 2002 (DSEAR) ☐ Yes ☐ No

d) Can you confirm that your premises are fitted with an intruder alarm, which ☐ Yes ☐ No

i) is Grade 3 or higher (EN0131)

ii) was installed by a NSI Gold accredited company

iii) has level 1 police response

If No provide details below.

e) Can you confirm that ☐ Yes ☐ No

ii) your premises are fitted with the protections shown in appendix 1.7 “security protections” and

ii) they are in full and proper use at all times when the premises are closed for business or left unattended and

iii) they are maintained in proper working order

If No provide details below.

f) Can you confirm that your premises are protected by a category P1, P2, L3, L2 or L1 fire alarm systems (BS 5839-1) which is signal to a central monitoring station. ☐ Yes ☐ No

If No provide details below.

g) Do your premises benefit from any additional protection e.g. ram protection, gated compounds, manned guarding, monitored CCTV, sprinklers, gaseous suppression systems, VESDA? ☐ Yes ☐ No

If Yes, please provide details below.

h) Do your premises have a valid electrical safety certificate (EICR) and all installations are considered to be of a satisfactory standard? ☐ Yes ☐ No

i) Are there any other features of the premises you use for your business that would be considered relevant to underwriters? ☐ Yes ☐ No

If Yes, please provide details below.

Business Interruption

16. Do you require business interruption insurance? ☐ Yes ☐ No

If Yes.

a. In the event of damage at your premises, would it take more than 90 days to source alternative premises and property (including stock, raw materials, research property, specialist tools/machinery and clean rooms etc.) needed for the business to continue trading? ☐ Yes ☐ No

b. Do you have a business continuity plan? ☐ Yes ☐ No

c. If Yes.

   i. Is the business continuity plan;

      1. documented and backed up off site.
      2. communicated to relevant employees
      3. included in employee training
      4. regularly tested and updated

   ii. and does the continuity plan include?

      1. key people to oversee disaster planning and response
      2. a business impact analysis
      3. risk mitigation strategies
      4. business continuity strategies

☐ Yes ☐ No

d. Do you require cover for business interruption caused by a loss at one of your suppliers premises? ☐ Yes ☐ No

If No, please provide details of what you would do to continue your business following damage at your premises?.

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e. If Yes.

Please provide their name and address and the amount of cover you require.

Name	Address	Sum Insured

i. Are the following statements correct in respect of the Your supply chain dependencies:

1. Your suppliers have business continuity plans to minimise the interruption to the Your business
2. You have identified alternative suppliers that are able to continue providing business critical items
3. You maintain a minimum of three months buffer stock

☐ Yes ☐ No

17. Do you require damage to portable property insurance? ☐ Yes ☐ No

18. Do you require transit insurance? ☐ Yes ☐ No

19. Do you require money and personal assault insurance? ☐ Yes ☐ No

Cyber Liability

20. Do you require Cyber liability insurance? ☐ Yes ☐ No

If Yes.

a. Do you collect, store or process more than 10,000 sensitive data records? ☐ Yes ☐ No

i) Please provide the number of records you collect, store or process

(1) Personal data records

(2) Health records

(3) Financial records

b. Any activities or have any involvement in data storage, data processing or data security ☐ Yes ☐ No

c. Do you undertake the following network security:

i) use and update anti-virus and firewall protections in accordance with suppliers recommendations ☐ Yes ☐ No

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ii) perform software security updates as they are released by vendors and deploy critical patches within 7 days of their release ☐ Yes ☐ No

iii) undertake a backup of data at least weekly ☐ Yes ☐ No

iv) store back-ups offline ☐ Yes ☐ No

v) encrypt back-ups ☐ Yes ☐ No

vi) test the ability to recover back-ups at least once throughout the year and immediately rectify any issues which are found. ☐ Yes ☐ No

vii) use multi factor authentication (MFA) for remote access to the your network, email accounts, administrator access and cloud based services. ☐ Yes ☐ No

d. Do you provide cyber security awareness training to your your employees at least annually ☐ Yes ☐ No

e. Do you operate any websites that include E-commerce, process payments or collects confidential/ sensitive data? ☐ Yes ☐ No

