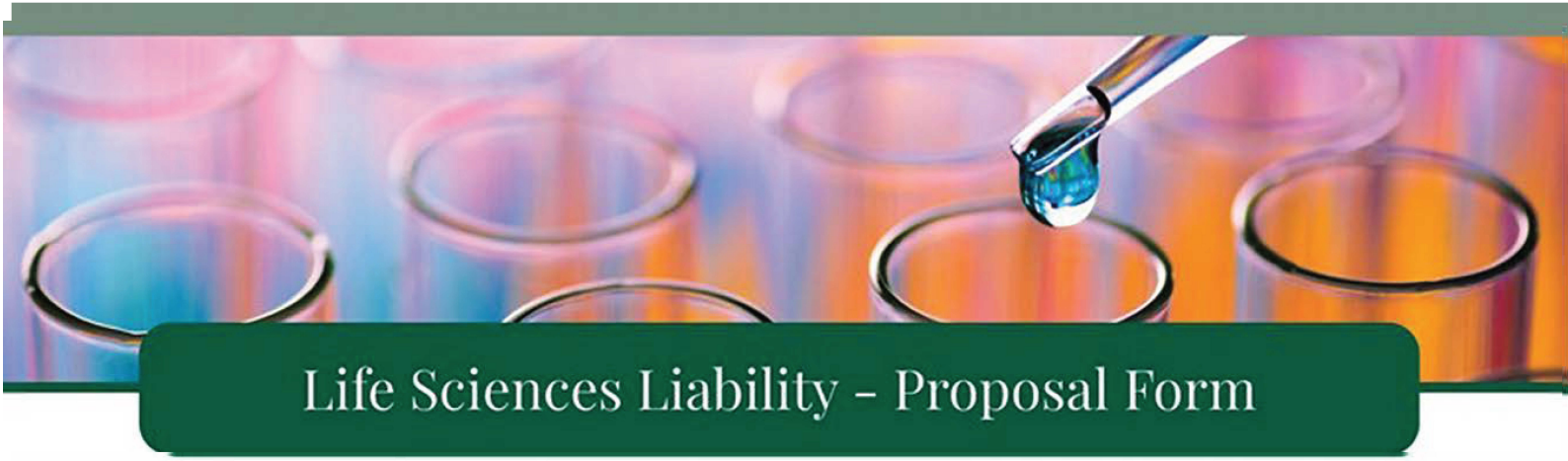

Life Sciences Liability - Proposal Form

Your Award Winning Insurer

IMPORTANT INFORMATION: PLEASE READ THE FOLLOWING INFORMATION BEFORE COMPLETING THIS PROPOSAL

Completing this Proposal Form

- Any references throughout this Proposal Form to "you", "your" or "insured" are to be read as references to "the proposer". Any reference to "we", "us", "our" or "BIA" are to be read as reference to "Berkley Insurance Company (limited company incorporated in Delaware, USA) ABN 53 126 559 706 | AFSL 463129 t/as Berkley Insurance Australia".
- Please answer all questions giving full and complete answers. If a question in the Proposal Form does not apply to the proposer, this should be marked as "Not Applicable" or "N/A".
- If the space provided on the Proposal Form is insufficient, please use a separate signed dated sheet in order to provide a complete answer to any question.
- It is the duty of the proposer to provide all information that is requested in this Proposal Form as well as to disclose relevant facts. A relevant fact is a known fact or circumstances that may influence the evaluation of risk by the the insurer. If you are uncertain about what a relevant fact is, please contact your broker.

A. Your Duty of Disclosure

Before you enter into an insurance contract, you have a duty to tell us anything that you know, or could reasonably be expected to know, may affect our decision to insure you and on what terms.

You have this duty until we agree to insure you.

You have the same duty before you renew, extend, vary or reinstate an insurance contract.

You do not need to tell us anything that:

- reduces the risk we insure you for; or
- is common knowledge; or
- we know or should know as an insurer; or
- we waive your duty to tell us about.

