How We Provide

Medical Device Assistance

At Cranage Veritas we make compliance and market access easier. This document details how we can assist medical device manufacturers with market access and compliance.

EU MDR Guidance and Assistance for CE Marking:

Providing a CE mark permits products to be sold in the European Economic Area (EEA) and countries included in the Mutual Recognition Agreement (MRA). At Cranage Veritas we can help you with the following:

- Technical File Review and Compilation
- Pre-compliance Product Design Review
- ISO 14971 – Medical Devices Risk Management
- Quality Management System Review (ISO 17065)
- Notified Body Opinion for EMC
- Person Responsible for Regulatory Compliance - MDR Article 15

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Making Compliance & Market Access Easier.

www.cranage.ie Email: Info@cranage.ie Call: +353 89 941 1701

CB Certification Assistance:

Operated by the International Electrotechnical Commission for Electrical Equipment (IECEE), this globally recognised certification can streamline the market access process to over 50 countries worldwide.

- Local Technical Representative (CB Testing Engineer) for compliance testing at your manufacturing site.
- Pre-compliance Guidance and Assistance, including product design reviews and identification of relevant product safety standards, directives, and regulations applicable to your medical device product.
- Assistance with compilation /review of test reports.

FDA 510(k) Premarket Notification

For North American Medical Device Market Access.

A 510 (k) is the technical documentation required for those intending to market a medical device in the US. 510(k)'s are usually for Class II medical devices (although also some Class I, and Class III medical devices). A 510 (k) premarket submission demonstrates a medical devices safety and effectiveness for use.

At Cranage Veritas we can help you with:

- Classification of your medical device or equipment
- Identifying a predicate device
- Identifying the relevant testing procedures required for your medical device or equipment
- Assistance in compiling your technical documentation
- Technical documentation review

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NRTL Certification

For North America and Canada

The Nationally Recognised Test Laboratory programme is used to gain market access to North American and Canadian markets, enforced by The Occupational Safety and Health Administration (OSHA).

Working under the authority of Metlabs, our engineers can provide you with:

- **NRTL Certification assistance for medical devices, including test scheduling, review of your safety report, and NRTL certification approval.**
- **Recurring factory visits to comply with NRTL Certification**

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Medical Device Assistance

Get in touch today to arrange a discussion with one of our compliance engineers or regulatory affairs specialists.

Email: **Info@cranage.ie**

Call: **+353 89 941 1701**

Or visit: **www.cranage.ie/medical-devices**

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