Does your Medical Device Technical File Comply with MDR 2017/745 Requirements?

S.No	Requirements	Yes	No	Document
1	**Device Description, Specifications and Accessories**			
1.1	**Device Description**	☐	☐	
	a) General description	☐	☐	
	b) Product or trade name	☐	☐	
	c) Principles of operation or Mode of action	☐	☐	
	d) Accessories included	☐	☐	
	e) Accessories not included but necessary for use	☐	☐	
1.2	**Intended Use**	☐	☐	
	a) Intended use (including clinical claims)	☐	☐	
	b) Intended user(s)	☐	☐	
	c) Patient population(s)	☐	☐	
	d) Indication(s) & Contraindication(s)	☐	☐	
	e) Warning(s) and Caution(s)	☐	☐	
1.3	**UDI-DI & EMDN code**	☐	☐	
	a) Basic UDI-DI and any other relevant UDI related information	☐	☐	
	b) EMDN code	☐	☐	
1.4	**Devices covered by Technical Documentation**	☐	☐	
	a) List of type	☐	☐	
	b) Sizes, Configurations, Variants	☐	☐	
	c) Catalogue numbers	☐	☐	
1.5	**Devices Features**	☐	☐	
	a) Novel feature(s)	☐	☐	
	b) Functions of element(s) /component(s)	☐	☐	
	c) Software, if any	☐	☐	
	d) Qualitative & Quantitative composition of device	☐	☐	

1.6	**Technical Specifications**	☐	☐	
	a) Dimensions	☐	☐	
	b) Performance attributes	☐	☐	
	c) Drawings and diagrams	☐	☐	
	d) Medicinal or Drug substance, if any	☐	☐	
1.7	**Device Classification**	☐	☐	
	a) Device class	☐	☐	
	b) Classification rule	☐	☐	
	c) Conformity assessment route	☐	☐	
1.8	**Materials**	☐	☐	
	a) Description and identification of key materials incorporated into the device	☐	☐	
	b) Primary packaging materials	☐	☐	
	c) Identification of any tissues or cells of human or animal origin that may have been utilised in the manufacture of the device	☐	☐	
	d) Bill of Materials	☐	☐	
1.9	**Marketing History or Equivalent Device**	☐	☐	
	a) Overview of relevant market history of the device (e.g. Date of first making available, Units sold, Previous models, Current and previous regulatory approvals)	☐	☐	
	b) Overview of similar device(s) available in EU or other markets	☐	☐	
	c) Equivalent device comparison document	☐	☐	
	d) AE or SAE or FSCA reported, if any	☐	☐	
	e) Market recalls, if any	☐	☐	
2	**Information Supplied by the Manufacturer**			
2.1.1	Device or Product labelling	☐	☐	
2.1.2	Sterile packaging labelling	☐	☐	
2.1.3	Single unit packaging labelling	☐	☐	
2.1.4	Sales packaging labelling	☐	☐	
2.1.5	Transport packaging labelling	☐	☐	

2.1.6	Instructions for use	☐	☐	
2.1.7	Patient/Physician handbook	☐	☐	
2.1.8	Implant card information	☐	☐	
2.1.9	Electronic IFU (e-IFU) information (if applicable, and as per (EU) 207/2012)	☐	☐	
2.1.10	Copies of promotional materials (that mention that the device fulfils the requirements of CE marking) including any that make specific claims related to the device	☐	☐	
2.1.11	URL of the website where the IFU (and any other labelling information as relevant) will be as per GSPR 23.1	☐	☐	
3	**Design and Manufacturing Information**			
3.1	**Design Stages**	☐	☐	
3.1.1	Summary of design stages applied to the device	☐	☐	
3.2	**Product and Design Specifications**	☐	☐	
3.2.1	Key product/design specifications of the device	☐	☐	
3.2.2	Component and raw material specifications	☐	☐	
3.2.3	Packaging details	☐	☐	
3.2.4	Specifications should include grade, quality, reference codes, full supplier details as relevant	☐	☐	
3.2.5	User requirements	☐	☐	
3.3	**Manufacturing Information**	☐	☐	
3.3.1	a) Overview of the manufacturing process which also identifies any critical processes involved	☐	☐	
3.3.2	b) Incoming inspections and acceptance criteria	☐	☐	
3.3.3	c) In-process inspections and acceptance criteria	☐	☐	
3.3.4	d) Final inspections and acceptance criteria	☐	☐	
3.3.5	a) Installation and commissioning, if applicable	☐	☐	
3.3.6	b) Details of suppliers and sub-contractors	☐	☐	
3.3.7	c) Sterilization details	☐	☐	
3.3.8	d) Approved suppliers list with their credentials	☐	☐	
3.4	**Design and manufacturing site**	☐	☐	
3.4.1	a) Legal manufacturer (as per EUDAMED registration)	☐	☐	

