

This checklist covers the ISO 13485-2, Edition 2.1, requirements for the labeling and the accompanying documents (PDI's) of Medical Electrical Equipment. It also includes information and interpretations for the above requirements, as applicable.

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The following is used for providing medical equipment labeling and user manuals to the requirements of the ISO 13485-2 standard. The above references the standards, and subclause/figure/2nd PDI and related standards should also be used.

ISO 13485-2	Ref. Clause	Items	Requirements	Standard
		1	<b>1.1 Equipment identification, marking and documentation</b>	
		1.1.1	General:	
		1.1.1.1	Aspects of the identification, marking and documentation (Identification)	
	1.1.1.2	Legibility of markings:		See Appendix Table 1.1.2
		1.1.1.2.1	End of marking: minimum 1.27 ± 0.13 mm. Character: raised height of 0.4 on the ISO Minimum Angle of Resolution (log MARR) scale or 400 (200%) and is able to read 50% of character height in normal view lighting condition (1-500 lux). Marking must be uniform luminance (100 to 1,000 lux), positioned for intended position of the operator, or, at any point within the field of a 30° cone (if not defined), at a distance of 1 m.	
	1.1.1.2.2	Removal of markings:		See Appendix Table 1.1.2
		1.1.1.2.2.1	Required markings can be removed only with a tool or by appreciable force, are durable, and remain clearly legible during expected service life of the equipment in normal use. Markings subject to tampering with a knife may be marked with each of the following, for 10 sec: tamper-evident, attached parts marked, and tampered without failure.	
		1.1.2	<b>1.1.2 Identification of the components of the equipment</b>	
	1.1.2.1	General Requirements for Marking on ME Equipment:		See Appendix Table 1.1.2
		1.1.2.1.1	It pays to the nature of products does not allow omission of all required markings, at least:	
		1.1.2.1.1.1	- 1.2.2 (manufacturer, model, serial number, date of manufacture, software ver., identifier).	
		1.1.2.1.1.2	- 1.2.3 (external power supply).	
		1.1.2.1.1.3	- 1.2.4 (Class II, 1.2.10 (Special Parts)).	
		1.1.2.1.1.4	- 1.2.1.1 (Physiological effects), as applicable, shall be affixed.	
	1.1.2.1.2	Marking markings fully recorded in accompanying documents.		Marking any other
	1.1.2.1.3	Markings applied to individual packaging when intended to apply to the equipment.		Marking any other
	1.1.2.1.4	- Single use item marked.		Marking any other
	1.1.2.2	Identification:		See Appendix Table 1.1.2
		1.1.2.2.1	ME Equipment marked with the following:	
		1.1.2.2.1.1	- Name or trademark.	
		1.1.2.2.1.2	- Contact information of the manufacturer.	
		1.1.2.2.1.3	- Model or type reference.	
		1.1.2.2.1.4	- Serial number or lot or batch identified separately or identification by technology - (PDI's, etc.).	
		1.1.2.2.1.5	- Date of manufacture or date of date of assembly.	
		1.1.2.2.2	Unless manufacturer does not present unexplained risk, identification could lead to a hazardous situation, detachable components marked with:	
		1.1.2.2.2.1	- Name or trademark of the manufacturer.	
		1.1.2.2.2.2	- Model or type reference.	
		1.1.2.2.3	If not marked, the risk management file includes an assessment of the risks relating to: misidentification of all detachable parts.	See Appendix Table 1.1.2
		1.1.2.3	- Software identified with a unique identifier (not required on outside of equipment, can be only available to designated people).	See Appendix Table 1.1.2
		1.1.2.4	Software accompanying documents:	See Appendix Table 1.1.2
		1.1.2.4.1	- Table 20, Symbol 11 (ISO) be used, to advise operator to consult accompanying documents.	See Appendix Table 1.1.2
		1.1.2.4.2	- Table 20, safety sign, 10 MUST be used if risk management uses the accompanying documents to reduce risk to an acceptable level, but only when the manufacturer uses the PDI as a risk control measure for a specific risk.	See Appendix Table 1.1.2

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**David Baud**

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*Considerations of Unaddressed Safety Aspects in the 2nd Edition of Iec 60601-1 and Proposals for New Requirements* British Standards Institute Staff,2003-09 Safety measures Electrical medical equipment Electrical safety Hazards Protected electrical equipment Radiation hazards Fire risks Electrical protection equipment Type testing Electrical testing Environmental testing Environment working Test equipment **Iec 60601 Standard Requirements** Gerardus Blokdyk,2018-08-08 How do your measurements capture actionable IEC 60601 information for use in exceeding your customers expectations and securing your customers engagement What are the Key enablers to make this IEC 60601 move How do we measure improved IEC 60601 service perception and satisfaction What tools do you use once you have decided on a IEC 60601 strategy and more importantly how do you choose What will drive IEC 60601 change This amazing IEC 60601 self assessment will make you the established IEC 60601 domain expert by revealing just what you need to know to be fluent and ready for any IEC 60601 challenge How do I reduce the effort in the IEC 60601 work to be done to get problems solved How can I ensure that plans of action include every IEC 60601 task and that every IEC 60601 outcome is in place How will I save time investigating strategic and tactical options and ensuring IEC 60601 costs are low How can I deliver tailored IEC 60601 advice instantly with structured going forward plans There s no better guide through these mind expanding questions than acclaimed best selling author Gerard Blokdyk Blokdyk ensures all IEC 60601 essentials are covered from every angle the IEC 60601 self assessment shows succinctly and clearly that what needs to be clarified to organize the required activities and processes so that IEC 60601 outcomes are achieved Contains extensive criteria grounded in past and current successful

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