STED (Summary Technical Documentation)

Contents and structure of the Technical Documentation as required by Annex II of the new MDR

Within the proposal from June 2016 for the new Medical Device Regulation, a new Annex II was established describing the contents of the Technical Documentation needed for the conformity assessment.

Within the new MDR it was emphasized, that "*to the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification criteria, conformity assessment procedures and clinical investigations*".

The following list was prepared as one way of structuring the Technical Documentation as per GHTF STED and the Annex II of the new MDR. The example shown was written for a non-active medical device, like for example a blood purification device or a catheter. For purpose of international registrations outside EU27, some additional requirements were added.

STED / Annex II Section	Document#	Content
6 / 1 Product description, variants and accessories	01_01	Product description, variants, intended use/users
	01_02	Product trade name and name equivalence
	01_03	Unique device identifier(s), Basic UDI
	01_04	Intended patient population and medical conditions
	01_05	Principles of operation
	01_06	Accessories
	01_07	Novel features
	01_08	Patents
	01_09	Product classification
	01_10	EAC, MD code(s)
	01_11	GMDN code and term
	01_12	Drawings
	01_13	Dimensions, physical data
	01_14	Material component lists including commercial names and suppliers
	01_15	CAS numbers, Material Safety Data Sheets

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STED / Annex II Section	Document#	Content
	01_16	Statement to Plasticizers and auxiliaries
	01_17	Statement to BPA, DEHP
	01_18	Statement to Latex
	01_19	Packaging materials
	01_20	Market History, previous generations of the device
	01_21	Similar devices available
7 / 2 Labeling	02_01	Product label
	02_02	Single unit packaging label
	02_03	Box label
	02_04	IFU
	02_05	Commercial brochure(s)
	02_06	Technical Data sheet
	02_07	Summary Safety Clinical Performance
	02_08	Implant Card
8 / 3 Design and Manufacturing	03_01	Design Philosophy / Design Summary Report
	03_02	Manufacturing Flow Chart
	03_03	Quality Controls
	03_04	Process Validations
	03_05	Release certificate, Lot History records
	03_06	Lot numbering system
	03_07	Manufacturing sites (Single Registration Numbers) including sub-contractors and suppliers
	03_08	Design sites including sub-contractors and suppliers
	03_09	Plant Master File
	03_10	Quality System Certificates, CE certificates, Free sale certificates
9 / 4 Essential Principles	04_01	List of applied standards and common specifications
	04_02	Checklist of general requirements for safety and performance (CE Marking)
	04_03	Checklist of essential principles (Canada)
	04_04	Checklist of essential principles (Australia)
	05_01	Risk Analysis

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STED / Annex II Section	Document#	Content
10 / 5 Risk management	05_02	Benefit Risk statement
11 / 6 Design verification and Validation	06_01	Performance Testing / Bench testing
	06_02	Animal testing
	06_03	Raw material Biocompatibility
	06_04	Final Finished Product Biocompatibility
	06_05	Clinical data
	06_06	Clinical evaluation plan/report
	06_07	PMCF plan/report
	06_08	Shelf life studies
	06_09	Reprocessing
	06_10	Stability studies active medicinal substances
	06_11	Sterilization Validation
	06_12	Environmental and microbiological conditions in manufacturing
	06_13	Transport Validations
	06_14	Connection to other devices
	06_15	Medicinal substances
	06_16	Substances of Human origin
	06_17	Substances of animal origin
	06_18	Nano materials
	06_19	Bibliography
12/- Approvals	07_01	Declaration of Conformity
	07_02	Communication to Notified Body
	07_03	Communication to Authorities

Annex IIa Section	Document#	Content
1 Post Market Surveillance	08_01	PMS Plan
	08_02	PMS Report / PSUR

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