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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 location s 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

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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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181 for dmr and iso 13485 2016 4 2 3 for mdf documentation the intent is to demonstrate how these compare as well as how a single system can fulfill the requirements of each what is a device master record dmr

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a device master record dmr is a compilation of all the instructions drawings and other records that must be used to produce a product the term is used in quality management systems that cover product design and production contents

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