EMC Testing of Medical Devices intended for the UK

Kiwa Electrical Compliance are UKAS accredited to the 4th edition of the EMC standard for medical electrical equipment, EN 60601-1-2.

The 4th edition of the standard defines tests and limits according to risk, medical devices are expected to perform according to their intended use and remain safe (essential performance and safety). For example, equipment intended to be used in a professional healthcare facility may have different requirements from that used in a home healthcare environment.

We have many years' experience of accredited EMC testing of medical electrical equipment to EN 60601-1-2 and can work with manufacturers who are planning to adopt new and wireless technologies.

EU directives are given effect in UK law through The Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

Under the UK MDR and in line with the MHRA guidance, medical devices placed on the market in the UK must be registered with the MHRA. If a manufacturer does not have a registered place of business in the UK, the UK Responsible Person will be responsible for registering the device with the MHRA.

EMC Testing of Medical Devices to meet the FDA

In the United States, medical devices must meet Food and Drug Administration (FDA) standards. IEC 60601-1-2 fourth edition has significant changes that impact both testing and risk management related to basic safety and essential performance. On December 31st, 2018, this standard became mandatory for new product submittals to the U.S. Food and Drug Administration.

Guidance on medical electrical equipment can be viewed here.

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