Weekly Whitepaper
Week #98

The Elements of Electrical Medical Product Compliance

UL, CSA, CE Certification of Electrical Medical Products

Required Elements for Certification

In order to certify your electrical medical product, the product must comply with the following standards. In addition, compliance reports for each standard are needed in preparation for, and as part of, the US-UL, CAN-CSA, & EU-CE product certification. Where noted below, some of the elements are only required when provided and considered safety critical or used to mitigate risk.

1) Risk Assessment (RA): covering all potential risks including hazards identified in 60601-1 and any applicable 60601-2 particular standards (see below).
2) Risk Management File (RMF): contains all the documents utilized to document and demonstrate product quality and compliance including those referenced in the completion of the RMF Checklist.
3) Risk Management File Checklist: must be completed, providing details on how the product complies with ISO14971 and the RMF requirements within 60601-1. This is a long, detailed checklist. All documents referenced in completion of the checklist should be in the Risk Management File.
4) General Product Safety 60601-1:
   a) Includes when applicable Programmable Electrical Medical Systems per Section 14.
   b) In the United States, the UL certification standard is published by AAMI and is titled AAMI ES 60601-1.
5) Particular Standard(s) 60601-2-"X": particular standards provide requirements for specific medical product types and product features. There is a long list of particular standards that should be reviewed for each new product. All applicable particular standards must be applied to the product. Some products have no particular standards.
6) EMC/Immunity 60601-1-2: for most electrical medical products.
7) Radiation Protection for Diagnostic X-Ray 60601-1-3: only when applicable.
8) Usability 60601-1-6: sometimes referred to as Human Factors, which involves compliance with ISO62366.
9) Alarm Safety 60601-1-8: not for all visible and audible indicators, only for safety critical alarms.
10) Home Healthcare 60601-1-11: for wearable medical devices and other medical products that are intended for use in the home. This is a very environmental test intensive standard.
11) Emergency Medical 60601-1-12: is only required for EMS equipment. This is also a very environmental test intensive standard.
12) Software Safety: per IEC62304 on the software lifecycle process when safety critical.
13) Biocompatibility: per ISO10993-1, this is only required for products in contact with the body.
14) Sterilization: is only required for sterilized medical products, per the applicable ISO standard.

Key Medical Product Certification Preparation Questions:

- *Do you have a Risk Assessment? Has all residual risk been mitigated to an acceptable level?*
- *Do you have a complete RMF that is compliant with ISO14971 & the RMF requirements of 60601-1?*
- *Have you completed the RMF Checklist? Are all documents you referenced in the checklist part of your RMF?*
- *Have you identified all applicable standards in the 60601 series? Especially 60601-2 particular standards?*
- *As applicable, do you have Compliance Reports for Usability, PEMS, Alarms, Biocompatibility, Software Safety, and Sterilization?*
- *Have you had an expert do a pre-compliance construction review to 60601-1, applicable -2's, as well as -1-11 and -1-12 if applicable? It saves time and money to find and fix your problems during pre-compliance.*

CertifiGroup can assist you with all steps in medical product compliance including gap analysis, design reviews, and preliminary reviews.
We can provide UL, CSA, & CE/International Certifications for your products.