Medical devices

keyfacts®

What is this key facts document?

This is a summary of the cover provided by this policy. It does not include the full policy terms and conditions, for full policy terms and conditions you should read the policy document.

The insurer

This Policy is underwritten by CFC Underwriting Limited on behalf of certain Underwriters at Lloyd's.

Significant features & benefits

A comprehensive package Policy designed to meet the insurance needs of UK based medical device companies, including:

- Cover for products liability, including efficacy (failure to function)
- Blanket professional indemnity cover with limit aggregated for products liability cover
- Cover for property damage, including stock throughout the supply chain and whilst in transit, including the resultant business interruption
- Our "flexible first loss" business interruption contains no average clause and no monthly sub-limit
- Cover for clinical trials
- Global jurisdiction, including USA available
- Cover for contamination, machinery breakdown, spoilage of perishable stock and ideologically motivated attack available on request
- Cover for intellectual property rights infringement
- Employers' liability and public liability cover

Significant and unusual exclusions

Whilst we try to offer the broadest cover possible, we do not provide cover for certain situations. A summary of the significant and unusual exclusions that appear in the Policy are listed below. However, it is important to read the policy to see the full list of exclusions:

- Claims arising in the course of your Business Activities, prior to the Retroactive Date
- Circumstances or occurrences known, or ought reasonably to have been known, at inception
- Failure to ensure feasibility of contracts
- Patents and trade secrets
- Catastrophe perils for unspecified supply chain partners
- Specified diseases
- Specified materials (Di (2-ethylhexl) Phthalate (DEHP), Latex, Mercury, Silicone and Lead)
- Medical Malpractice
- Product Recall
- Product Guarantee
- Unreasonable restriction of our rights of recovery
- Liquidated damages and service credits
- Damage to your equipment due to inadequate maintenance
- Any claim or part thereof that results in you being in a better financial position as a direct result of the wrongful act
- War and terrorism (except to the extent provided by Pool Re)

Limits of liability and deductibles

The limits of liability and deductibles are as specified in the Schedule.

Conditions

What we believe to be the most significant conditions are listed below, however all conditions in the policy are significant. It is important to read the policy and see the full list of conditions.

- Actions which must be taken in the event of a claim or loss (details of how a claim or loss should be notified and the subsequent actions you should or should not take and that the insurer may or may not take).
- Your duty to advise of changes (failure to disclose all material changes may cause this contract to be void and may result in Insurers repudiating liability entirely).

Right of cancellation

There is no cooling off period under this Policy but it may be cancelled with 30 days written notice by either you or us.

Duration of the policy

Insurance policies normally run for a period of 12 months. We strongly urge you to review your Policy each year to ensure you have adequate cover in place.

Claims notification

Should you wish to notify a claim under this Policy, please contact the Claims Managers shown on your Policy Schedule. You must do this as soon as is reasonably practicable and no later than the end of any applicable extended reporting period.

Our regulatory status

CFC Underwriting Limited is authorised and regulated by the United Kingdom Financial Conduct Authority (FCA). CFC Underwriting Limited's Firm Reference Number at the FCA is 312848. These details may be checked by visiting the FCA website at www.fca.org.uk/register. Alternatively the FCA may be contacted on 0800 111 6768.

We are covered by the Financial Services Compensation Scheme (FSCS). You may be entitled to compensation from the scheme if we cannot meet our obligations to you in respect of insurance policies that we have underwritten on behalf of insurers.

This depends on the type of business and the circumstances of the claim. In respect of general insurance business the FSCS will cover 90% of the claim, without any upper limit and for compulsory classes of insurance, the FSCS will cover 100% of the claim, without any upper limit. Further information about compensation scheme arrangements is available from the FSCS.

How to submit a complaint

We intend to provide an excellent service to you. However, we recognize that there may be occasions when you feel that this has not been achieved. If you are unhappy with any aspect of the service that you receive from us, please contact your insurance broker in the first instance, stating the nature of your complaint, the certificate and/or claim number.

Alternatively, you can contact us directly at complaints@cfc.com or please write to:

Chief Executive Officer
CFC Underwriting Limited
11th Floor, 8 Bishopsgate
London EC2N 4BQ
United Kingdom

If after taking this action you are still unhappy with the response it may be possible in certain circumstances for you to refer the matter to Lloyd's of London. The contact details are as follows:

Complaints Department
Fidentia House
Walter Burke Way
Chatham
Kent ME4 4RN

Telephone: +44(0)20 7327 5693
Email: complaints@lloyds.com

Your complaint will be acknowledged promptly in writing.

A decision on your complaint will be provided to you, in writing, within 8 weeks of the complaint being made.

If you remain dissatisfied after receiving the response, you may have the right to refer your complaint to the Financial Ombudsman Service (FOS). The contact details are as follows:

Financial Ombudsman Service
Exchange Tower
London
E14 9SR
United Kingdom

Telephone: +44 20 7964 0500 (from outside the UK)
Telephone: 0800 023 4567 (from inside the UK)
Fax: +44 20 7964 1001

The existence of this complaints procedure does not affect any right of legal action you may have against CFC Underwriting Limited or Lloyd's as detailed in the Service of Suit condition on the last page of your policy.