If you do not tell us something

If you do not tell us anything you are required to, we may cancel your contract or reduce the amount we will pay you if you make a claim, or both.

If your failure to tell us is fraudulent, we may refuse to pay a claim and treat the contract as if it never existed.

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B. Claims Made and Notified Policy

Sections 1.1 Products-Completed Operations Liability, 1.5 Clinical Trial Coverage, 1.8 Professional Indemnity, 1.9 Biological Agents Liability and 1.10 Data Breach Expense Coverage of this policy are issued on a 'claims made and notified' basis. This means that they respond to:

a) claims first made against the insured during the policy period and notified to us during the policy period, provided that the insured was not aware at any time before policy inception of facts, matters or circumstances which would have put a reasonable person in the insured's position on notice that a claim may be made against the insured; and

b) written notification of facts pursuant to section 40(3) of the Insurance Contracts Act 1984. If the insured chooses to tell us in writing about facts which might give rise to a claim against the insured as soon as reasonably practicable after the insured becomes aware of these facts but before insurance cover provided by the policy expires, then we are not relieved of liability under the policy for the claim, when made, by reason only that it was made after the expiration of the period of insurance cover provided by the policy .

After the policy expires, no new notification of facts may be made on the expired policy even though the event giving rise to the claim against the insured may have occurred during the policy period. An exception to this is where an extended reporting period applies to the policy. If an extended reporting period applies, then cover may be available for notifications of facts or claims made up to expiry of the extended reporting period.

When completing the proposal the insured is required to provide full details of all facts, matters and circumstances of which they are aware and which a reasonable person in the insured's position would consider may give rise to a claim. It is important that the insured make proper disclosure. Refer to the Duty of Disclosure above to understand the insured's disclosure obligations.

C. Retroactive Date

Where cover is provided on a claims made and notified basis, this policy does not provide cover for claims arising from or in connection with an act, error, omission or event occurring or alleged to have occurred before the policy's retroactive date, where such a date is specified in the schedule.

D. Subrogation Agreements

Where another person would be liable to compensate you for any loss or damage otherwise covered by the insurance, but you have agreed with that person either before or after the loss or damage occurred that you would not seek to recover any monies from that person, we will not cover you under the insurance for such loss or damage.

E. Privacy Statement

We are a member of the W. R. Berkley Corporation, which we refer to as WRBC.

We take privacy seriously and are committed to handling and protecting your personal information in accordance with the Privacy Act 1988 (Cth) and Australian Privacy Principles (APPs). This Privacy Statement explains how we collect, hold, use and disclose your personal information and who we share it with. It should be read with our Privacy Policy which provides more information about our privacy practices.

Our Privacy Policy is available at www.berkleyinaus.com.au. Alternatively, you can use the details in Contact Us at the end of this Privacy Statement to request a copy of Our Privacy Policy.

Consent

You agree to us collecting, holding, using and disclosing your personal information as set out in our Privacy Policy when you: (i) provide us with your personal information; or (ii) apply for, use or renew any of Our products and services.

Personal information about others

If you provide us with personal information about another person, then you must: (i) have their consent to do so; and (ii) tell them that you are disclosing their personal information to us and provide them with a copy of this Privacy Statement.

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How we collect your personal information

We collect your personal information directly from you, your agents and through others including the parties listed in Our Privacy Policy. This includes our agents and service providers. We will use a variety of methods to collect your personal information from these parties, including written forms, telephone calls and electronic delivery.

Not giving us your personal information

You may choose not to give us your personal information. However, this may affect our ability to provide you with any, some or all of the features of our products or services, including processing a claim.

How we handle your personal information

We will use your personal information for the purposes we collected it. This usually includes: (i) providing you with assistance, a product or service you have requested; (ii) handling claims and complaints you have made; and (iii) facilitating our business functions and operations.

Your personal information may also be used for other purposes that are set out in our Privacy Policy.

We may disclose your personal information to other members of WRBC, agents or service providers (either yours or ours), other insurers, reinsurers, persons involved in a claim and other parties set out in our Privacy Policy. These disclosures will be for the same purposes described above or as otherwise permitted by law.

