Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 1.1 Device Description and Specification	Please provide a detailed overview about the device including any combination(s) with other equipment(s). This enclose: - A description of the device, which should enable understanding of the design, packaging, sterilization, or other characteristics of the device. - Sufficient information to distinguish different variants of the device, and the intended purpose of different design features. (For example, if one variant of a device has a coating and another does not, what is the intended purpose of that coating, and why are both variants considered to meet the requirements for safety and performance?)			
Annex II, Section 1.1 a)	Product or trade name and a general description of the device including pictures and schematics, which should be provided wherever possible to enable an understanding of the device design features and intended purpose. The enclose also a reference list between the tradename of the equipment and the type number of the equipment (if applicable)			
Annex II, Section 1.1 a)	Intended purpose including any clinical claims The intended purpose or intended use should provide enough detail to explain the disease conditions the device is intended to treat or monitor, the basic principles of operation (i.e. intended users and environment), the intended patient population and the indications and contraindications of the device. • Indications and contraindications should be supported by objective evidence (e.g., evidence provided in the risk assessment and clinical evaluation reports). • The intended use must include use of the device as a “medical device” as defined by MDR Article 2 unless the device is a product without a medical purpose as listed in MDR Annex XVI. • Please ensure the intended use been described consistently throughout the file (e.g. in the IFU, risk management documentation, clinical evaluation report, and design requirements). • If the application includes a change to the intended use, all sections of the file must reviewed for potential impact. • For clarity it is suggested that this should be separate from the device description.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 1.1 a)	Intended users / intended use environment Identify the intended users of the device (i.e. medical professionals in a specialty, clinical nurses, lay persons, etc.).			
Annex II, Section 1.1 b) Annex VI, Part C	Basic-UDI-DI The Basic UDI-DI assigned by the manufacturer have provided. Additional guidance on Basic UDI-DI can found in the MDCG documents published on the EU Commission website.			
Annex II, Section 1.1 b)	The European Medical Device Nomenclature code (EMDN code; previously referred to as CND code) should be identified (not mandatory for Class III and IIb implantable non-WET devices).			
Annex II, Section 1.1 c)	The intended patient population			
Annex II, Section 1.1 c)	The medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;			
Annex II, Section 1.1 d)	principles of operation of the device and its mode of action, scientifically demonstrated if necessary;			
Annex II, Section 1.1 e)	the rationale for the qualification of the product as a device;			
Annex VIII Annex II, Section 1.1 f)	Please indicate the device classification and rationale per MDR Annex VIII. The rationale should address each point of the selected classification rule. If multiple classification rules apply, all should be identified and the strictest rules resulting in the higher classification shall apply. If the device contains multiple components that on their own might be classed differently, please note the higher classification shall apply. If the device is a Well-Established Technology (WET) as per Articles 52.4 and 52.5 of MDR, a rationale supporting the determination of the device as a WET should be included considering any published guidance available on such devices.			
Annex II, Section 1.1 g)	If the device enclose any novel features, provide detailed description of these feature(s) and their effect(s).			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 1.1 h)	A description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it; Note: The Technical Documentation should identify any accessory including these which are not included/delivered in/with the device, but which are necessary for its use.			
Annex II, Section 1.1 i)	A description or complete list of the various configurations/variants of the device that are intended to be made available on the market;			
Annex II, Section 1.1 j)	A general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;			
Annex II, Section 1.1 k)	A description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids; Where possible, it is recommended to provide an overview of the device, were all controls and their materials are identified including their classification regarding EN ISO 10993-1. It is also important to note that all materials must meet the relevant requirements (RoHS, REACH, PAC); corresponding evidence have to be included in the technical documentation.			
