TECHNICAL DOCUMENTATION CONTENT GUIDE

This guidance has been prepared for informative purposes for manufacturers, taking into account the MDCG 2022-14 guideline and with reference to the Team-NB Position Paper (Best Practice Guide for the Submission of Technical Documentation under Annex II and III of the Medical Device Regulation (EU) 2017/745).

November 2023

CONTENTS

1. TECHNICAL DOCUMENTATION-GENERAL	**Table of Contents**
	- Technical documentation must include a table of contents.
	Revision Information
	- Technical documentation shall be prepared according to the specified document control rules and shall comply with the methods determined for monitoring the revision status. - The change made in each revision should be clearly followable.

2. PRODUCER NAME, ADDRESS, PRODUCTION SITE ADDRESS, STORAGE ADDRESS	**Manufacturer Information**
	- The manufacturer's name, address and short history of the manufacturer should be identified. - Official documents of the manufacturer and QMS documents, if any, should be submitted.
	Production, Storage, Sterilisation, Reprocessing Addresses
	-Address information if there is contract manufacturing, -Storage address information, -Sterilisation address information, -Reprocessing address for reusable product, -If appropriate for the measurement characteristics of the product, a special test/confirmation address shall be defined.
	EC-Rep Information
	If the manufacturer is located outside the economic area of the European Union, the EC-REP title, address and contract (draft power of attorney for the appointment of the authorised representative and letter of intent to accept the power of attorney from the authorised representative) must be submitted.
	If the medical device also falls under another directive (e.g. Machinery, Pressurised Equipment, Medical Product, ROSH etc.)
	It should be stated which Regulations and/or directives apply. If a device is covered by more than one regulation or directive, all applicable regulations / directives must be identified. For example: Machinery, Pressure Equipment, Medical Product, ROSH etc. If the device has a valid certificate in these areas, it should be presented and a list of basic requirements should be created.

3. PRODUCT DESCRIPTION	**Name of the device, models, components, software and accessories, if any, and a complete list of the various configurations/variants of the device intended to be offered on the market**
	- The device description shall describe the models of the device, its components and, where applicable, software and accessories. - A complete list of device configurations/variants intended to be placed on the market should be determined. - Where applicable, the name, models, dimensions, components of the reusable device, including the hand tool, should be identified. - The name, models, dimensions, components, system/procedure package status should be clarified where appropriate. - Identification must be made for all accessories associated with the device. A short description of the accessory(s) and how they are used with the device, the classification of the accessory(s) and the rationale for the classification, whether the accessory(s) are packaged with the device or provided separately, whether the accessory(s) are already certified, the compatibility of the device with the accessory(s). Identify all accessories that are not supplied with the device but are necessary for the use of the device.

	Device group to which the device belongs (EMDN code and description) and UDI-DI number (MDR Annex VI - C)
	- The Basic UDI-DI assigned by the manufacturer must be provided. - EMDN code must be defined.
	Intended purpose of the device.
	- The intended use should describe the disease states the device is intended to treat or monitor, the basic principles of operation, the targeted patient population, and the indications and contraindications of the device. - The intended use must include the use of the device as a "medical device" as defined in Article 2 of the MDR (except for non-medical devices specified in Annex XVI of the MDR) - The intended use must be consistently defined within the technical documentation (e.g. IFU, risk management documents, clinical evaluation report and design requirements). - If the application includes a change in the intended use, all parts of the file must be reviewed for potential impact. - Intended users (health professionals or patients), - Organs / body parts / tissues / body fluids that the device will come into contact with and the duration of contact with the body, - Restrictions on the number and duration of repeated applications, - Mucosal membrane/implant/invasiveness status, - Warnings provided by the manufacturer, - Disposable/reusable status should be defined.
	General definition of medical device
	- The Technical Documentation should identify the processes critical to device safety and performance (e.g. coating) and the raw materials incorporated into the basic functional elements of the device. Substances that come into direct or indirect contact with the user and/or patient must be indicated together with the body parts they come into contact with. - The mode of contact with the human body (e.g. direct or indirect contact, circulating body fluids of the device, etc.) must be clearly defined. - The general description of the device must include the following; Physical and/or chemical description (if applicable, with visuals of the device and reference to technical drawings), Justification for the characterisation of the product as a device Technical specifications and mechanical characteristics, Sterilitis, Radioactivity, The mechanism of action of the device (scientifically demonstrated mechanism of action, if necessary), Working principles, Whether the device contains medicines, human blood and its derivatives and animal tissue, and if so, the purpose of this component, Definition of accessories for a device, other devices and other non-device products intended for use with the device, Description of any new feature, Other considerations, Reprocessing information.
	If the device has a market history, reference and overview of the previous generation(s) of the device produced by the manufacturer and identification of similar devices available on the Union or international markets where such devices are available
	- If the device is new and has never been marketed by the manufacturer, it must be specified. - For initial applications under the MDR, it should be identified whether the device has been previously marketed under the MDD and whether any changes have been made compared to the MDD-approved device. - Market history should be available for all countries of the world. - If available, information on identified similar Devices available in the EU or international markets should be provided.

	Special Performance and Safety claims of the device
	Specific performance and safety claims of the device shall be reported with reference to all performance and safety tests. Compliance with design requirements must be assessed, including measurement accuracy and range, output produced, stability, functions, features, dimensions, accuracies, etc.
	Classification rule and justification
	Indicate the device classification and justification in accordance with Annex VIII of the MDR. The justification should address each point of the selected classification rule. If more than one classification rule applies, they should all be identified and the most stringent rules that result in higher classification should be applied. If the device contains more than one component that can be classified differently on their own, justification for the choice of class should be provided. If the device is a Well Established Technology (WET), according to MDR 52.5, a justification supporting the designation of the device as WET should be added, taking into account published guidance on such devices. - Identification must be made for all accessories associated with the device. A brief description of the accessory(s) and how they are used with the device, the classification of the accessory(s) and the rationale for the classification, whether the accessory(s) are packaged with the device or provided separately, whether the accessory(s) are already certified, and the compatibility of the device with the accessory(s) should be provided.
	Conformity Assessment Route
	The conformity assessment route must be specified for the device submitted during the application.
	Planned Changes
	Definitions should be made on how the process related to the planned changes will be managed.
	Appropriate description of the technical specifications such as features, dimensions and performance characteristics of the device and any variants/configurations and accessories that typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications
	- In the documents provided to the user (brochure, catalogue, etc.), the complete device list, variants and accessories must be specified.