Overseas Disclosure

Sometimes we need to provide your personal information to, or get personal information about you from, persons or organisations located overseas. We will do this for the same purposes as in the 'How we handle your personal information' section above.

The complete list of countries is contained in our Privacy Policy.

From time to time, we may need to disclose your personal information to, and collect your personal information from, persons and organisations located in countries that are not on the list.

Marketing

Every now and then we might let you know – including via email, telephone or online - about news, products and services that we think may be of interest to you.

We will engage in marketing unless you tell us otherwise. We want you to be able to exercise your marketing preferences. Accordingly, you can contact us to update your marketing preferences by using the details in Contact Us below. Alternatively, you can simply follow the unsubscribe instructions in the relevant communication. More information about our marketing practices can be found in our Privacy Policy.

Access, correction and complaints

You have the right to request access and correct your personal information held by us. Our Privacy Policy provides information about how you can: (i) access your personal information; (ii) ask us to correct your personal information; and (iii) complain about a breach of the APPs and how we will deal with such a complaint.

Contact Us


www.berkleyinaus.com.au


02 9275 8566


privacy@berkleyapac.com


Berkley Privacy Officer, PO Box Q296, QVB NSW 1230

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GENERAL INFORMATION

1. Full Name of the Organisation	
2. Trading Names	
3. Have you operated under any other names?	
4. ABN / ACN	
5. Principal Address	
6. Website Address	
7. Contact Person and E-mail address	
8. Country of Registration	
9. Date of Incorporation / Number of Years in Business	

10. Gross Turnover	Last Financial Year	Current Financial Year	Coming Financial Year
Financial Year Ending	/	/	/
Australia			
USA / Canada			
Elsewhere			
Total			
If elsewhere, please breakdown income and specify location below:			

11. Please provide a brief description of your operations and/or products:

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12. Please provide a breakdown of your products / activities below:

Type of work	% of income last financial year	% of income next financial year
Prescription Medication		
Over the counter medication		
Dietary Supplements, Complementary Medicines, or Nutritional Products		
Medical Devices (implantable)		
Medical Devices (non-implantable)		
Contract Manufacturing		
Clinical Research Organisation		
Research & Development		
Distribution		
Other (please detail below)		

13. Will you be introducing any new products or services in the next 12 months? If yes, please provide details	☐ No	☐ Yes

14. Please identify and classify your products based on the following:

(M) Manufactured by You; **(I)** Imported and Distributed by you; **(D)** Distributed Only - sourced from an Australian Supplier

Product	Classification (M, I or D)	Percentage of Total Revenue	Origin of Imports
Prescription Medication			
Over the counter medication			
Dietary Supplements, Complementary Medicines, or Nutritional Products			
Medical Devices (implantable)			
Medical Devices (non-implantable)			
White-Labelled Products			

15. Please confirm your wages:

Actual for last 12 months: Estimate for next 12 months:

16. Please confirm your employee numbers:

Actual for last 12 months: Estimate for next 12 months:

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17. Do you engage contractors or sub-contractors?

No ☐ Yes ☐ If yes, please estimate annual payments split between:

	Actual Payment to Sub-Contractors over the last 12 months	**Estimated payments to sub-contractors over the next 12 months**
a) Labour only		
b) Labour and services		
c) Labour and materials		
d) Type of work carried out		

18. Do you engage or intend to engage labour hire personnel, either from labour hire companies or 'internal' labour hire (other than contractors mentioned in Question 12 below)?
Please note: Internal labour hire refers to the hire of staff between insured entities named within this policy of insurance

No ☐ Yes ☐ If yes, please provide an annual spli between:

Labour Hire Companies	**Actual payment for the last 12 months**	**Estimated payment for the next 12 months**
a) Payment to external labour hire companies or other parties		
b) Number of people engaged		
c) Type of work undertaken		
Internal Labour Hire	**Actual payment for the last 12 months**	**Estimated payment for the next 12 months**
a) Payment to internal labour hire companies or other parties		
b) Number of people engaged		
c) Type of work undertaken		

