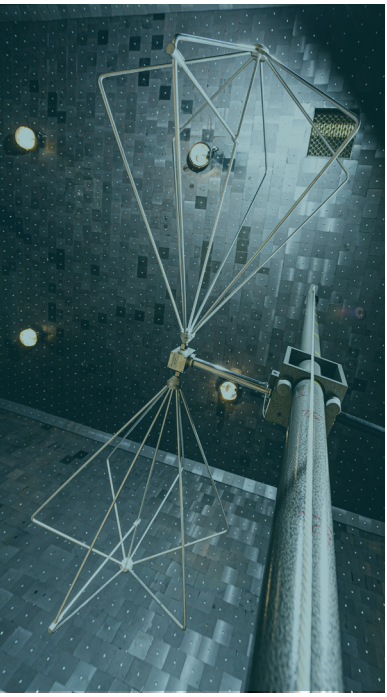
Prevas

Hello EN 60601

Medical device Safety testing and evaluation

Product development within Life Science requires solid knowledge about regulations and standards. Prevas specialists within Quality & Regulatory Compliance have long track record of testing/evaluation according to EN 60601-series.



Guidance towards fulfilment of the EN 60601-standard

Our service within medical device safety testing/evaluation, evaluates your device and it's associated documentation in any stage of the product life cycle, from early concept to final product. Evaluating potential non-compliances in early product development, mitigate the cost of repeated certification & compliance testing.

Extensive experience and complete lab setup

In our labs we have the equipment needed, as an electrical safety tester, EMC chamber and other equipment to, perform pre-compliance tests according to the standards. This, in combination with our extensive experience within the field will guide you towards compliance with EN 60601. We can also perform detailed gap analysis of most standards in the EN 60601-series.

EN 60601 is the internationally recognized and EU harmonized safety standard used for all electrical medical devices. According to the standard, medical devices will among other things be evaluated to protect against electrical hazards, mechanical hazards, unwanted and excessive radiation, ignition hazards, abnormal operation, single faults and constructional defects.

We customize a solution based on your request.

Examples of areas to be covered during pre-compliance testing/evaluation

Electrical safety testing
Protection against electrical hazards from Medical Electrical Equipment, such as:

- Touch Current
- Patient Leakage Current
- Patient Auxiliary Current
- Earth Leakage Current
- Dielectric Strength
- Protective Earth Resistance

Mechanical testing/evaluation

- Review of design
- Accessible parts ("finger test")
- Spillage test

Review of marking and documentation

- Review marking on device and packaging
- Review of accompanying documents
- Review of Risk Management File to comply with EN ISO 14971
- Review of Usability Engineering File to comply with EN 60601-1-6 and EN 62366-1
- Review compliance with PEMS (§14 in EN 60601-1) and EN 62304

Pre-Compliance EMC-test

- EMC-lab for pre-compliance testing according to EN 60601-1-2

Is your device an IVD product?
Prevas also offers safety testing/evaluation according to EN 61010/61010-2-101

Interested to know more? Please contact:

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