4. TECHNICAL DRAWINGS	**Information on Technical Drawing**
	Preparer, approver, material information, drawing revision information, all dimensions and tolerances must be included on the Technical Drawing.
	Technical drawing traceability
	Technical drawings must include all device models and be traceable by model numbers. There should be a detailed diagram showing features such as all important parts, accessories and circuits of the device.
	Special standards for technical drawings
	For requirements within the framework of measurement requirements / sterilisation requirements / reprocessing requirements, the requirements must be documented by specifying specific standards.

5. PRODUCTION	**Production flowchart**
	The processes applied must be defined and reference must be made to the relevant QMS documentation. Outsourced processes must be indicated in the flow chart.
	Machine List Used in Production
	A complete list of equipment used in production, including outsourced processes, should be included. The list should include machine codes and descriptions of which product is produced on which coded machine.
	All supporting documentation for the production method (Procedure, Plan, Instruction, Form)
	All supporting documentation (procedures, plans, instructions, forms) related to production, including outsourced processes, must be submitted and records of a sample production batch must be attached.

6. DEFINITIONS AND EXPLANATIONS NECESSARY FOR THE USE OF THE DEVICE, UNDERSTANDING	**Surgical technique guide**
	If there is a separate surgical technical manual for the product, this must be provided according to the requirements of the relevant standard.
	Principle of operation of the device for Active Devices
	For active devices, the operating principle of the device (signalling in circuits, etc.) must be presented.

7. STANDARD LIST	**List of Standards/OS(s), all standards/OS(s), all special standards, current versions**
	A list of standards and OSs that are fully or partially applied for the design and manufacture of the relevant medical device should be provided, including their current versions.

8. RISK MANAGEMENT	**Document Defining the Risk Management Method**
	- A comprehensive Risk Management Assessment should be carried out to cover the entire life cycle of the device. This risk management document should be periodically updated with data from after sales surveillance information. - The risk analysis must show that appropriate controls (design followed by protective measures) have been implemented for all risks. - All risk management documentation, including a copy of the risk management procedure, should be included.
	- Risk Management Plan **- Risk Analysis Process and Risk Assessment** **- Implementation and verification of risk control measures;** Acceptability assessment for each residual risk(s); Benefit/Harm Analysis for each risk; Risk Arising from Risk Control Methods **- Completion of Risk Control**

	- Total/Holistic Residue Risk Assessment **- Risk Management Report - Review** **- Production and Post-Production Activities;** **- Information Collection**
	The risk management plan should include the following: -Scope of risk management activities -Full description of the devices and accessories in question -Description of the stages of the device life cycle -Responsibilities and authorisations for risk management -Requirements for the review of risk management activities -At a minimum, a system for qualitative or quantitative categorisation of the likelihood of harm occurring and the severity of harm -Criteria for acceptable risk levels -Assessment of the acceptability of any residual risk, including total residual risk -Criteria for the acceptability of total residual risk, methodology and assessment of total residual risk -Verification of the implementation of risk control measures -Verification of the effectiveness of risk control measures -Determination of activities for the collection and review of production and post-production information Evidence should be provided that the risk management team includes appropriately qualified persons, including an expert familiar with the clinical application of the product. Risk analysis / risk control measures should include the following information: - Benefit-risk analysis referred to in MDR Annex I Parts 1 and 8 -Risk control measures and the results of risk management referred to in Chapter 3 of Annex I of the MDR - Including informing users about the residual risk(s) Evidence of the implementation of safety requirements in accordance with Chapter 4 of Annex I of the MDR - Risk assessments of all design stages of the device - Risk assessment by considering the production processes of the device - Risk assessment for the clinical use and application of the device For design risk assessment, an assessment should be provided as to whether any design changes add new hazards or reduce the likelihood of existing hazards occurring, regardless of whether the risk assessment has changed. The mitigation of risks related to failure to use shall cover the requirements specified in Chapter 5 of Annex I of the MDR. For usability assessment, Annex I shall include the MDR requirements specified in clauses 14.6, 21.3, 22.1, 22.2, 23.1a and the requirements of EN 62366-1. The risk analysis should include: - All known and foreseeable hazards associated with each device must be identified and analysed (estimation and assessment of risks for each hazardous situation). - All known and foreseeable risks and undesirable side effects, risks assessed for the patient and/or user resulting from the achieved performance of the device during normal conditions of use are minimised and must be assessed for acceptability. - Risks arising from intended use and reasonably foreseeable misuse are estimated and assessed, including the elimination or control of those risks. - Appropriate controls (process validations, biocompatibility, sterilisation, clinical, shelf-life or other essential validation/validation tests) should reduce all risks to acceptable levels as far as possible, taking into account the state of the art for the product(s) being evaluated. - Risk control measures must be implemented for each hazard (with references to the documents where these measures are implemented). - The effectiveness of risk control measures should be verified (with reference to documentation demonstrating the effectiveness of risk control measures). - The acceptability of the risks must now be assessed. - A statement must be made that the medical benefits outweigh any remaining risks.

	- Production and post-production information should be assessed in terms of hazards and associated risks, as well as overall risk, benefit-to-risk ratio and acceptability of risk, and control measures should be taken if necessary. The risk management report should include the following: - Assessment of the acceptability of the residual risk(s). - Assessment of overall residual risk acceptability. - Assessment of the benefit-risk ratio. Data from production and after-sales activities should be assessed in the risk analysis report.

9. DESCRIPTION OF THE METHODS USED FOR PRODUCTS TO BE PLACED ON THE MARKET IN STERILE FORM	**Standard used for the selected sterilisation method**
	EN ISO 17665 Moist Heat EN ISO 11137 Gamma /Electron Radiation EN ISO 11135 ETO EN ISO 13408-1 Aseptic EN ISO 20857 Dry Heat Other
	Sterilisation procedure
	- There should be a procedure to verify sterilisation controls such as validation, revalidation, routine release and frequency according to the relevant sterilisation standard used. - Annual sterilisation assessment is required to verify changes in the sterilisation process, manufacturing process, packaging, etc.
	If sterilisation is subcontracted
	There must be a contract between the device manufacturer and the sterilisation company in which responsibilities are clearly defined.
	Sterilisation protocol
	Sterilisation protocol should be prepared to include IQ, OQ, PQ data The justification for the suitability of the sterilisation method for the product and the sterilisation parameters must be specified.