19. Have you acquired or sold any companies or product lines in the last 5 years in which you have or had 50% or greater ownership interest? If yes, please explain	☐ No	☐ Yes
20. Have you discontinued any product lines in the last 5 years? If yes, please explain	☐ No	☐ Yes
21. What percentage of your sales are generated from license agreements, cooperation or collaboration agreements, or royalty agreements? If greater than 25% please provide copies of the 2 largest agreements in terms of revenue		
22. Are any of your products approved for use in a user population of less than 200,000 or a medical device approved or otherwise eligible for the Orphan Drug Designation Program or the Humanitarian Use Device (HUD) Program (or equivalent programs outside of the U.S.)?	☐ No	☐ Yes
23. Do you have any new products, active pharmaceutical ingredients (APIs) or dietary supplement ingredients that have been on the market less than 3 years? If yes, please describe them, and if applicable, please list those that include new APIs.	☐ No	☐ Yes

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CLINICAL TRIALS INFORMATION (SKIP IF COVERAGE NOT REQUIRED)

1. Please provide details of any clinical trials being conducted by you:

Protocol Number	Product	Trial Phase	No of participants	Length of trial	Protocol / Informed Consent Attached

2. Please provide the total number of human clinical trial participants enrolled in the last 3 years.		
3. Have any trials been suspended or placed on hold? If yes, please provide details	☐ No	☐ Yes
4. Have any of your clinical trials been approved by an Institutional Review Board (IRB) or Ethics Committee that were previously rejected by a different IRB or Ethics Committee? If yes, please explain.	☐ No	☐ Yes
5. Have you incurred medical expenses to treat participants for adverse events that occurred during your clinical trials in the past 5 years? If yes, please provide details	☐ No	☐ Yes
6. Have any Serious Adverse Events been notified? If yes, please provide details:	☐ No	☐ Yes
7. Have you or any of your Clinical Investigators been cited for regulatory violations or been issued with any warning letters associated with any clinical trials? If yes, please provide details.	☐ No	☐ Yes
8. Are you aware of any serious regulatory non-compliance or fraud by Clinical Investigators and/or their staff in the past 3 years involving your trials? If yes, please provide details		
9. What grade level do you require your informed consent documents to be readable at		
10. Do you have, or plan to have, expanded access or compassionate use patients? If yes, please describe any formalised policies for expanded access or compassionate use.	☐ No	☐ Yes
11. How do you ensure compliance with applicable local, state and federal laws and IRB or Ethics Committee requirements regarding human clinical trials?		
12. Please describe your process for selecting, training and monitoring your Clinical Investigators including how you audit your Clinical Investigators.		
13. How do you determine if there may be a conflict of interest with any Clinical Investigators or employees? If such risk is identified, how do you address and manage the risk?		
14. Are there any duties of the principal investigator that you do not allow to be delegated to investigator support staff? If yes, please identify.	☐ No	☐ Yes

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REGULATORY / SAFETY SURVEILLANCE INFORMATION		
1. Have you received any warning letters from, or have you been cited for any GMP, GLP, GCP, QS, or Advertising & Promotion violations by, the TGA, ACCC, or any equivalent governmental authority in the last year? If yes, please describe.	☐ No	☐ Yes
2. Other than the TGA or ACCC, have you been investigated or cited by a regulatory or governing body for violation of or non-compliance with any local, state, provincial, regional or federal law in the last five (5) years? If yes, please explain.	☐ No	☐ Yes
3. Have any of your directors, officers, partners or members been investigated for alleged criminal violations relating to your business in the last five (5) years? If yes, please explain	☐ No	☐ Yes
4. Has your product, or any product containing your product, or any product on which your work was performed, been banned, seized, or discontinued for safety reasons by the TGA or any equivalent regulatory agency or government entity? If yes, please provide details	☐ No	☐ Yes
5. Have you had any product recalls in the last year? If, yes, please advise how many recalls, noting how many were Class I Recalls.	☐ No	☐ Yes
6. Please identify any recalls not yet classified that you expect to be classified as Class I Recalls.		
7. Please identify any safety surveillance team or member recommendations requiring remedial actions that have yet to be implemented (e.g. additional studies, black box warning label / updates, "Dear Healthcare Professional" letter, expanded product monitoring, product recall / withdrawal, etc.)		
8. Who are the members of your safety surveillance team? How many years of experience do you require a member of the team to have? To whom does the team report?		
9. Does your safety surveillance team have contact with and/or report to your outside board of directors (if applicable)?	☐ No	☐ Yes
10. Who has the authority to suspend a trial, approve a label change, or withdraw a product from the marketplace? Do you have written procedures to address and communicate these actions?		
11. Under what circumstances do you use independent parties to analyse your processes or data?		
12. What steps, if any, would you take if you became aware of a pervasive off- label use of any of your products?		

