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**Lauren Gardner**



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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

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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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