	Sterilisation validation results and reports
	The manufacturer's assertions that the validation performed covers the entire product group should be detailed. Explanation of the worst case scenario should be included. If the product is to be sterilised by the end user, the sterilisation method and the validated parameters should be described. Sterilisation validation should include the following: -Bioburden controls -Product qualification (Dose verification, BI conformity testing, SAL calculations, etc.) -Process qualification (Performance qualification, Dose Map, BI Inactivations, etc.) Additional information requested for the most commonly used sterilisation methods; • **Radiation sterilisation** - Protocol (describing the worst case scenario) - Dose mapping - Bioburden determination and test reports - Method selection - Determination of the test dose and indication of the routine sterilisation dose - Sterility testing of specimens used for the test dose - Max. dose study • **ETO Sterilisation** - Protocol (describing the worst case scenario) - Pre-conditioning - Bioburden determination and test reports - Loading plan, temperature, humidity sensor distributions - Physical and microbiological validation (including IQ, OQ, PQ) - Partial, half, full cycle data and sterility tests - Ethyleneoxide residue test - Full and reduced validation plans and revalidation criteria
	If the product is supplied unsterilised and sterilised by the end user
	- Sterilisation parameters - Validate processes such as washing, cleaning, repackaging, sterilisation, reprocessing according to the maximum number of uses and provide them to the user in the user manual - If applicable, provide residue tests for the disinfectant used
	Reusability / Reprocessing - Class Ir
	- The product performance test covering the maximum number of reuses should include cleaning, disinfection and sterilisation. This performance assessment should be prepared by considering the worst condition and including the maximum number of cycles.

10. APPLIED CONTROLS AND VALIDATION	**Input, inprocess and finished product quality plans** **Quality control protocol, procedure, instructions**
	- Justification for sample size and selection, test equipment used, justification for sample size and selection before quality controls are carried out for input, in-process and finished products must be specified. - Acceptance criteria for the control of input, inprocess and final product must be determined. - If subcontracted, the company documentation for the assessment of the subcontractor and the contract between them should be included in the technical documentation. If there is an acceptance criterion in the harmonised standard, the relevant acceptance criterion should be determined according to this standard. If the standard does not specify acceptance criteria, the manufacturer's justification should be included. - If the device is installed, the tests performed after installation should be specified. - How each quality control test will be performed, test method and protocol should be prepared. The revision content must be clearly traceable.

	Validation master plan
	The relevant harmonised standard, validation parameters, revalidation criteria, review frequency, report number should be included in the validation plan.
	Packaging and clean room validation protocol and report for sterile devices;
	- Environmental monitoring and validation should be carried out if the controlled environment is available. - Clean room microbial monitoring and physical clean room validations must be available and the most recent clean room validation report must be included in the technical documentation. - All reporting for compliance with the EN ISO 14644 standard series must be included. - The specifications of the primary packaging material and a description of its suitability for the sterilisation method should be included. - Packaging validation protocols and reports should be prepared. Worst case scenario should be specified. - Package tests must be carried out according to the relevant standards. Protocol/test report should be prepared for transport test covering standard storage and transport conditions, product functionality and post-transport packaging test etc.
	Protocol and software verification report for devices containing software
	A clear explanation and documented evidence of why the product is a Software as a Medical Device (SaMD) is required. If medical devices are stand-alone software or based on software, a checklist is required according to the requirements of EN 62304. Based on the standard used for compliance, a standard compliance checklist is proposed for requirements according to the risk category of the software. If the medical device is standalone software, the guideline for qualification and classification of the software should be considered as MDCG 2019-11 and rule and class justification is requiredDirect references to the section of the technical dossier in which evidence of fulfilment of the requirements of the selected standard is found should be included in each compliance checklist submitted. If a standard other than the harmonised version is used, then a detailed document describing how the requirements of the harmonised version have been met or exceeded should be provided. Software security classification must be provided and the rationale for this must be clearly stated in the technical file. The software version used in the application must be clearly indicated. Traceability matrices, which include the identification of protocol reports and test data documents with respect to requirements and their verification and validation test evidence respectively, with retrospectively traceable sources (risk, regulatory performance, etc.) are useful for review. As already mentioned, these documents should also be submitted in the technical documentation. The software standards applied to the device must also be specified in the technical documentation and evidence must be provided that all relevant compliant and non-compliant / Wireless Secure (SOTA) software standards / guidelines have been considered **Common necessary documents** Among the selected notified organisations, the following common documented evidence is required at least in the technical document. Please note that this list depends on the software risk classification of the referenced device. All required activities of the selected standard for compliance must be shown in the file. Among the notified bodies selected, the following common documented evidence is required, at least in the technical document. This list depends on the software risk classification of the referenced device. All required activities of the selected standard for conformity must be shown in the file. **Software Development Plan** Software development procedures and activities completed as part of the software development life cycle should be included in the software plan.

(e.g. software requirements specification, software architecture, software detailed design, software unit test procedures/reports, software integration test procedures/reports and software system test procedures/reports). Documentation on software maintenance and software configuration management processes should also be provided (e.g. software maintenance plan, configuration management plan).

Software requirements analysis

The analysis of software requirements should include at least the following:

• Functional and non-functional (timing, stress, language, scalability, etc.) requirements.
• Requirements derived from potential software errors and information from previous designs.
• Requirements for the use of the device, e.g. installation.
• Evidence that the requirements analysis has taken into account MDR Annex II 17.4, in particular hardware requirements, IT network specifications (if applicable) and security requirements relating to access control and unauthorised access.
• Evidence in the documentation of information on functions, capabilities, input data, output data, system interfaces, alarms, security requirements, cyber security requirements, user interface requirements, database requirements, installation requirements, requirements on operation and maintenance methods, regulatory requirements, etc.

Software architecture design

The manufacturer shall provide an architectural design that includes graphical representations (UML, class diagrams, blocks, etc.) and shows how the requirements are allocated to the software elements that make up the overall software system.

The architectural design should take into account the internal and external interfaces of the software, the functional and performance requirements of the Software of Unknown Provenance (SOUP) and additional hardware and software requirements. Depending on the risk class, it may also be necessary to include segregation measures for risk control purposes, which should also be included here.

A documented list of the Software of Unknown Provenance (SOUP) in tabular form should be provided, including libraries and clearly identifying:

- Name
- Version
- Manufacturer Information
- Functional and performance requirements for the software or reference to relevant requirements are required.

Software detailed design

The software architecture for Class B and C risk-based devices needs to be further improved.

This should include design data for each software unit and the interfaces between the units and external components. Details should be given on the expected inputs and outputs for each software unit.

Software units derived from software elements should be clearly defined.

Verification and Validation

All plans, protocols, reports and test data relating to verification and validation tests performed in-house or in a simulated use or real use environment must be submitted.

Documents detailing the test environment should also be included in the application. Where automated testing is used in verification activities, it should be clearly indicated and test cases and test log results should be organised in the documentation.

System level test plans/protocols and reports should be submitted.