PROFESSIONAL INDEMNITY (SKIP IF COVERAGE NOT REQUIRED)	
1. What is your average contract size?	
2. What is your largest contract size? (If possible, please attach a copy of your contract template)	
3. What is the average term of your contracts?	
4. What is the longest contract term?	

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5. Do you hold any customer supplied materials as part of any service you provide? **6.** If yes, what is the average value and the largest value?		☐ No	☐ Yes
Average Value		Largest Value	
7. How often in the past 3 years have you accepted changes to your contract template, or agreed to use your customer's template?			
8. Do you have any contracts past due or any active contract disputes? If yes, please explain.		☐ No	☐ Yes

CONTRACTUAL MANAGEMENT / INDEMNITIES		
1. Do you have formal written contracts in place with your customers?	☐ No	☐ Yes
2. Do you ever assume the liability of any other third parties in your contracts?	☐ No	☐ Yes
3. Do your contracts include any:		
a. Limitations of Liability	☐ No	☐ Yes
b. Hold Harmless Agreements	☐ No	☐ Yes
c. Guarantees or Warranties	☐ No	☐ Yes
4. If you import and/or distribute products manufactured by a third-party, do you obtain written indemnification from those third parties for any product liability claims arising from their products?	☐ No	☐ Yes

DATA BREACH EXPENSES COVERAGE (SKIP IF COVERAGE NOT REQUIRED)		
1. Please estimate the number of unique individual records in the care, custody or control of you and your subsidiaries and proposed insured entities.		
2. Do you encrypt data in transit, at rest or stored on laptops or other portable media?	☐ No	☐ Yes
3. Have you implemented a network and data security policy and/or an Incident Response Plan?	☐ No	☐ Yes
4. Do you have a formal business continuity/disaster recovery plan and/or back up critical data on a regular basis?	☐ No	☐ Yes
5. Do you use firewalls at the perimeter of your network?	☐ No	☐ Yes
6. Do you utilise antivirus/anti-malware software on all computers?	☐ No	☐ Yes
7. Do you require employee passwords of at least eight characters that include at east one number and a special character?	☐ No	☐ Yes
8. Do you deploy critical (software/firmware) updates, patches/hot-fixes or Service Packs on a regular basis?	☐ No	☐ Yes
9. Do you use any software or hardware that has been officially retired (end-of-life) that the manufacturer or developer is no longer supporting with updates and/or software patches?	☐ No	☐ Yes
10. Do you revoke employee computer access when an employee is terminated?	☐ No	☐ Yes
11. Do you have physical security controls of the Insured's Premises where computers, networking equipment, written and electronic records are kept?	☐ No	☐ Yes
12. Have you implemented a network-based Intrusion Detection System?	☐ No	☐ Yes
13. Do you perform vulnerability scanning/penetration testing on a regular basis?	☐ No	☐ Yes
14. Do you provide security awareness training for employees?	☐ No	☐ Yes
15. Are you currently compliant with Payment Card Industry Data Security Standards (PCI DSS) based on your merchant level? Check Here if you do not store, maintain or process credit card data ☐	☐ No	☐ Yes
16. Do you comply with local, state, federal and international security and privacy laws affecting your business?	☐ No	☐ Yes
17. Do you review content prior to posting on your website or your controlled social media site to ensure it does not contain any defamatory or libellous material or infringes on another's copyright, trademark, service mark or collective mark?	☐ No	☐ Yes