Annex II, Section 1.1 l)	Technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications. Therefore please provide: - Instructions for use / Device Operating Manual(s) it must ensured that information especially related to intended purpose, indications, contra-indications, and other safety related information such as side effects, warnings is aligned with similar information from other sections such as risk management, clinical evaluation etc. (see Annex I, Point 23)			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 1.1 l)	- Patient handbook Some devices incorporate all the information relevant for the patient/user within the IFU itself. Some devices are accompanied by a patient handbook with additional instructions specific to the patient, for example with devices (or parts, components of the devices) that are patient operated. - Physicians handbook If a separate physicians' handbook is relevant for the device. - Implant card information If applicable, the implant card and other information per Article 18 of MDR, and any additional information as specified in the MDCG guidance on Implant cards should be included. The location of the implant card within the device or system packaging should be clearly specified. The planned approach for translation of any information not in harmonized symbols should be described if applicable. - Electronic IFU (e-IFU) information If electronic IFU will be utilised, ensure compliance has been clearly outlined and evidence included to demonstrate compliance with all relevant aspects of Regulation 207/2012. - Copies of promotional materials Only marketing literature that mention that the device fulfils the requirements of CE marking or includes the CE mark itself is required to be provided. Supporting evidence should be provided in the relevant preclinical and clinical sections to substantiate any claims made in the labelling or marketing literature. - URL of the website GSPR 23.1 requires that information related to identification, and safety and performance of the device shall be made available and kept up to date on the manufacturer's website if the manufacturer has a website. The URL of the website where such information will be made available should be included.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 1.2	All submissions should be accompanied by a market history to enable an understanding of the context of device development. • If the device is new and has never been marketed by the manufacturer anywhere in the world, please state this explicitly. • For existing devices: - Ensure that a market history is provided indicating the nature and timing of any changes and that any associated documents (i.e. risk analyses, labelling, clinical evaluation reports, verification / validation data, etc.) account for these changes. - Provide evidence (e.g., DQS-Med file/project numbers of previous reviews) to demonstrate that DQS Med has been notified of all significant changes (if applicable). - For initial applications under MDR, please confirm whether the device has been previously marketed under MDD and whether any changes have been made in comparison to the MDD-certified device - Market history should include EU and approvals in other geographies. - If the device is a system, ensure that the number of units sold is broken down by device component and per year Provide Periodic Safety Update Report if applicable (see Annex III, Point 1.2 and Article 85-86) Provide an overview of identified similar devices available on the EU or international markets, if such devices exist.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
	VOM HERSTELLER ZU LIEFERNDE INFORMATIONEN			
Annex II, Section 2, 1. intend Annex I, Pkt. 23.2, 23.3	The label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold. These labels include: - Devices or product labeling - Labeling of the sterile packaging - packaging labeling - Labeling the sales packaging - Identification of the transport packaging			
Annex II, Section 2, 2. intend Annex I, Pkt. 23.1, 23.4	The instructions for use in the languages accepted in the Member States where the device is envisaged to be sold. The content must comply with the requirements of Annex I, points 23.1, 23.4, and any additional requirement from harmonized standards.			
	DESIGN AND MANUFACTURING INFORMATION			
Annex II, Section 3 a)	Information to allow the design stages applied to the device to be understood has to be provided. This includes a description of the design phases the device has gone through and the history of any major changes to the design. For previously marketed or “legacy” devices certified under the Directives and applying for MDR certification, it is necessary to provide the following: • any changes in the design of the device as approved under the Directives vs the application under MDR • an explanation and a map of previously conducted testing and outline what testing is relevant to the current version of the device. If historic testing is referenced but a subsequent change was made and only some specifications were re-tested, please explain what test reports have superseded and should be reviewed for each relevant specification.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 3 b)	Overall, manufacturers should demonstrate that design requirements have been identified in accordance with the intended use, safety and performance requirements, risk assessments, and relevant harmonised and other key standards or CS. The source of design requirements should be indicated. Although compliance to harmonised and other key standards is expected, please be aware that testing beyond that required by the standards may be necessary to demonstrate compliance of your device to the relevant Safety & Performance Requirements. Design requirements should be mapped to the intended use, performance and risks identified for the device.			
