Medical Device Manufacturer Insurance

Manufacturing & products - coverage overview, limitations and how to get a quote



OVERVIEW

Medical device makers need specialty products and clinical trial coverage, and carriers look at device class, FDA clearance and quality systems.

WHAT'S COVERED

Products liability
Injury claims from device failure or misuse.

Clinical trials
Injury to participants in device studies.

Product recall
Pulling devices from hospitals and patients.

Property and stock
Clean rooms, equipment and finished devices.

Errors and omissions
Financial loss from design or software errors.

Good to know
ISO 13485 certification and a clean FDA inspection history help most with pricing, and Class III devices need specialty markets.

WHY SOCIETIES INSURANCE

Independent agency
We work for you, not for one insurance company.

50+ carriers compared
We shop A-rated markets for coverage and price.

Licensed advisors
Licensed in 29+ states, with real people to call.

Free, no obligation
Quotes cost nothing and you choose what to buy.

LIMITATIONS & EXCLUSIONS

Typically not covered for this product:

- × Implanted devices without disclosure
- × Clinical trials unless added and off-label uses on many policies

All policies:

- Each coverage carries its own limits, deductibles or retentions and sublimits, which vary by insurer.
- Only the operations, locations, vehicles and exposures described in your application and policy are covered.
- Prior or known incidents, intentional acts and contractual obligations beyond the policy terms are generally excluded.
- Some coverages (for example professional or management liability) are written on a claims-made basis and must be reported during the policy period.

HAVE THESE READY

- Device list and FDA class
- 510(k) or PMA numbers
- ISO 13485 certificate
- Complaint and MDR history

HOW COVERAGE GETS STARTED

1. **Request a quote**
   Online or by phone - it takes a few minutes.
2. **We shop for you**
   Your licensed advisor compares 50+ carriers.
3. **Review and choose**
   Compare coverage, limits, deductibles and price.
4. **Confirm in writing**
   Coverage starts only once your written confirmation is issued.

Questions? Talk to a licensed advisor.

Scan the code or visit the product page to request your free, no-obligation quote.

800-616-3490 **info@societiesinsurance.com**

societiesinsurance.com/medical-device-manufacturer/

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