RISK MANAGEMENT INFORMATION		
1. Provide an overview of your audit procedures. To whom does the audit team report? Who receives a copy of the audit report?		
2. Do you have a Compliance Officer? If yes, to whom does the position report?	☐ No	☐ Yes
3. Do you have an Enterprise Risk Management program? If yes, please describe it.	☐ No	☐ Yes

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4. How do you prequalify and monitor foreign suppliers?		
5. What is your internal procedure for change control?		
6. If you use contract production vendors, do you require sign-off on vendor change orders that can impact product quality or performance?	☐ No	☐ Yes
7. Do any of your employees have direct patient contact? If yes, please provide details.	☐ No	☐ Yes
8. Do you follow trade or industry guidelines as respects interactions with Healthcare Professionals?	☐ No	☐ Yes
9. Please describe your claims escalation procedures.		
10. Do you have formalised information privacy policies and procedures that are compliant with applicable local, state and federal laws?	☐ No	☐ Yes
11. Do you have a written information security policy?	☐ No	☐ Yes
12. Do you have a code of conduct and annual training / certification for employees?	☐ No	☐ Yes
13. Do you have a system for documenting compliance violations and corrective actions?	☐ No	☐ Yes
14. Is there a method for employees to report compliance issues anonymously? What is the escalation process for such reports?	☐ No	☐ Yes
15. How do you communicate that new employees should not bring intellectual or personal property with them from former employers?		
16. If you perform work on behalf of others, how do you evaluate the risk to you associated with your customers design / formulation, labelling & marketing of that product?		

SALES & MARKETING INFORMATION

1. Please describe the extent of your direct-to-consumer advertising, if any. How do you ensure your advertisements to consumers are both balanced and informative?		
2. How do you ensure that your internal and external sales and marketing representatives conform to product safety, label indication and adverse event information when communicating with customers		
3. How do you manage and conform to approved methods for communicating off-label information regarding your products?		
4. Do you allow employees to advertise direct product comparisons against competitors' products? If yes, which employees are authorised to make these comparisons?	☐ No	☐ Yes
5. How often do you train your sales and marketing staff on how to insulate your company from products liability exposures?		

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6. To what extent is your marketing group involved with scientific educational programs? Is your grant-giving function independent of your sales and marketing department?		
7. Do any of the individuals or entities to which you sell your product have an ownership or other financial interest in your company or any of your products or services? (For purposes of this question, ownership or other financial interest does not include ownership of an immaterial amount of stock) If yes, please describe.	☐ No	☐ Yes
CONTRACT MANAGEMENT INFORMATION		
1. Describe how you monitor your contractual obligations for confidentiality agreements and granting of additional insured status.		
2. Under what circumstances does someone other than a senior officer or an lawyer in your legal department have the authority to sign contracts?		
3. Do you have a standard contract template that you utilise? If yes, please attach	☐ No	☐ Yes
4. If applicable, who has the authority to deviate or make changes to the standard template wording? Does your legal department sign off on any and all changes?	☐ No	☐ Yes
5. Are all contract changes required to be in writing and signed by both parties?	☐ No	☐ Yes
HISTORICAL AND LOSS INFORMATION		
1. Has any insurance company cancelled, rescinded, or refused to renew your insurance coverage for Products Liability, General Liability, Professional Liability, or Cyber Liability?If yes, please explain.	☐ No	☐ Yes
2. Have any of your products or services ever been involved in class action or multi-district litigation? If yes, please provide details	☐ No	☐ Yes
3. Has a claim, demand for damages, or loss or expense exceeded your deductible or retention in the last 5 years? Please provide details.	☐ No	☐ Yes
4. In the last 12 months, have there been any:		
a. Suspension of a clinical trial or changes made to trial documents for safety reasons	☐ No	☐ Yes
b. Class I Product Recall	☐ No	☐ Yes
c. Boxed Warning label additions or changes	☐ No	☐ Yes
d. "Dear Healthcare Professional" letter advising of a serious adverse event	☐ No	☐ Yes
e. Criminal investigation of the insured	☐ No	☐ Yes
f. Serious Adverse Event reported to the TGA which resulted in recommendations being made that a product label be changed or product be redesigned or reconstituted	☐ No	☐ Yes
g. Actual defects, malfunctions or errors that without correction, would potentially cause a serious adverse event	☐ No	☐ Yes
h. Mass litigation risk (three (3) or more claims first made against the insured in the past 12 months each of which alleges that the same or a substantially similar defect or malfunction in your product or error in your work caused a serious adverse event)	☐ No	☐ Yes
i. Incidents of unauthorised access to or use of a computer system, a denial of service attack or introduction of malicious code or computer virus	☐ No	☐ Yes
j. Theft, loss or unauthorised public disclosure of confidential information	☐ No	☐ Yes
k. Violations of intellectual property or privacy rights due to content on the insured's website or in social media	☐ No	☐ Yes
If you have answered "yes" to any of the above, please provide further information below		