Annex II, Section 3 b)	A detailed overview of the manufacturing processes should be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes. This also includes the process descriptions, work instructions, test instructions (e.g. for the final inspection), including the calibration process and calibration evidence of the used measuring and testing equipment. If automated processes are used at relevant points in the course of production or final testing, there must be an assessment of whether this is a critical process (or software). If so, this process (or software) must be validated. The corresponding documents (e.g. specification of requirements, validation plan, validation approval) including reports or protocols must be submitted. In principle, if one of the information requested in the "Production" section is not available in German or English, the manufacturer should provide either translations or supplementary summary reports with translations of relevant information / sections or in cases where the information / reports are data-intensive (or the manufacturer can annotate translations of relevant words in the reports).			
Annex II, Section 3 b)	Site with Design responsibility The site(s) responsible for design should be clearly identified. This may be the same as the legal manufacturer or may be another internal or external subcontractor site. If a site other than the legal manufacturer is responsible for design provide copies of their ISO 13485 certificates (see also 3.4.5 below)			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 3 b)	Please identify critical verified processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document. As a part of the initial submission, Manufacturer should include verification protocols/plans/reports for processes that are verified (as opposed to validated) and are considered critical for the safety and performance of the device. BSI Reviewers may request this information for other verified processes (not originally included with the submission) during the review process if required.			
Annex II, Section 3 b)	Please identify the critical validated processes. If verified and validated processes are documented in an overall Master Validation plan, please provide this document. As a part of the initial submission, Manufacturer should include validation protocols/plans/reports for processes that are validated and are considered critical for the safety and performance of the device. DQS-Med Reviewers may request this information for other validated processes (not originally included with the submission) during the review process if required.			
Annex II, Section 3 b)	Incoming / outgoing goods Inspections MDR Annex VII Section 4.5.3 2nd indent requires that NBs examine the implementation by manufacturers of incoming, in-process and final checks and their results as a part of Technical Documentation assessment. So, Technical Documentation should include the following: • Acceptance criteria & results of incoming inspections from a sample batch for the critical raw materials and/or sub-assemblies and/or components • Acceptance criteria & results of in-process inspections from a sample batch for the critical processes identified in sections 3.3.2 and 3.3.3 above • Acceptance criteria & results of final inspections from a sample batch for the finished devices • Identification of party responsible of inspections of subcontracted processes.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 3 b)	Installation and Commissioning tests If the device is required to be installed and/or commission at the user location, provide information on tests to be carried out as a part of the installation and commissioning of the device.			
Annex II, Section 3 c)	Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed. A detailed overview of the manufacturing processes must be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes The name and address of any critical subcontractors or crucial suppliers (as per Commission Recommendation 2013/473/EU) should be identified, along with the service or material supplied by each. Provide copies of critical subcontractor ISO 13485 certificates. If a critical subcontractor does not have an ISO 13485 certificate from a Notified Body, additional supplier audits may need to be arranged (see Section 6.4 of the main document for further information). If you have changed a supplier please include a justification for identifying the supplier as a Critical Subcontractor, Crucial supplier or neither based on the guidance in MDF4102. If you remove a supplier, please provide a justification for removing them.			
Annex II, Section 3 c)	Legal Manufacturer (as per EUDAMED registration) The application should identify the name and location of the legal manufacturer who is placing the devices on the market. This should be consistent across the device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the legal manufacturer should be identified.			
Annex II, Section 3 c)	European Representatives The name and location of the EU Authorised Representative should be identified if required. Only one EU Representative should be identified, and this should be consistent across the device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the EU Authorised Representative should be identified.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 3 c)	Site with Design responsibility The site(s) responsible for design must clearly identified. This may be the same as the legal manufacturer or may be another internal or external subcontractor site. If a site other than the legal manufacturer is responsible for design provide copies of their ISO 13485 certificate.			
