

EQulP – Earnings Quality Insurance Protection for Medical Devices

Key Features

EQulP is an innovative non-damage business interruption cover. EQulP protects Medical Device Manufacturers from losses arising from a suspension of manufacture due to regulatory non-compliance at Named Own and Named Supplier facilities.

Fully customizable dependent on client profile but with core key features as follows:

Coverage triggers

- Regulatory Order issued or instigated by a Defined Regulatory Agency (DRA*) including withdrawal of CE Mark or equivalent by an approved Notified Body resulting in suspension of manufacture due to irregularities in the manufacturing process
- Voluntary Suspension of manufacture to pre-empt a Regulatory Order including where due to use in manufacture of non-compliant inwards components, from a non-regulated named Supplier facility
- An order for Prohibition of Sale or Supply applied by a DRA to a named facility located in a non-DRA country (optional sub limited coverage)

Basis of indemnity

- Loss of Gross Margin and direct Increased Costs of Working including Remediation, Recall Costs, On-site Repair and Start-Up Costs
- Extra Expenses including Regulator Expert Fees and Product Destruction Costs (including compliance with European WEEE Regulations)

Indemnity period

- Up to 24 months (includes ongoing loss of Market Share AFTER re-start of manufacture)

Key exclusions

- Products and Prototypes not yet approved for sale
- Physical damage events (as covered in standard PDBI policies)
- Cyber and Network Outage Incidents (as covered in specialist cyber policies)

*DRA – authorities that are covered as standard in respect of enforcement of good manufacturing practices are USA, Canada, EU, Switzerland, Norway, Israel, Japan, Taiwan, South Korea, Singapore Australia, New Zealand.

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