	Evidence that different hardware and, if applicable, different operating systems have been verified/validated needs to be clearly identified and provided by the manufacturer. If the software is to be used with mobile platforms, information demonstrating compliance with General Security and Performance Requirement (GSPR) 17.3 must be provided. The standards used in the verification of stand-alone software should be clearly presented and the necessary verification documentation should be provided. The traceability matrix(es) between software testing and features (system specification/system verification, unit specification/unit verification, etc.) should be presented. Evidence of verification of items of Software of Unknown Provenance (SOUP) should be included. In addition to individual reports, it may also be useful to provide an overall Verification and Validation summary report that sets out • Software version. • Summary of test results. • Details of any errors or unresolved anomalies, their acceptable causes and evidence together with risk justification. • Conclusion about admissibility. • Details about approving roles and functions. **Software version** Known unresolved anomalies should be listed. The following information should be included for each remaining anomaly: • Unique Identifier. • Brief description of the issue. • Severity/Risk Level. • Justification for why it is acceptable to release the software with the anomaly. Evidence in the technical documentation should also include evidence of how the released software was created (e.g. the procedure and environment used to create the released software). The final released software version number should be clearly identified in this documentation. Evidence should be included describing how the released software is archived and how it can be reliably delivered (e.g. to the producer environment or to the user of the software). Evidence that all required tasks have been completed before release should be included in the release notes. **Software risk Assessment** The manufacturer should include all software risk assessment documentation (e.g., software hazard analysis, software failure mode and effects analysis, fault tree analysis, traceability etc.). **Cyber security** The documentation in relation to the secure design and ongoing maintenance of the medical device in respect to cyber security should be submitted. The manufacturer shall clearly state the harmonised or SOTA standard(s) of compliance used for conformance to the relevant GSPRs. The manufacturer shall provide evidence of a security risk management system that supports a secure development lifecycle, some examples are listed below: Security risk management plan, security risk assessment and evidence of the incorporation of security risk controls as identified requirements and evidence of their subsequent verification and validation The defined threat protections are compatible with the principles of Confidentiality, Integrity and Availability is required (MDCG 2019-16 Guidance on Cyber Security for Medical Devices can be referred to).

	The manufacturer should provide the technical documentation that clearly identifies the method for identifying the ongoing monitoring of threats and vulnerabilities as well as the methodologies used e.g., STRIDE, attack surface analysis, data flows etc. Documentation shall show how cybersecurity is an active part of ongoing post market surveillance of the device. The manufacturer shall provide documented evidence for the monitoring of ongoing risks associated with SOUP vulnerabilities and their mitigation. Where required, evidence of certified/accredited penetration testing should be provided, which should include third party certification details and test reports. Where cloud-based software providers are utilised, there should be evidence in the technical file of the assigned responsible parties for post market surveillance and the reporting of security issues.
	Validation protocols and reports for special processes
	- Validation protocols/plans/reports for processes considered critical to the safety and performance of the device should be attached. - Revalidation criteria should be determined. - Justify whether the samples selected for validation fulfil the worst case scenario. - Test reports performed for validation shall document objectives, acceptance criteria, materials and methods, results, protocol deviations and conclusions.
	Reusability / Reprocessing - Class Ir - Reusable surgical instruments: *Cleaning, Disinfectant, Sterilisation Validation Protocols* *Cleaning, Disinfectant, Sterilisation Validation Reports*
	- Approved cleaning, disinfectant and sterilisation parameters must be specified in the user manual (the term "standard hospital practice" is insufficient). - The validation protocol and report for the sterilisation parameters specified in the IFU must be included in the technical documentation. - The verification protocol and report for the cleaning parameters specified in the IFU must be included in the technical documentation. - The performance assessment of the reusable product before and after processing should be included and should include the maximum number of cycles (cleaning, disinfection, sterilisation), taking into account the worst case conditions.
	Stability (real-time and accelerated) protocols and reports (including sterility, package performance, pre- and post-aging device performance test reports) *Stability/shelf life validation protocols (performance including both device and packaging)* *Stability/shelf life validation results and reports* *Transport validation*

	- Shelf life is different from service life. The period during which the device can be kept in its packaging is considered the shelf life. - Shelf life testing is not limited to the packaging. The device itself must also be subjected to a shelf life test or a justification must be provided to show why its characteristics are not expected to deteriorate over the claimed shelf life. - If the shelf life study is based on an accelerated ageing test, a real-time ageing test should also be included. - Shelf life extensions are critical changes and should be notified to us. - Shelf Life Validation should include: • Protocol (with acceptance criteria for each test performed) and appropriate test references, • intended shelf life, • A clear statement describing the sterilisation status of the test specimens, how many times they have been sterilised • A summary of how accelerated ageing parameters (temperature and humidity) and ageing times are calculated, •A statement covering real-time ageing plans and justification of how often sterility and product performance tests will be carried out,, • Clear definition of statistically significant sample sizes, • Actual physical/microbiological test data reports supporting the expiration date, or post aging, claim (peel testing, burst testing, dye testing, etc.); - Considering the worst case scenario, the product should be shipped under standard storage and transport conditions and a transport validation protocol/test report covering product functionality and post-transport packaging test etc. should be prepared.
	Instruments with measuring function Protocols for tests related to the determination of the correct measurement of the instrument, calibration, etc. Reports for tests related to determination of the correct measurement of the instrument, calibration, etc.
	If the device has a measurement function, test protocols and reports must be established to verify or determine the accuracy, precision, calibration, etc. of the device.
	Devices that need to be connected to other devices to function as intended and availability studies *If it will work in conjunction with another device, protocols should be prepared for tests to determine the safety and performance of the device and combination for interoperability* *If it will operate in conjunction with another device, reports should be prepared for tests to determine the safety and performance of the device and combination for interoperability*
	If the device must be connected to other devices to function as intended, test protocols and reports should be included that establish the safety and performance of the combination of devices, including interoperability and usability considerations.
	Usability
	A usability study must be carried out in accordance with EN ISO 62366, EN ISO 60601-1-6 standards. The usability study should include the following; -Identification of user interface features related to usage specification, security and potential usage errors, -Identification of known and foreseeable hazards and dangerous situations, -Identification and explanation of hazard-related usage scenarios, -Selecting hazard-related usage scenarios for summary evaluation, -User interface specification, -User interface evaluation plan, -User interface design and implementation, -Summary evaluation must be submitted.