	General Safety and Performance Requirements (GSPRs)			
Annex II, Section 4 Annex I	MDR Annex II Section 4 requires the Technical Documentation to include a demonstration of conformity with the applicable General Safety & Performance Requirements (GSPRs) of Annex I. Please indicate which Regulations and / or Directives apply. If a device is governed by multiple regulations or directives, all applicable regulations / directives should be identified. For example: • If the device is intended to be used in accordance with both the MDR and Regulation (EU) 2016/425 (previously 89/686/EEC) for personal protective equipment, ensure that fulfilment of the relevant basic health and safety requirements of (EU) 2016/425 have been met. • If the device is also machinery (within Article 2a of 2006/42/EC), ensure fulfilment of the relevant basic health and safety requirements of Directive 2006/42/EC Annex I have been met. • If the devices have been impacted by subsequent directives / regulations (e.g. 2005/50/EC, 2003/12/EC, 722/2012, 207/2012) ensure that these are identified, and any new requirements met.			
Annex II, Section 4 a)	The basic safety and performance requirements applicable to the product and an explanation as to of why other requirements do not apply. This can made using a checklist that contains clear references to the associated verification documents and identifies applied standards, guidelines and guidance documents.			
Annex II, Section 4 b)	The method (s) used to demonstrate compliance with the individual applicable basic safety and performance requirements must named.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 4 c)	The applied harmonized standards, GS or other solutions have to be identified. This can made using a table that clearly identify (incl. revision date) the applied standards. This table should also identify observed guidelines and guidance documents.			
Annex II, Section 4 d)	The precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS, or other method applied to demonstrate conformity with the GSPR. This shall include a cross-reference to the location of that document within the full Technical Documentation and summary Technical Documentation (if applicable). The more specific the references are to documents supporting compliance, the faster the review can be conducted. For example, references to an entire section such as “Design Verification Testing” are not “precise” and all testing may not truly be applicable to each of the GSPRs. It is recommended that the above information is provided in the form of a checklist against the GSPRs to show how compliance with the GSPRs has been achieved.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
	BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT			
Annex II, Section 5 a) Annex I, Section 1 and 8	A complete risk management file covering all aspects including product development, manufacturing, application and disposal must be submitted. The assessment must demonstrate that the benefits outweigh all the residual risks when the device is used as intended. Usually this file consists of: - a description of the risk management process - Risk management plan - Description of the risk assessment system - Design risk assessment - Risk assessment of the manufacturing / manufacturing process - Clinical / application / product related risk assessment - Risk / benefit analysis - Risk management report			
Annex II, Section 5 b) Annex I, Section 3	The selected solutions and the results of risk management are to be documented in accordance with Section 3 of Annex I.			
	PRODUCT VERIFICATION AND VALIDATION			
Annex II, Section 6.1	Pre-clinical and clinical data			
Annex II, Section 6.1 a)	results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;			
Annex II, Section 6.1 b)	detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions have to be provided			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 1. intend	Bio-Compatibility Please provide a biological safety risk assessment for the device. As specified, this may either be a stand-alone document or part of the risk management section. The external laboratories used to comply with normative requirements (e.g. ISO 10993 series) must be accredited for this activity. Biological safety assessments should include evidence of compliance for the finished device (including consideration of all materials and all manufacturing steps). It is not enough to simply state that devices have been manufactured from materials of well-established biological safety – an assessment which considers the impact of manufacturing and sterilisation processes, intended use, etc. must be provided. The assessment should categorise the nature and duration of body contact for each component and identify any tests that are required or can be waived to establish evidence of compatibility. Justifications must be included for any tests that have been waived.			
