+353 89 9411701 www.cranage.ie info@cranage.ie

MEDICAL DEVICE CONSULTANCY

Are you looking for a simple and effective route to market for your medical device?
The Medical Device Consultancy service from Cranage Veritas could help.

Working closely with designers and manufacturers, our medical device consultants can help you navigate the process of bringing a device to market, from initial concept through to approved product.
Using their years of industry experience, our expert medical device consultants offer a bespoke service to assist Irish medical device designers, developers and manufacturers to ensure compliance with regulations, and all aspects of the medical device regulatory approvals process.

Our medical device consultants offer multiple solutions, from initial guidance at design concept, which helps to ensure compliance with IEC60601-1, through to achieving full regulatory compliance against the MDR.

Our range of Medical Device Consultancy service include:

- **Quality system and regulatory compliance reviews**
- **Reviewing your product design prior to product testing**
- **Reviewing technical documentation, including risk assessments**
- **Reviewing or compiling technical files prior to submitting it to a Notified Body.**
- **Assistance in preparation for FDA 510(k) application**
- **Assistance in gaining NRTL certification against IEC60601-1**
- **Performing onsite CB certification testing for IEC60601-1**

Please get in touch for a no obligation discussion about our extensive range of Medical Device Consultancy services:

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