If Yes.

xvii) What percentage of turnover is generated from online/internet sales? ☐ %

xviii) Are all payments made via the website processed through an independent third party site that is PCI-DSS (Payment Card Industry Data Security Standard) compliant, with no payment details being captured or recorded by you before transferring to the third party site? ☐ Yes ☐ No

f. Do you require contingent business interruption cover? ☐ Yes ☐ No

If Yes.

i) Are your IT network managed by an external provider who is contractually responsible for the ongoing management of IT and data security? ☐ Yes ☐ No

ii) Do you use any hosted software (including website applications) which would cause them to lose revenue if the system were unavailable for 24 hours? ☐ Yes ☐ No

iii) Do all external service providers contractually provide indemnity in respect of their errors & negligence? ☐ Yes ☐ No

g. Do you require cover for social engineering losses? ☐ Yes ☐ No

If Yes.

i) Do you have a process in place to verify any changes or additions of bank account details for all accounts payments with a known client contact, prior to actioning? ☐ Yes ☐ No

ii) Are at least two people required for appointing new suppliers or awarding contracts? ☐ Yes ☐ No

h. In the last three years has the proposer suffered a loss under a cyber policy or experienced any cyber or privacy incidents? ☐ Yes ☐ No

If Yes.

i) For each claim or incident please provide details including the financial loss and cause of loss. ☐ Yes ☐ No

Directors and officers liability

21. Do you require directors and officers liability insurance? ☐ Yes ☐ No

If Yes.

a. Can you confirm that

1) You have funding in place to continue your business for at least the forthcoming 12 months?

2) You have not had a pre-tax loss or negative net worth (share capital plus reserves) in any of its last two complete financial years nor is a pre-tax loss or negative net worth anticipated in its current financial year

3) You are solvent and able to pay your debts as they fall due?

4) the company which is the subject of this insurance is registered in England and Wales, Scotland or Northern Ireland?

☐ Yes ☐ No

If No provide details below.

b. Are at least 80% of the company's shares owned by the Directors of the company or members of their families? ☐ Yes ☐ No

If No.

(1) Are all of the shares owned by the Company's parent or ultimate holding company? ☐ Yes ☐ No

If Yes.

(1) What is the name of the ultimate holding company

(2) What is the country of registration in respect of ultimate holding company

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If No.

(1) Please provide details of all shareholders holding in excess of 20% of the shares including: Name of shareholder; percentage of shares held; relationship to the company (e.g. investor, parent company, former director, employee, family trust etc.)

Fidelity Guarantee

22. Do you require fidelity insurance? ☐ Yes ☐ No

If Yes.

a) Do your employees handle money? ☐ Yes ☐ No

i) How many employees handle money

b) Do you engage in any of the following activities: ☐ Yes ☐ No

i) trading securities, commodities, currencies and the like

ii) make loans or extend credit

iii) transport or store valuables for others

iv) leasing

If Yes please provide full details below.

c) Does

i) the amount above which all cheques and other bank instruments require two hand-written signatures does exceed £25,000 ☐ Yes ☐ No

ii) You use pre-signed cheques ☐ Yes ☐ No

iii) the maximum value of stock at any one location can exceed £250,000 ☐ Yes ☐ No

iv) the annual amount of funds transfer instructions given to banks or other financial institutions exceed £1,000,000 ☐ Yes ☐ No

If Yes please provide full details below.

d) Do you

i) ensure that physical stock and inventory checks are carried out at least annually by persons other than those responsible for such stock ☐ Yes ☐ No

ii) operate and maintain a system of controlled access to computer systems which utilise individual user IDs and passwords, the latter being changed at least every 60 days ☐ Yes ☐ No

iii) obtain written references for all persons applying for employment where they have the responsibility for money, stock or computer operations ☐ Yes ☐ No

iv) ensure that professional external auditors audit their accounts at least once a year and that all recommendations are acted upon? ☐ Yes ☐ No

If No provide details below.

