

Elektromedisinsk utstyr

Å skaffe til veie dokumenter som eks. brukermanual, liste over kritiske komponenter, tekniske tegninger osv. er en del av prosessen med å få et elektromedisinsk produkt testet og deretter sertifisert. I listen under finner du de vanligste dokumentene som må være på plass før prosessen kan påstartes.

- CB Scheme Report and Certificate for the Power Supply - Must be certified to IEC/EN 60601-1 3rd ed.
- User/Instruction Manual + Technical/Service Manual
- Risk Management File according to ISO 14971
- Schematics (.pdf format)
- Circuit board trace layouts (.pdf format)
- Component layouts (.pdf format)
- Operating instructions
- Input Power Rating (e.g. 100-240VAC, 50/60Hz, 3.5A max)
- Copy / Drawings of labels
- Agency report for internal rechargeable Lithium-Ion batteries/packs (IEC 62133) and UL1642/UL2064 if applicable
- Agency report for Laser/Fiber Optics to IEC 60825-1 and/or high intensity LEDs to IEC 62471 if applicable
- Detailed List of Critical Components (with Nemko project engineer), including manufacturer, part#, ratings and agency certifications (Critical Components are defined as all components in Mains, enclosure and secondary circuit components that may be relied upon to prevent a safety hazard)
- Spare Parts: motherboard, power supply
- List of ALL production facilities/factories
- Software documentation according to IEC 60601-1, cl. 14, and IEC 62304
- Agency report for MED software evaluation, if applicable
- Usability engineering file according to IEC 60601-1-6 & IEC 62366
- Definition of EUT essential performance including program/instructions to verify these
- EUT classifications (Class I/II, or internally powered) mode of operation (continuous or intermittent) mobility classification, type of applied part, etc.
- Insulation diagram
- Interconnected equipment / MED system
- Definition of EUT use to determine if EUT can be used in the home healthcare environment (including nursing homes)
- Completed Nemko checklists for Risk Management File related to IEC 60601-1, Usability, Software, Alarms etc.

Våre testingeniører kan gjennomføre en dokumentevaluering slik at du kan være trygg på at du har det du trenger før testing. Dette vil spare deg for mye tid senere i prosessen.

For mer informasjon, vennligst kontakt:

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Links

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