



# Philips Cd645 Manual

**A Loxley**



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the device master record dmr is one of the holy trinity of files that developers need to collate and maintain in order to prove compliance with fda medical device regulations these files specified in fda 21 cfr part 820 181 are the design history file dhf the device history record dhr and the device master record dmr itself

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feb 10 2023 the terms dhf dmr and dhr which stand for design history file device master record and device history record respectively have had associations with design controls for some time now but the similarity of letters in each respective name is enough to cause ongoing confusion among medical device professionals

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device master record dmr is the term used in the quality system qs regulation for all of the routine documentation required to manufacture devices that will consistently meet company requirements section 820 3 j of the qs regulation defines device master record as a compilation of records containing the procedures and specifications for a



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the mdr requires existing legacy medical devices to undergo conformity assessment to the mdr and to be ce marked anew even if they have been on the market previously under the mdd aimdd no grandfathering

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device master record index template upon compilation of all documents to be included in the master record a device master record index template should be prepared to identify all items in the record and locations of these records eng104 2 device master record index includes descriptions such as product specification and product literature

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the device master record procedure prescribes the responsibilities for preparing device master records dmr and to ensure the completeness of dmr indexes indices a device master record should be prepared and maintained for all devices products manufactured or under development all equipment specifically including medical devices

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description medical device standard operating procedure template describes the organization content creation and use of the device master record employed in the production of all medical devices distributed by the company package consists of the procedure and a device master record index log

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jan 7 2021 the device master record is a design document specifically requested by the fda quality system regulation as per 21 cfr 820 181 if we follow the definition reported in the regulation device master record dmr means a compilation of records containing the procedures and specifications for a finished device

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