Entity

23. Do you require Entity insurance? ☐ Yes ☐ No

Legal Expenses Insurance

24. Do you require Legal expenses insurance? ☐ Yes ☐ No

Declaration

25. Has any director, manager, partner or trustee of yours or any person insured or proposing for insurance.

a) been convicted, or charged but not yet tried, of any criminal offence other than a motoring offence? ☐ Yes ☐ No

b) been declared bankrupt, gone into insolvent liquidation or been the subject of receivership or an administration order? ☐ Yes ☐ No

26. Have you ever had an application for this type of insurance declined by an insurer, had a renewal of such insurance declined or had similar insurance cancelled or made subject to special conditions? ☐ Yes ☐ No

27. Within the last five years have you or any person insured or proposing for insurance to which this proposal relates.

a) had any claim, prosecution, proceedings or investigations made or instigated against them whether successful or otherwise? ☐ Yes ☐ No

b) suffered any loss or made any claim (whether insured or not) which would have fallen within the scope of the proposed insurance irrespective of whether or not such loss or claim relates to the property insured or proposed for insurance? ☐ Yes ☐ No

28. Are you or any person insured or proposing for insurance aware, AFTER ENQUIRY, of any CIRCUMSTANCE OR INCIDENT which they have reason to suppose might afford grounds for any future claim that would fall within the scope of the proposed insurance which has not already been advised to us? ☐ Yes ☐ No

If Yes provide details below.

Data protection

Markel are committed to protecting your privacy. Insurance involves the use and disclosure of your personal data to various insurance participants such as intermediaries, insurers and reinsurers. If you would like to know how Markel deals with any personal data you have provided us, please contact your Agent or Broker who will provide you with our contact details. Alternatively, please visit our privacy page at: https://www.markel.com/privacy-policy

Important information concerning your duty to make a fair presentation of risk

Please carefully read the following before you sign and date the declaration.

Before the insurance policy takes effect you have a duty to make a fair presentation of the risks to be insured.

A fair presentation of the risk is one
- which discloses to us every material circumstance which you know of or ought to know of, or
- gives us sufficient information to put us on notice that we will need to make further enquiries for the purpose of revealing those material circumstances, and
- which makes that disclosure in a manner which is reasonably clear and accessible to us, and
- in which every material representation as to a matter of fact is substantially correct and every material representation as to a matter of expectation or belief is made in good faith.

A material circumstance is one that would influence our decision as to whether or not to agree to insure you and, if so, the terms of that insurance. If you are in any doubt as to whether a circumstance is material you should disclose it to us.

Failure to make a fair presentation of risk could prejudice, reduce or modify your rights under the policy.

29. I declare that

- I am authorised to complete this proposal on behalf of the Proposer
- every statement and particular within this proposal form
  - which is a statement of fact, is substantially correct, and
  - which is a matter of expectation or belief, is made in good faith

If any such facts, expectations and/or beliefs materially change before the insurance policy takes effect I will undertake to provide details of all such changes to you in order to comply with my obligation to provide a fair presentation of the risk to be insured under the insurance policy.

*Signed:	Name:
*Capacity:	Date:

*the signatory should be a director or senior officer of, or partner in, the Proposer.

Appendix 1

1.1 "Medical devices"

You have no past, present or planned future products classified as, or include, or are specifically design for use with;
- 3d printed personalised medical devices
- silicone liquid or gel used in a implanted product
- di-2-ethylhexyl phthalate (DEHP) that are designed to carry liquids to or from a patient
- Birth control or fertility products
- Class IIa or IIb device (not left in the body for more than 30 days)
- Class IIa or IIb device (left in the body for more than 30 days)
- Class III medical device
- Human or animal biological material
- In vitro diagnostic products classified as annex II
- Infusion pumps
- Livestock, laboratory animals, working animals or sport animals
- Anaesthesia
- Metal on metal implants
- Permanent contraception devices (i.e. occlusion technologies)
- Silicone breast implants
- Surgical mesh

1.2 "Medical devices - IOT"

