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Conference Abstract

CE Marking: stay mobile through the regulation maze

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Abstract

Mobile health devices generally use wireless technology to transmit physiological data from sensors and monitoring equipment and patient electronic diaries to another location for review by relevant specialists. Such devices allow for remote management of patients with a range of chronic diseases.

This presentation aims to help manufacturers that are new to CE marking navigate through the regulatory maze. There are a number of regulatory issues that a manufacturer of such devices may not have fully considered including:

• EU regulations require a clear medical purpose for CE marking as a medical device; the intended use statement can be broader but one or more therapeutic or diagnostic purposes must be identified. The next stage is classification of the medical device – this dictates whether or not notified body involvement is required for CE marking. If the device monitors any vital physiological parameters, the device classification is Class IIa or IIb. If not, the device is Class I can be self-certified.

• Risks associated with design, manufacture and use should be managed as part of a comprehensive quality management system. The harmonised standard ISO 14971 can be a useful tool to help satisfy the essential requirements. The risk analysis should also consider foreseeable misuse, sources of electromagnetic disturbances and reciprocal interference in the specific use environment. Data integrity and security are concerns particularly when the data is transmitted wirelessly.

• Software development is a special process because the design cannot be verified; only validated. Hence, software lifecycle processes become an important part of the design process. The applicable harmonised standard in this area is EN 62304. This standard also recommends software segregation to control risk and hardware mitigations instead of software mitigation to reduce risk.

• Usability is another area where the regulations have tightened. Compliance can most easily be demonstrated by integrating the requirements in the harmonised standard EN 62366 into the design process. Since patient interaction is a primary feature of mobile health devices, studies should be carried out on a sample of the target population and on the readability of the accompanying user documentation.

• Electromagnetic compatibility should be considered as an integral part of the development lifecycle. The harmonised standard EN 60601-1-2 provides electromagnetic emissions and immunity requirements. There are reference standards that may be applicable which are harmonised against the R&TTE Directive, which also applicable for these devices. Wireless coexistence testing is also recommended to verify that the wireless medical device will function properly in its expected use environment.

• In addition to the manufacturer verifying that their device performs as intended, the manufacturer must also ensure that the device complies with the safety and essential performance requirements contained in the EN 60601 family of standards. The 3rd edition was recently harmonised with a stronger focus on risk management.

Unless the regulatory framework and requirements are taken into account in the early stages of the design process, manufacturers could find themselves investing significant additional time and resources to obtain regulatory approval.

Keywords:

regulatory, ce, risk, usability, emc

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