3.4.2	a) European representatives, for Non-EU manufacturer	☐	☐	
3.4.3	b) Site with design responsibility	☐	☐	
3.4.4	c) Sterilization sub-contractors	☐	☐	
3.4.5	d) Packaging sub-contractors	☐	☐	
3.4.6	e) Stability/shelf life studies, if outsourced	☐	☐	
3.4.7	f) Other critical sub-contractors and crucial suppliers relevant to the device(s) including copies of certification held by such entities	☐	☐	
3.4.8	g) Revised agreement with the provision for unannounced audit	☐	☐	
4	**General Safety and Performance Requirements (GSPRs)**			
	a) General safety and performance requirements	☐	☐	
	b) Method use to demonstrate conformity	☐	☐	
	c) List of applicable harmonised standards	☐	☐	
	d) If certain section(s) of GSPR may not be applicable, justification to be provided	☐	☐	
5	**Benefit-Risk Analysis and Risk Management**			
5.1	Benefit-risk analysis (as per GSPR, Section #1 and #8)	☐	☐	
5.2	Risk analysis procedure	☐	☐	
	Risk team details	☐	☐	
	Results of risk management	☐	☐	
5.3	Risk management File	☐	☐	
6	**Verification and Validation**			
6.1	**Biocompatibility**	☐	☐	
	a) Biological safety risk assessment (either standalone or as a part of the risk management section)	☐	☐	
	b) Material characterization test protocols and reports (following ISO 10993 or relevant guidelines)	☐	☐	
	c) Biocompatibility test protocols and reports, preferably from a GLP certified lab	☐	☐	
	d) Biological evaluation report	☐	☐	
	e) Technical team's detail	☐	☐	

6.2	**Electrical safety and electromagnetic compatibility (EMC/EMI)**	☐	☐	
	a) Electrical safety test protocols	☐	☐	
	b) Electrical safety test reports	☐	☐	
	c) EMC/EMI test protocols	☐	☐	
	d) EMC/EMI test reports	☐	☐	
6.3	**Software Verification and Validation**	☐	☐	
	a) List of standards applied	☐	☐	
	b) Verification and validation plan	☐	☐	
	c) Verification and validation report	☐	☐	
6.4	**Stability/Shelf Life Studies**	☐	☐	
	a) Stability/shelf-life validation protocols (to include both device and packaging performance)	☐	☐	
	b) Accelerated stability/shelf-life plan and report	☐	☐	
	c) Long term stability/shelf-life plan and report	☐	☐	
6.5	**Design Verification and Validations**	☐	☐	
	a) Design control matrix	☐	☐	
	b) Design requirements	☐	☐	
	c) Verification and validation plan and reports	☐	☐	
	d) Usability study protocols and results	☐	☐	
	e) Evidence to support the device lifetime in use	☐	☐	
	f) Sample size procedures	☐	☐	
6.6	**Clinical Evaluation**	☐	☐	
	a) Clinical development strategy	☐	☐	
	b) Clinical evaluation plan	☐	☐	
	c) Clinical evaluation report	☐	☐	
	d) Team members and their CV's	☐	☐	
	e) Clinical investigation protocols	☐	☐	
	f) Clinical investigation results	☐	☐	
	g) Statistical analysis plans	☐	☐	

