

IEC 60601-1 Compliance Checklist

Scope & Classification

- Identify if the device under test shall be a production equivalent or a prototype
- Clearly identify the accessories to the device
- Identify the correct working voltage for the device
- Confirm the device falls under the scope of medical electrical equipment or medical electrical system.
- Understand the differences between intended use and normal use as defined in standard
- Document the intended use, patient contact type and operating environment.
- Identify applied parts by definition

Risk Management

- Complete FMEAs, PHA, and Risk Management Plan
- Identify applied parts through the risk management process

Electrical Safety

- Verify insulation, creepage/clearance distances, and grounding.
- Perform protective earth continuity if applicable and applicable leakage current tests.

Mechanical Safety

- Ensure that the test methods for the applicable mechanical hazards are adequate and represent worst case scenario
- Consider the recommendations if any by the device specific standard applicable to your device

Thermal Safety

- Test results must represent worst case scenario in terms of operating condition
- Evaluate enclosure and applied parts temperature under normal/ single fault conditions.
- Thermal safety should be evaluated for the entire single working/application session of the device

Marking & Documentation

- Add required warnings, symbols, and instructions in the labeling of the device

Testing & Verification

- Carefully evaluate the applicability of the different type tests
- Record justifications if design changes are made during the testing
- Test plan should consider the difference in test methods especially when country-specific applicable standards are involved
- Record test results with traceable evidence.

Collateral & Special Standards

- Apply IEC 60601-1-2 for EMC, IEC 60601-1-6 for usability, and IEC 60601-1-11 for home healthcare, as relevant.

Regulatory Submission

- Align with the compliance evidence required by the applicable national regulations