Where your medical device is able to connect to the internet the following precautions are enabled
- The product is provided with a unique access password
- The firewall (where included) is automatically enabled or will warn the user that it is not enabled
- The software (including antivirus/anti malware, apps and operating systems) is:
    - Up to date, or is updated to the most recent version when used for the
    - first time; or
    - Securely updateable, or updated on a timely basis; or
    - When being up-dated there is no impact to the functioning of the device;
- The minimum time the device will receive updates is explicitly stated to the end user
- Any credentials and security sensitive data are stored securely within servers or on devices
- Security sensitive data is encrypted to transit a computer network
- The product operates on the "principle of least privilege"
- The product incorporates a mechanism for secure booting

1.3 "Medicines"

You have no past, present or planned future products classified as, or include, or are specifically design for use with;
- Blood Products
- Herbal or homeopathic remedies
- HIV, AIDS, TSEs, and Viral Hepatitis
- Human or animal biological material
- Livestock, laboratory animals, working animals or sport animals
- Opiates or opioids to customers in the USA or Canada
- Pharmacy 'P' medicines
- Prescription Only 'POM' medicines"
- Prophylactic Vaccines
- Ranitidine

– Regenerative medicine
– Thalidomide
– Traditional Chinese/Herbal Medicines not granted a Traditional Herbal Registration (THR)
– Weight loss

1.4 "Cosmetics"

You have no past, present or planned future products classified as, or include, or are specifically design for use with;
– Carcinogenic, Mutagenic or Reprotoxic (CMR) under regulation (EC) No 1272/2008
– Hair dyes containing p-Phenylenediamine (PPD)
– Laser systems, intense pulsed light (IPL) equipment and light emitting diode (LED) devices"
– Nail products containing dibutyl phthalate (DBP), Toluene or Formaldehyde
– Prohibited substances as defined by Annex II of Regulation 1223/2009
– Skin penetrating rejuvenation devices
– Sunscreen containing retinyl palmitate or oxybenzone
– Tattooing equipment and accessories / tattoo ink / black or natural henna"

1.5 "Vitamins and food supplements"

You have no past, present or planned future products classified as, or include, or are specifically design for use with;
– Has the Proposer ever sold sports nutrition supplements
– Animal feed/animal feed supplements
– Food other than food supplements, food for specific medical purposes or total diet replacement for weight control.
– Meal replacement for weight control (as opposed to total diet replacement for weight control) e.g. weight loss shakes, low fat foods, "healthy" options"
– Has the Proposer ever sold steroids or steroid-like substances used in body building or sport?

1.6 "Cannabidiol"

You confirm that:

a. You are not exporting Cannabidiol (CBD) containing products to the USA.

b. You do not supply Vapes or e-cigarette liquids or products

c. All CBD ingredients

   i) Are certified as THC free by a third party lab

   ii) Are sourced from EEA or North America

d. Where CBD products are ingested by a person

   i) They are registered as a novel food and;

   ii) The packaging contains warnings that the product

   – Should not to be used by pregnant women or children

   – May have possible interactions with prescription medicines and that the user should consult a doctor before use

   – Does not have the properties for preventing, treating or curing a human disease.

1.7 "Security Protections"

a. All external doors (and any internal doors leading to any part of the **buildings** not in **your** sole occupation) to be secured with either

i. if an aluminium door: a cylinder operated mortice deadlock, or

ii. if an armoured plate door: the door manufacturer's locks as supplied, or

iii. If a UPVC door: a cylinder operated mortice deadlock with a multi-point locking system incorporating a minimum of 3 deadbolts

iv. if any other type of single leaf door

- a five lever mortice deadlock to at least British Standard 3621 together with a boxed steel striking plate, or
- a deadlocking rim latch to at least British Standard 3621 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:

- 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
- 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 single or double leaf and also outward opening: hinge bolts fitted top and bottom

vii. if a designated fire door: either

- an emergency release lock complying with BS8621:2004, or
- a proprietary emergency release system.

2. All external ground floor and accessible windows and/or skylights

i) re secured with key operated window locks with the keys removed when in operation or

ii) screwed shut with heads countersunk and plugged, or

iii) secured with metal bars or grilles, external or internal metal shutters or internal collapsible metal security grilles

3. Roller shutter doors to be secured with a cylinder profile lock welded to the shutter channel on each side one metre from ground level.

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