	h) Copies of literature articles	☐	☐	
	i) Summary of safety and clinical performance	☐	☐	
6.7	**Post Market Surveillance (PMS) & Post Market Clinical Follow-up (PMCF)**	☐	☐	
	a) Post market surveillance data (market history, worldwide and EU sales volumes, complaints data and trend analyses; vigilance data and trend analyses; data from other PMS sources)	☐	☐	
	b) Post market surveillance plan and report	☐	☐	
	c) Periodic safety update reports	☐	☐	
	d) Post market clinical follow-up plan	☐	☐	
	e) Post market clinical follow-up reports	☐	☐	
	f) Justification when post market clinical follow-up is not applicable	☐	☐	
6.8	**Devices Incorporating Medicinal Substances**	☐	☐	
	a) Source of the medicinal substance	☐	☐	
	b) Device development, manufacture, intermediate, end product specifications and tests, and stability details (CMC)	☐	☐	
	c) Non-clinical data relating to the medicinal substance and device	☐	☐	
	d) Clinical data relating to the safety and efficacy of the medicinal substance	☐	☐	
6.9	**Devices utilizing tissues and cells of human or animal origin or their derivatives or other nonviable biological substances**	☐	☐	
	a) Source of the material or derivative	☐	☐	
	b) Country of origin	☐	☐	
	c) Conformity assessment	☐	☐	
	d) Risk management	☐	☐	
	e) Microbial validation studies, if applicable	☐	☐	
6.10	**Devices composed of substances that are absorbed by or locally dispersed in the human body**	☐	☐	
	a) Test protocols for determining the absorption, distribution, metabolism, excretion (ADME) of those substances	☐	☐	
	b) Test reports and data for determining the absorption, distribution, metabolism, excretion (ADME) of those substances	☐	☐	

	c) Test protocols for determining the local tolerance of those substances	☐	☐	
	d) Test protocols for determining the possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances	☐	☐	
	e) Complete toxicity studies/profile depending on the level and nature of exposure	☐	☐	
6.11	**Devices containing CMR or endocrine-disrupting substances (GSPR 10.4.1 of Annex I of MDR)**	☐	☐	
	a) Data related to the estimation of potential patient or user exposure to the substances	☐	☐	
	b) Information/data on analysis of possible alternative substances, materials or designs	☐	☐	
	c) Rationale for the presence of CMR and/or endocrine-dis rupting substances above 0.1% (w/w) considering the alternatives	☐	☐	
	d) Labelling indicating the presence of CMR and/or endocrine-disrupting substances above 0.1% (w/w)	☐	☐	
6.12	**Packaging and Transit (Transport) testing**	☐	☐	
	a) Packaging drawings and/or configurations	☐	☐	
	b) Packaging validation protocols and report	☐	☐	
	c) Transit/transport/drop test protocol & report	☐	☐	
6.13	**Sterilization**	☐	☐	
	a) Type of sterilization	☐	☐	
	b) In-house or Outsourced	☐	☐	
	c) Allowable microbial count/limit	☐	☐	
	d) Sterilization validation protocol	☐	☐	
	e) Sterilization validation results and reports	☐	☐	
	f) Product/Process bioburden test report	☐	☐	
	g) Pyrogen test, if applicable	☐	☐	
6.14	**Reusable surgical instruments**	☐	☐	
	a) Cleaning, disinfectant, sterilization validation protocols in support of the IFU	☐	☐	
	b) Cleaning, disinfectant, sterilization validation reports and data in support of the IFU	☐	☐	

6.15	**Devices with a Measuring or Diagnostic function**	☐	☐	
	a) Protocols for tests associated with establishing the device limits of accuracy, precision, calibration etc	☐	☐	
	b) Reports for tests associated with establishing the device limits of accuracy precision, calibration etc	☐	☐	
6.16	**Devices intended to be connected to other devices to operate as intended**	☐	☐	
	a) Protocols for tests associated with establishing the safety and performance of the device and the combination while connected to other devices and their interoperability	☐	☐	
	b) Bench test report	☐	☐	
	c) Supporting radiation or ionising or immunity test reports	☐	☐	

Reference:
Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Annex II-Technical Documentation).

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