Testing and certifying medical devices for electromagnetic compatibility

UL Solutions can help you efficiently meet regulatory requirements for medical devices and increase global market access.

For medical devices, the risk of electromagnetic interference has long been important in the evaluation of their safety by regulatory authorities. But the expanded scope of environments in which medical devices are being used today, along with the growing prevalence of all types of medical and nonmedical systems and devices utilizing wireless communications technologies, have created new challenges for medical devices with increased potential risks to patients.

However, regulations and standards are keeping pace. For example, IEC 60601-1-2 fourth edition, and its 2020 amendment, have significant changes that impact both testing and risk management related to basic safety and essential performance of medical equipment. On Dec. 31, 2018, the fourth edition of the standard became mandatory for new product submittals to the U.S. Food and Drug Administration (FDA) and medical products entering the European Union. The consolidated version, 4.1, includes the 2020 amendment and becomes mandatory for new product submittals to the FDA on Dec. 17, 2023, and on March 18, 2024, for medical products entering the European Union. Risks resulting from reasonably foreseeable electromagnetic disturbance must be taken into account during the risk management process.

Full compliance testing to global EMC and wireless requirements

UL Solutions can help medical device manufacturers meet the requirements of IEC 60601-1-2, 4th Edition, and IEC 60601-1-2 Edition 4.1 by reviewing their electromagnetic compatibility (EMC) risk assessments, test plans and supporting documentation as required under the scope of the standard. For manufacturers of legacy devices that may be subject to retesting, we can conduct a GAP analysis against the fourth edition's requirements to assess the scope of work that may be required to achieve compliance. We have several EMC testing facilities around the world, such as Northbrook, IL; Carugate, Italy; Singapore and more that are recognized under the IECEE CB Scheme for IEC 60601-1-2, (Editions 4.0 and 4.1). Our global presence enables us to conduct testing to the standards and prepare test reports that are recognized by regulators in jurisdictions around the world.

UL Solutions

Why UL Solutions?

Meet the right standards, fast
A full suite of automated test platforms allows us to operate efficiently and price competitively, while reducing your time to market.

Knowledge of global standards and regulatory requirements
We have helped to set more than 1,600 standards defining safety, security, quality and sustainability requirements.

Top-to-bottom provider
By combining EMC and Wireless testing services with safety certification and our Global Market Access expertise, we can help you navigate every step of the compliance process.

We can help with:

- EMC risk management evaluation to IEC 60601-1- 2 fourth edition and Edition 4.1
- IECEE CB Scheme to IEC EMC and safety standards
- Pre-compliance services that include risk management, test plans, and instruction for use review as part of full IEC 60601-1-2 fourth edition and Edition 4.1 projects
- EMC pre-compliance testing services
- Coexistence testing to IEEE/ANSC C63.27
- RFID testing of Medical Electrical Equipment to AIM 7351731
- Specific absorption rate (SAR) testing for human exposure to electromagnetic fields requirements
- Wireless Global Market Access services

Our extensive global resources allow us to be a Telecommunication Certification Body (TCB) for the U.S. Federal Communications Commission (FCC), a Foreign Certification Body (FCB) for Canada and a Conformity Assessment Body (CAB) – Notified Body for the European Union for EMC Directive, RED Directive, and Approved Body for the U.K. Radio Equipment Regulations (R-ER).

UL Solutions can help

The fourth edition and the amendment of IEC 60601-1-2 present several compliance challenges for medical device manufacturers. Most notably, the requirements for the manufacturer to conduct an analysis of the risk to the essential performance and basic safety of their device in connection with the effects of electromagnetic interference, as well as to develop a comprehensive test plan to evaluate compliance with fourth edition requirements in light of those risks. We can help.

For more information about how we can help you navigate compliance challenges for your medical devices, please visit us at UL.com/60601 or contact us at UL.com/contact-us.

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Safety. Science. Transformation.™

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