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5.	Do you have any reason to expect that any of the events listed in 4. a-k above will occur during the upcoming policy term? If "yes", please explain in detail	☐ No	☐ Yes
6.	Are you aware of:		
	a. any fact, circumstance or situation which one might reasonably expect to give rise to a claim, loss or expense that would fall within the scope of the insurance being requested?	☐ No	☐ Yes
	b. any claim, demand for damages, loss or expense not yet reported to any prior or current insurance carrier?	☐ No	☐ Yes
	c. any claim that has become part of multi-claimant litigation, or part of a class action?	☐ No	☐ Yes
	d. any multi-claimant litigation or class action involving any product on the market that contains the same ingredient as is contained in your product, or is in the same device family as your product, or in which your product was incorporated or on which you performed a service?	☐ No	☐ Yes
	If you have answered "yes" to any of the above questions, please provide further information:		
OTHER			
7.	Describe or detail any information not previously included in this application which you feel would help us to better evaluate your company.		

8. Please provide a break-down of either turnover or clinical trial participants on a state-by-state basis

NSW	VIC	QLD	SA	WA	TAS	NT	ACT	O/S

If income is generated in NSW, please answer the following additional questions:

a. Is the proposer a Capital Gains Tax small business entity (within the meaning of section 152-10(1AA) of the *Income Tax Assessment Act 1997* (Cth))? No ☐ Yes ☐

b. Is the proposer a small business individual, partnership, company and/or trust, which is carrying on a business, and the business has an aggregated turnover of less than $2,000,000? (Aggregated turnover is your Australia wide annual turnover plus the annual turnovers of any business entities that are your affiliates or are connected with you).
No ☐ Yes ☐

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SPECIFIC PRODUCTS

1. Do you manufacture, distribute, label, advertise, test, or sell any product made of, a derivative of, known as, or containing any of the following:

a. Belladonna (Atropa belladonna), including but not limited to teething products, when used in or on a person under the age of 18;
b. Benzocaine when used either orally, or in or on the ear, nose or throat, to treat person under the age of 18;
c. Birth control or fertility goods or products;
d. Bisphosphonates;
e. Breast Implants;
f. Cold therapy products, meaning any device that operates by pumping liquid through a plastic bag or other receptacle and is applied to the body to reduce temperature;
g. Depakote (divalproex sodium);
h. Di-(2-ethylhexyl) Phthalate (DEHP neonatal goods or products, meaning any good or product containing DEHP used to treat neonatal patients or to which such patients are exposed;
i. Diethylstilbestrol (DES);
j. Ephedra, Ephedrine or pseudoephedrine except where used in prescription products;
k. Hormone replacement products approved for menopause treatment, or which is intended to be used for such treatment;
l. Inferior vena cava filters (IVC filters);
m. Isoretinoin;
n. Kratom;
o. Mesh Implants, meaning surgical mesh or other similar product or woven fabric either temporarily or permanently implanted into a human;
p. Metal-on-metal implant meaning any knee, hip or other joint implant, replacement or resurfacing system and the component parts of any of the foregoing ("implant") where: (1) a part of the implant designed for motion is made of metal; and (2) the moving part, while either at rest or in motion, contacts another metal part of the implant that is designed for motion, or designed to meet or serve as a socket or contact surface against which the moving part comes to rest;
q. Metoclopramide;
r. Nitrosamines including but not limited to N-Nitrosodimethylamine (NDMA), N-Nitro-N-methyl-4-aminobutryic acid (NMBA), N-Nitrosodiethylamine (NDEA), N-N-Dimethylformamide (DMF);
s. Phentermine used in combination with flenfluramine (including but not limited to Pondimin) or dexfenfluramine (Redux);
t. Phospho soda, sodium phosphate, or any phospho soda or sodium phosphate-based agents;
u. Proton Pump Inhibitors;
v. Rosiglitazone;
w. Selective Serotonin Reuptake Inhibitors (SSRI);
x. Silicone product (Implanted), meaning any good or product containing liquid or gel silicone which is intended to be, or which is implanted;
y. Talc;
z. Thalidomide;
aa. Tianeptine;
bb. Tobacco or tobacco-related products; or
cc. Vaping products.

If yes, please provide additional information below:

Berkley Insurance Australia
| a Berkley Company

PO Box Q296, QVB NSW 1230
1300 800 772
australia@berkleyinaus.com.au
berkleyinaus.com.au

CURRENT INSURANCE DETAILS

1. Do you currently have insurance in force for the activities for which cover is being sought?

No ☐ Yes ☐ If yes, please provide the following details:

Insurer:	
Limit:	
Excess:	
Renewal date:	
Retroactive Date:	

INSURANCE REQUIRED

Please indicate the limit of indemnity you require and the excess you would prefer (Note: an excess will apply).

Coverage Section	Limit 1	Limit 2	Limit 3
Products Completed Operations and Clinical Trials			
Product Withdrawal Expenses			
Professional Indemnity			
Clinical Trials Only			

Coverage Section	Excess	Excess	Excess
Products Completed Operations and Clinical Trials			
Product Withdrawal Expenses			
Professional Indemnity			
Clinical Trials Only			

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DECLARATION

This Declaration must be completed and signed on behalf of all persons making the application for insurance.

I declare that:

- I am authorised by each of the persons making the application for insurance to complete and sign this Proposal Form.
- after making inquiries, all facts, information and statements given in this Proposal Form and any supporting documents attached or otherwise supplied ("**representations**") are true, correct, accurate and complete.
- no material representations have been omitted, misstated, withheld or suppressed which may affect the decision to accept the application for insurance or the terms and conditions on which any insurance is offered or provided.
- I undertake that, should there be any change to the representations after they have been provided to BIA, then I will immediately inform BIA about these changes before the relevant policy is entered into.
- I understand that BIA relies on the representations in forming its decision to offer any policy and that (except where otherwise indicated) BIA will treat the representations as being made by all persons to be insured.
- I understand that no insurance is in place until such time as BIA has confirmed acceptance of the application for insurance, and that if the application for insurance is accepted, the insurance cover will be subject to the terms, conditions and exclusions of the policy.
- I consent to BIA collecting, using, holding and disclosing personal information in accordance with the Privacy Statement contained in this Proposal Form, and that if I have provided or will provide information to BIA about any other individuals, I am authorised to disclose the other individual's personal information to BIA and also to give the previously mentioned consent on both my and their behalf.
- I acknowledge receipt of the Important Information contained in this Proposal Form and that I have read and understood the content of them.

		/			/	2	0		

Date

Name of authorised individual/partner/principal/director

Signature of authorised individual/partner/principal/director

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