	Usability-related risks should be identified and usability documentation should be aligned with the risk management process. It should include usability engineering (device design, user interface, displays, controls, etc.), information included with the device (warnings, operating instructions, maintenance guides, cleaning instructions, etc.), labeling information (including warnings, contraindications, symbols, etc.). Specific to devices intended for use by lay persons; Verification that the device is functioning as intended should be carried out, taking into account the skills of lay persons and the effects of misuse that may be foreseen in their environment. In addition, understanding and application of information and instructions specific to devices intended for use by lay persons must be ensured and validated. A brief description of the medical device should be included, including its operating principle, significant physical properties, important performance characteristics, and the intended user profile.
	Magnetic resonance imaging safety of implants MRI safety testing protocol MRI safety test results
	For the MRI safety of implants, test protocols, reports and labeling prepared in accordance with ASTM standards, harmonized and/or international standards should be documented.
	Subcontractors and suppliers
	-All critical suppliers must be submitted to us at the application stage. -Suppliers that affect the performance and safety of the product should be identified and risk-based assessments should be made. -If applicable, quality certificates regarding subcontractors and suppliers should be submitted. Material safety certificates and lot-based analysis certificates for raw materials must be provided by companies. The certificate of analysis must be checked by the manufacturer. -Contracts should be made with critical suppliers to clarify their responsibilities, and if a contract cannot be made, justification should be included.

11. GENERAL SAFETY and PERFORMANCE REQUIREMENTS and COMPLIANCE CHECKLIST	**Disclosures regarding all substances must be made in accordance with the Annexes or OSs of the relevant standard.** **Explanation for non-applicable items** **All referenced documents are included in the technical documentation**
	MDR Annex II Part 4 requires Technical Documentation to comply with the applicable General Safety and Performance Requirements (GSPRs) of Annex I: - An explanation of why GSPRs and others that apply to the device do not apply, - the method or methods used to demonstrate compliance with each applicable GSPR, - Harmonized standards, OS or other implemented solutions, - Controlled documents providing evidence of compliance with each harmonized standard, OS or other method applied to demonstrate compliance with the GSPR must include a cross-reference to the location of that document in the full technical documentation and summary technical documentation (if any). The more specific the references to documents supporting compliance, the faster the review can be performed. For example, references to an entire section such as "Validation file" are not "clear". Documentation must demonstrate that all common specifications (OS) and relevant standards, both harmonized and product-specific, have been taken into account. This is usually achieved through a list of applicable standards and OS, as well as reference to the appropriate standards and OS in appropriate documentation (e.g. test reports).

12. VIGILANCE	**Post Markt Surveillance (Procedure) (MDR Annex III)**
	The PMS procedure must be submitted according to MDR Annex III. **Post Market Surveillance data;** (Market History, worldwide and EU sales volumes, complaint data and trend analyses; vigilance data and trend analyses; data from other PMS sources) -Sales and complaints data must include sales outside the EU. Documentation must be provided so that sales and complaints can be evaluated by region. -Complaint data should be evaluated; Complaint rate Trend analysis Corrective preventive actions Incorporating PMS data into risk assessment Field Safety Corrective Actions Adverse event notifications/reports
	Post Market Surveillance Plan (MDR Annex III)
	A Post-Market Surveillance Plan (PMS Plan) should be provided for each device/device family, commensurate with product risk, lifetime and available clinical data. -The PMS plan should ensure that the security and intended performance of the device is monitored. -Post Market Surveillance procedure should be provided. The procedure and plan should be prepared separately from each other. The procedure refers to the manufacturer's quality system requirements and is general for all devices marketed by a manufacturer. The plan is specific to the device and can only be created based on data obtained from clinical evaluation and risk assessment for the device in question.
	Post-Market Surveillance Report (for Class I medical devices)
	For Class I devices, manufacturers must submit a PMS Report summarizing the results of post-market surveillance data analysis as a result of the PMS plan described above for each device or group of devices.
	Periodic Safety Update Reports (for Class II-a, II-b and IIII devices)
	-For Class III, IIb and IIa devices, manufacturers must prepare a periodic safety update report ("PSUR") summarizing the results of post-market surveillance data analysis as a result of the PMS plan described above for each device or group of devices. -PSUR must include all elements specified in MDR Article 86 and applicable MDCG guidance documents.
	Summary of Safety and Clinical Performance (for Class III and implantable devices)
	Summary of Safety and Clinical Performance (SSCP) Report; -According to MDR Article 32, all class III and implantable devices (except custom-made devices) require a SSCP. -The content of the SSCP Report should comply with the guidance provided in MDCG 2019-9 and take into account the following: All information provided in the SSCP must be traceable to technical documentation. Preferred languages must be confirmed for verification of SSCP with the notified body. The SSCP should be in PDF format, printable and searchable and should follow the template provided in MDCG 2019-9. The SSCP must be updated annually (in accordance with Article 61), as required throughout the life of the device if specified, and the SSCP data must be updated as post-market data are updated. For Class IIa implantable and Class IIb implantable WET (Well-Established Technologies) devices, the MDR allows notified bodies to select sample devices from each device category or general device group

	respectively for technical documentation assessment. SSCPs for sampled devices will be verified by the notified body as part of the technical documentation assessment. SSCP verified by the notified body must be specified by the manufacturer. MDCG 2019-9 requires notified bodies to also upload to EUDAMED unverified SSCPs of devices that are not selected as representative devices (but are part of the same device categories or generic device groups) and these will therefore need to be provided before the certificate is issued.
	Vigilance/ Recall (Procedure)
	Vigilance/recall procedures should be submitted in accordance with MDR Annex III.
	-Post-Market Clinical Follow-up Plan and Report **-Reason for not applying a Post-Market Clinical Follow-up Plan or PMCF** **- Post-Market Clinical Follow-up Report (Class III) or justification for not applying PMCF**
	PMCF plan; The content of the PMCF plan should, at a minimum, take into account the requirements of Annex XIV Part B and the template provided in MDCG 2020-7 by providing the following information: - General PMCF methods and procedures to be applied - Specific PMCF methods and procedures to be applied - If the PMCF plan includes a PMCF study, a detailed study protocol with statistical analysis plans and a clear statement from the manufacturer demonstrating its adherence to the PMCF plan must be provided. - If the PMCF plan does not include a PMCF study, a justification must be provided in accordance with MDR Annex III. **Post Market Clinical Follow Up (PMCF) Evaluation Report;** The content of the PMCF Assessment Report should comply with MDCG 2020-8 and take into account the following: - Any information obtained from previously conducted PMCF activities - The PMCF assessment report must include all general PMCF methods and procedures applied (Annex XIV) and specific PMCF methods and procedures applied (Annex XIV). - The report must describe the PMCF studies and evaluate the data against the current indication for use and include all models/variants.
	Have there been any cases of vigilance so far? **If it happened; how was the process managed?** **- Have the necessary information and reports been generated from the customer regarding the negative event?** **- Has the Ministry been contacted and received information about the outcome of the negative incident?**
	In case of a vigilance case, the whole process should be presented.

