Medical devices

Life sciences risks vary significantly, and as a leading insurance provider, QBE recognizes the importance of staying informed about the industry's complexities. Through educational resources like this one, QBE aims to empower brokers to ask meaningful questions that address their clients' concerns.

Medical equipment plays an important role in modern healthcare by enabling accurate diagnoses, effective treatments and improved patient care. From diagnostic tools like MRI scanners to life-saving devices such as ventilators, medical technology has revolutionized the healthcare industry. At the same time, there is a significant risk when devices are used for medical purposes. This document is designed to help our broker partners better understand these tools and safely guide them through the risk selection process of medical device companies and distributors.

What is a medical device?

- Tools ranging from simple (e.g., canes) to advanced digital applications and wearables.
- Used for diagnosis, treatment, and wellness.
- Subject to strict regulatory oversight for safety and effectiveness.[1]

Medical device classifications

The U.S. Food and Drug Administration (FDA) categorizes medical devices into three distinct classes:[2]

CLASS	RISK LEVELS	EXAMPLES
I	Low	Elastic bandages, manual wheelchairs, tongue depressors
II	Moderate	Powered wheelchairs, infusion pumps, pregnancy test kits
III	High	Pacemakers, artificial heart valves, implantable devices

The FDA evaluates devices based on:

- Intended use
- Technological characteristics
- Risk level
- Existing classification and guidance documents[2]

Higher-risk devices require

- More regulatory oversight
- Extensive safety and efficacy data

Other countries may use different classification systems, but the core principle remains: *Greater risk = greater regulatory scrutiny.*

Devices marketed for general wellness may face lighter regulation. However, if a product claims to affect body structure or function, it may trigger stricter FDA requirements.[3]

Regulatory oversight

- **FDA (Food and Drug Administration):** Primary regulator for medical devices.
- **CPSC (Consumer Product Safety Commission):** Oversees consumer safety for crossover products.
- **DOJ (Department of Justice):** Investigates fraud and compliance breaches.
- **State-level Authorities:** May impose additional marketing or usage requirements.

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General questions

- What is the FDA classification (e.g. Class I, II, III)?
- Therapeutic v. diagnostic?
- What is the intended use of the device?
- What is the patient population that this device serves?
- Are there required regulatory approvals? (FDA, CE Mark, etc.)
- If the US regulator isn't the FDA, who is?
- Is the product manufactured in lots?
- What are the distribution channels for this device?

Ownership and usage

- What is the frequency and location of use?
- Is this device utilized in a home or clinical setting?
- Who operates it?
- Are there any safety features that help prevent misuse?

Product documentation

- What kind of training is required for this device?
- Who performs said training?
- Is there proof of training or other certifications required to use the device?
- Do you have regulatory compliance certificates available?
- Are there warranty and service contracts?
- Are there user manuals and maintenance logs? What is the reading level of these documents?

Complaints handling

- How do you document customer complaints? How often are these reviewed and by whom?
- Do you have incident/accident reports available?

Building on our extensive industry knowledge, the QBE Life Sciences team specializes in offering customized insurance solutions that address the distinct risks and challenges associated with clinical trials and other life sciences activities. We take pride in providing a wide range of comprehensive coverage options across the life sciences sector.

We understand the importance of safeguarding your endeavors, and our products are crafted to provide peace of mind as you navigate the complexities of the industry.

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1. https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device
2. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
3. https://c3mdc.com/blog/how-the-fda-differentiates-wellness-devices-from-medical-devices/

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