13. PRE-CLINICAL EVALUATION	**Biocompatibility and chemical characterization** **Standards and references applied for medical device related to biological evaluation**
	The standards and references used for biological evaluation should be stated.
	Formulation, description, production and use of medical device

	The description of the medical device formulation should be documented. A definition of the expected and intended biological effect should be achieved. Detailing the impact of the entire life cycle of the product on the biological evaluation should be reported. Detailing the use of the medical device in the target population, including claimed clinical performance, lifespan, shelf life and storage conditions should be documented.
	Classification of medical device: nature and duration of contact
	The location and duration of contact with the human body should be specified.
	Identification of potential biological risks / possible biological hazards of the medical device
	A toxicological risk assessment of the medical device must be carried out.
	Description of the physical and chemical properties of the product, material characterization test protocols and reports
	A material characterization protocol needs to be prepared. Comprehensive characterization of materials according to ISO 10993-1 (see ISO 10993-17 for toxicological acceptance levels), including potential device leaks, based on a literature review of available toxicological data on ingredients/adjuvants, should be reported. Copies of test reports performed in accordance with ISO 10993-18, if available, should be attached. Justification of the selection of tests to be performed for chemical characterization (representative of the device) and the test results performed, justification of the choice of solvent for chemical characterization should be reported. In cases where the potential for degradation exists, the degradation products and their effects on the body need to be discussed. Characterization of degradation products should be carried out according to ISO 10993-9 and subsequently 10993-13, 10993-14 and 10993-15, at different stages of the life cycle of the device, depending on the material involved. Copies of the articles used and the ISO 17025 accreditation of the testing laboratory should be attached. All material characterization test protocols and reports should be detailed. In particular, substances specified in Annex I GSPR 10.4.1 and containing substances that are carcinogenic, mutagenic or toxic to reproduction ("CMR") (in accordance with Part 3 of Annex VI of Regulation (EC) No 1272/2008) or substances with endocrine disrupting properties or, for devices incorporating them, justification of the presence of these substances It must meet the requirements of MDR. Special labeling requirements for these substances must also be met (GSPR 10.4.5). Where this information on CMR or endocrine disrupting substances is provided by suppliers, manufacturers must confirm that this information is complete and disclose the information and any additional testing or analysis performed to confirm the presence of these substances.

	Biocompatibility testing protocols and reports
	-The selection of biological tests needs to be detailed, and if there are biological tests that are not performed, their justification should be presented. As a result of the information obtained from the characterization/toxicological assessment and the toxicological risk assessment, biological testing may not be necessary if sufficient data are available for the biocompatibility of the product. -In cases where biological tests are performed; The test program needs to be determined. For each test defined in the test program; Description of the test method used, Which standard is applied, Adequacy of the testing laboratory, Justification of the selection of the test product representing the medical device, Test conditions, Obtained results, Evaluation of all tests, including the suitability of the tests performed, Report copies of all tests performed, Evidence of the testing laboratory's ISO 17025 accreditation or equivalence must be included.
	Overall biological safety assessment
	Biological safety assessments must be performed in accordance with ISO 10993-1. Biosafety assessments should be representative of the finished final device. (The sterilization process should also be taken into account if all materials and all manufacturing steps are present) An overall assessment should be made to demonstrate that all potential risks have been controlled to an acceptable level and the health benefit against any possible risks of injury or disease arising from the use of the device as intended by the manufacturer. Reference to the risk management file and evaluations of monitoring the analysis and controlling risk management should be included. Reference should be made to the data collected under Post-Market Surveillance (PMS) to confirm that these are taken into account in the biological risk assessment report.
	Curriculum Vitae of the assessors involved in the biosafety assessment
	A justification must be provided for the qualifications of those involved in the planning, conduct and analysis of the biocompatibility assessment.

	EN ISO 60601 series standards test reports and protocols for active devices
	Electrical Safety and Electromagnetic Compatibility (EMC) This section applies only to electrical medical device(s). The manufacturer must provide the following documents: **- Electrical safety test protocols & Electrical safety test reports** • Test protocols and reports must be provided for electrical safety testing. **- EMC test protocols & EMC test reports** • Test protocols and reports must be provided for EMC testing. Test protocols should be included as part of the test report. • Performed tests should be added. • For tests performed by a testing laboratory, test reports, certificates and proof of accreditation of the testing laboratory must be attached. • For safety tests, a description must be provided for the requirements for periodic tests and post-repair tests (e.g. EN 62353). • For in-house testing, evidence of the implementation of testing equipment/facilities and QMS procedures is required, as well as the competence of the relevant personnel. • If the device/system has an MRI safety claim, MRI safety testing (MDR Annex II) should be included. • If there is no change in the device; Where an assessment refers to an assessment report or any company document that is more than 5 years old, relevant data must be provided and a justification must be included explaining why it is still valid. Notes: • Documentation provided must describe the ESSENTIAL PERFORMANCE of the device and be consistent with risk management documentation (including analyses, plans and reports). Test reports should include evaluation of data and results. • If a subset of devices has been selected for testing and this subset is intended to represent a broader range of devices, justification must be provided that the configurations tested are representative of a broader set of devices/configurations. • Standards related to essential performance are standards in the 80601 series as well as the EN 60601 series, including EN 60601-1-2 for EMC and EN 60601- 1-6 and/or EN 62366 for usability • When the device is designed to be used sterile, electrical safety tests should be performed on the sterile device.İyonlaştırıcı radyasyon yayan cihazların ve elektrikli cihazların bu özelliklerle ilgili güvenliği dikkate alınmalıdır.
	Product performance and standard compliance
	-If the product has a relevant harmonized standard, a checklist is expected for its compliance with the standard. Protocols and reports of tests performed in accordance with the standard should be included. -If there is no standards, protocols and reports containing evidence of compliance with design requirements must be created to demonstrate the performance of the product.

	-The protocol and report must provide evidence for all variants/configurations of the device, covering interconnections to accessories and parts of the device. -The evidence must show compliance with the environmental conditions specified for the device and the useful life (or anticipated service periods) of the device. -If the device must be connected to another device(s) to function as intended, it must also provide evidence and test that it complies with general safety and performance requirements when connected to such device(s), taking into account the specifications specified by the manufacturer. For tests performed by a testing laboratory, test reports, certification and proof of accreditation of the testing laboratory must be attached. -If testing is carried out in-house by the manufacturer, evidence of the competence of the relevant personnel and validation of quality control test devices must be provided for in-house tests. Test reports; they should include acceptance criteria, materials and methods, protocol deviations, and results. If a sample was selected within the product group and that product or products were tested, the worst case scenario should be explained and it should be detailed that it covers all devices. If tests are carried out for compliance with the relevant standard, but there is no acceptance criterion in the standard, the company must create and justify its own acceptance criteria.
	Devices containing CMR or endocrine disrupting substances specified in MDR Annex I GSPR 10.4.1
	GSPR 10.4.1- 10.4.5 describes specific requirements for devices containing substances that are carcinogenic, mutagenic or toxic to reproduction and substances with endocrine disrupting properties. Information and/or test data regarding these requirements should be included in the technical documentation. This information can either be presented as a stand-alone section or included in other relevant sections, such as biocompatibility. If the evidence is based on published literature, manufacturers should consider the nature of their devices, intended use, contact with various body tissues and other substances, etc. should consider the applicability of these literature data to their own devices.

14. CLINICAL EVALAUTION PREPARED ACCORDING TO ANNEX XIV OF THE REGULATION	**Clinical evaluation plan**
	At a minimum, the Clinical Evaluation Plan should outline: -Identification of general safety and performance requirements that must be supported by relevant clinical data. -A specification regarding the intended use of the device. -Clearly stating the intended target groups with clear indications and counter-indications. -A detailed description of the intended clinical benefits to patients with relevant and established clinical outcome parameters. -Specifying the methods to be used to examine qualitative and quantitative aspects of clinical safety, with clear reference to the identification of residual risks and side effects. -An indicative list and specification of the parameters to be used to determine, based on the latest advances in medicine, the acceptability of the benefit-risk ratio for the various indications and the intended purpose or purposes of the device. -An indication of how to address benefit-risk issues regarding specific ingredients, such as the use of pharmaceutical, non-living animal or human tissues. -A clinical development plan. A clinical development plan must be provided for the device in accordance with Annex For deficiencies; Justification should be set out in the PMCF development plan with references to ongoing PMCF activities for legacy devices (and where applicable) or to the PMCF Plan described in Annex XIV. -Klinik gelişim planı, Klinik Değerlendirme Planının bir parçası olmalıdır.

	Literature search
	-Methodology for literature search should be determined. - A copy of all literature articles selected and analyzed in the clinical evaluation report should be included in the technical documentation.
	Clinical investigations
	If a pre-marketing clinical investigation was conducted, • Appropriate documentation (evidence that the ethics committee has been contacted and there are no objections, all regulatory approvals of the clinical investigation from all countries including non-EU, clinical trial plan, completed clinical trial report signed by principal investigators) • The final clinical investigation protocol must be consistent with the protocol submitted to the Competent Authority / if there have been any deviations from the protocol, justifications for these deviations must be submitted along with copies of the original and amended protocols. •A final report must be prepared showing that the requirements for all safety and performance endpoints have been met. When clinical investigations are conducted outside the EU, an analysis of whether the results are transferrable to the European population. A clear definition should be made of the statistical tools and techniques used in the analysis of clinical data within the scope of analyzes and overall clinical evaluation used in the design and conduct of clinical trials.
	Validity of the technique specified, clinical and bioequivalence with other devices, evidence of equivalence, appropriateness of non-equivalence and outcome data and similar devices *For Class III and implantable devices, compliance with MDR Article 61 should be investigated.*
	-If the clinical evaluation of the device is based on justification of the equivalence of comparative devices: detailed demonstration of equivalence regarding technical, biological and clinical properties and the intended use, information on all differences with comparable devices according to technical or biological factors should be provided. -Justifications for permitted differences must be presented with scientific evidence and this evidence must be provided separately. -For Class III and implantable devices: If the proposed generic device is manufactured by a different manufacturer, a copy of the contract signed between the two manufacturers that expressly allows full access to the technical documentation of the equivalent marketed device on an ongoing basis and evidence that the equivalent device is MDR certified must be provided.
	Clinical Evaluation Report
	Clinical evaluations are required for all medical devices. Representative clinical data should be provided for all indications and variants. Justifications for why one set of data is representative of another must be clearly demonstrated. If clinical investigation data are not available for the device in question and if the evaluation is based on the justification of equivalence of comparative devices, the justification should identify and discuss the potential clinical impact of any differences between the devices in question and the comparable devices according to the intended use, technical or biological factors (MDR Annex XIV). Manufacturers must include additional information necessary to demonstrate compliance with the requirements of MDR Article 61.5 for implantable devices and Class III devices, where equivalent. If the device is a system with multiple components, clinical evaluation should consider all components of the device. Similarly, clinical evaluation should consider accessories associated with the device.

	Justifications for clinical investigations not conducted or post-market clinical follow-up plan
	Pre-market clinical investigation may be required for devices that do not have suitable equivalents and/or for which there are insufficient data in the literature. In addition, for Class III devices and Class IIb implantable devices, pre-market clinical investigation will be required, except in the following cases: • Where the device demonstrates that it is equivalent to an already marketed device from another manufacturer and a contract has been made that expressly allows continued access to that manufacturer's technical documentation, • For listed device types where the clinical evaluation is based on sufficient data and is compatible with the relevant OS, • The device has been lawfully placed on the market or put into service in accordance with directives 90/385/EEC or 93/42/EEC, where the clinical evaluation and post-market surveillance data are based on sufficient clinical data and are compatible with the relevant OS, • Annexes XIV and XV describe clinical evaluation and clinical investigations, respectively. Also EN-ISO 14155 Medical For Human Subjects There is also a Clinical Investigation of Devices - Good Clinical Practice standard. The content of the PMCF plan must provide the following information and, as a minimum, take into account the requirements of Part B of Annex XIV and the template provided in MDCG 2020-7: -General PMCF methods and procedures to be applied -Specific PMCF methods and procedures to be applied -If the PMCF plan includes a PMCF study, a fully detailed study protocol must be prepared along with statistical analysis plans. -If the PMCF plan does not include a PMCF investigation, a justification must be provided in accordance with MDR Annex III.
	CVs and declaration of impartiality of the Clinical Evaluation Report Team
	-The CVs and declarations of impartiality of all persons (end user of the device, medical specialist in the relevant field, etc.) who conduct/approve the clinical evaluation appropriate for the device must be submitted.

15. LABEL and INSTRUCTION for USE	**Label & instructions for use that should be included in the technical documentation**
	The technical documentation must include all of the following: -The label or labels on the device and its packaging, such as single unit packaging, sales packaging, and, in the case of certain management conditions, transport packaging, must be in the languages accepted in the Member States where the device is intended to be sold; -Instructions for use in languages accepted in the Member States where the device is intended to be sold. -Legit versions of all applicable label levels must be provided (e.g. secondary package, primary package) and must represent the finished form by showing all symbols included. -If possible, drawings containing packaging configuration (showing placement of all labels) and label specifications should be provided. -The position of the labels on the finished product should be clear. If the device has sterile packaging, the label of the sterile packaging must be clearly identified. Packaging containing information for the user (device image, etc.) should be identified. -The website where the user manual and labeling information will be published Its URL must be specified. -If available, a definition of SSCP should be made on the label and instructions for use.

	Standards and/or OSs applied for labeling and user manual, where appropriate
	The specific requirements of the relevant harmonized standards or OS must be addressed on the labels and in the instruction for use. For example, EN 15223-1, EN 1041, EN 14602, EN 14630, EN 13795 etc.
	Compliance with MDR Annex-1 Chapter 3 Article 23
	Manufacturer Name, address Product name, type, model Production date, shelf life, expiration date Sterility status, method, sterilization status Information obligation under the responsibility of the manufacturer for products sold non-sterile and to be used sterile Storage conditions It should include security precautions information.
	Specification regarding reprocessing requirements stated on the Label/Instructions for Use
	-Reprocessing information for the disposable device and associated risk(s)/warning(s)/disposal method must be stated on the instruction for use/label. -The label must state 'reprocessed' and the status of the disposable device. ('disinfected' or 'sterilized' followed by the sterilization method or disinfection method and shelf life.) -The name and address of the healthcare provider and the external reprocessor must be clearly stated on the label and instructions for use of the disposable device. (Original manufacturer name and address should not be stated on the label/instruction for use.) - The maximum number of reprocessing cycles allowed and the number of reprocessing cycles performed must be clearly stated on the label. - The label must bear the CE mark.

16. DECLARATION of CONFORMITY	**Contents of the Declaration of Conformity**
	The declaration of conformity must meet the requirements of MDR Annex IV. - Manufacturing company - Name and registered trade name of the authorized representative - If the SRN has already been issued - European Union Representative with address of registered office - a statement that the EU declaration of conformity has been issued under its sole responsibility; - UDI-DI - the intended use together with the product name and trade name, product code, catalog number or, where applicable, other unambiguous references such as photographs, which allow the identification and traceability of the device covered by the EU declaration of conformity. Information allowing identification and traceability, with the exception of the product name or trade name, can be provided by the Basic UDI-DI referred to in point 3; - EMDN Code - Product class in accordance with the rules specified in the annex VIII - Conformity Assessment Method - References to any OS used - Notified Body (name and identification number) - CE certificate(s) - CE marking start date - Publication date and place - Signature (including name and title)

17. QUALITY SYSTEM COMMITMENT	**Quality System Commitment**
	-The manufacturer must have a commitment to fulfill the requirements of the quality system and to maintain the quality system completely and effectively.

18. DESIGN and DEVELOPMENT	**Design and Development History File** **Design and Development Plan** **Design and Development Inputs-Outputs** **Design and Development Review** **Design and Development Verification** **Design and Development Validation** **Design and Development Transfer** **Design and Development Evaluation**
	Manufacturers must demonstrate that design requirements are determined in accordance with the intended use, safety and performance requirements, risk assessments and relevant harmonized and other essential standards or OS. Design requirements must be matched to the intended use, performance and risks identified for the device. An understanding of the design stages applied to the device should be ensured. Design stages should be documented with meeting minutes and an informative report.

19. DEVICES CONTAINING A MEDICINAL PRODUCT WITHIN THE MEANING OF ARTICLE 1, SECTION 2 OF DIRECTIVE 2001/83/EC	- Including a medicinal product derived from human blood or human plasma as defined in Article 1 of Directive 2001/83/EC, when used separately, as a medicinal product as defined in Article 1(2) of that Directive A declaration must be prepared for devices that contain as an integral part a substance that is acceptable and assists the function of the device. -Documentation must identify the source of that substance and include data from tests carried out to evaluate its safety, quality and usefulness, taking into account the intended use of the device. For medicated products, there must be DMF, EDMF files and EDQM certificate. -The Medical file provided must comply with MEDDEV 2.1/3 and the Drug file must be a file independent of the Technical Documentation as it may be sent to a Competent Authority for further evaluation. -It should be clearly stated whether the device uses any medicinal substance or whether it is used with any medicinal substance. If the device is a system and contains more than one component, the components containing these medicinal substances must be identified.

20. MEDICAL DEVICE CONTENT DECLARATION	-When the medical device is used alone, the presence/absence or, if any, of drugs, non-viable or non-viable human-derived tissue or cells or derivatives, non-viable or non-viable animal-derived tissue or cells or derivatives, or CMR and/or endocrine disrupting substance or phthalate content. A declaration of the exact amount must be prepared.

21. IMPLANT CARD	Inside the implant card; -Device name, serial number, lot number, UDI, device model -Manufacturer's name, address and website, -Any warnings, precautions or precautions to be taken by the patient or healthcare professionals, -Expected lifespan of the device and -Information about all kinds of follow-up should be included. **** Sutures, staples, dental fillings, dental brackets, dental crowns, screws, wedges, plates, wires, pins, clips and connectors are exempt from the stated obligations.**

22. DEVICES COMPOSED OF SUBSTANCES OR OF COMBINATIONS OF SUBSTANCES THAT ARE INTENDED TO BE INTRODUCED INTO THE HUMAN BODY VIA A BODY ORIFICE OR APPLIED TO THE SKIN AND THAT ARE ABSORBED BY OR LOCALLY DISPERSED IN THE HUMAN BODY TO ACHIEVE	**Test design, complete test or study protocols, data analysis methods, test results with data summaries** Devices composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body to achieve their intended purpose (Rule 21, MDR Annex VIII), MDR Annex I, GSPR 12.2: For these devices, it requires consideration of the relevant requirements of Directive 2001/83/EC regarding absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and the potential for adverse reactions. -Notified body for devices that are systemically absorbed by the human body to achieve their intended use or the metabolic products of these devices; a scientific opinion is requested from one of the competent authorities appointed by the member states in accordance with Directive 2001/83/EC or from the EMA regarding the compliance of the device with the relevant requirements specified in Annex I of Directive 2001/83/EC. The following extra information is requested for the product group falling within the scope of this floating rule 21; -Presence of substances that are systemically absorbed or locally distributed -Identification of products that are systemically absorbed by the human body or locally distributed in the human body -Absorption, distribution, metabolism and excretion tests, toxicity tests -Test protocols and reports to determine the absorption, distribution, metabolism and excretion of these substances. -Test protocols and reports to determine local tolerance of these substances -Test protocols and reports to determine possible interactions of these substances or products of metabolism in the human body with other devices, medical products or other substances. -Test protocols and reports to determine the toxicity of these substances, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity, and reproductive and developmental toxicity