Annex II, Section 6.1 b), 2. intend	physical, chemical and microbiological characterization;			
Annex II, Section 6.1 b), 3. intend	Please provide the test protocols and reports for electrical safety testing, if applicable to the device. Ensure the provided documentation clearly defines the ESSENTIAL PERFORMANCE of the device and is in line with the risk management documentation. Evidence of electrical safety of the product and compliance with the requirements regarding electromagnetic compatibility (if applicable) must be provided. This can be done by submitting test reports from accredited laboratories or by test reports prepared by the manufacturer on their own responsibility. In the latter case, the manufacturer's own laboratory must meet the same requirements that are placed on an accredited laboratory (e.g. GMP, ISO 17025: 2018), which will be part of the subsequent audit. If a subset of devices has been selected for testing and this subset is intended to represent a larger range of devices, provide supporting documentation that demonstrates how the configurations that have been tested can be considered representative of the wider set of devices/configurations.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 3. intend	Magnetic resonance imaging safety of implants MR safety of implants must be established following relevant harmonised and/or international standards such as ASTM standards. Include test protocols, reports and associated labelling (if not already included in the labelling section above) • MRI safety characterisation should be undertaken according to the ASTM standards or ISO/TS 10974:2018 as appropriate depending on the nature and classification of the device. This information must be related back to the safety and performance requirements of the device while allowing a clinically acceptable MRI to be performed. If this Technical Specification is not used as guidance, justification should be provided for the validity of assessment methods and conclusions. • The guidelines of the Design Verification section of this document should generally be applied during the MR safety assessment. • If RF test results are considered representative of a group of devices (i.e. worst-case devices or comparative devices) extensive justification should be provided, typically including objective evidence. • An MRI safety assessment summary should be provided, with evidence that hazards associated with each clause of ISO/TS 10974:2018 have been assessed and appropriately mitigated if necessary. • Labelling/IFU related to MRI safety should be provided. Details of any assumptions and configurations used in the assessment should be disclosed in the labelling/IFU. It is important that the labelling/IFU clearly communicates which scenarios and configurations have been shown to be safe and which are untested. • Evidence that any safety critical labelling/IFU is clear and correct and can be accurately interpreted by the typical user (MR technologists and/or radiologists), should be provided. • Assessment of the clinical benefit of allowing patients to get MRI vs. the residual risk			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 4. intend	Verification and validation of the software This area of software validation affects to software that is used on medical devices or is a stand-alone medical software. Software that is used in the course of the manufacturer for final inspection of the products and that may be considered to be subject to validation must also be validated. Appropriate documentation is required if the medical devices are either standalone software or based on software. Please submit a checklist against the requirements of EN 62304. If medical device is stand-alone software, guidance for the qualification and classification of the software can be found in MDCG 2019-11 and Classification guidance documents. There should be a rationale for why the software is a medical device and for its classification. If applicable, the software should be broken down into modules, some that have a medical purpose and some that do not. The modules with a medical purpose must comply with the requirements of the medical device directives and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices. Ensure all relevant harmonised and non-harmonised software standards have been considered. Ensure the software systems/modules/items have been assigned safety classifications based on standards. Include documentation on the medical device software life-cycle processes implemented (e.g. software design/development, maintenance/change management, risk management, configuration management, problem resolution, verification, and validation processes). If software is intended to be used with mobile computing platforms, include information on specific features of mobile platforms demonstrating compliance with GSPR 17.3.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 4. intend	- Software development plan Include software development procedures and the software development plan (SDP) detailing the activities completed as part of the software development lifecycle (e.g. software requirements specification, software architecture, software detailed design, software unit testing procedures/reports, software integration testing procedures/reports, and software system testing procedures/reports). Documentation related to the software maintenance and software configuration management processes should also be provided (e.g. software maintenance plan, configuration management plan). Note: Some documentation may or may not be required per the standards based on software system/module/item risk classification.			
	- Software requirements analysis Include the software requirements specification (SRS). An explanation regarding how the software requirements have been derived from higher level system requirements should be included and traceability to those higher-level requirements should be established. Risk controls implemented in software should also be included in the SRS. Software requirements should be clearly stated, unambiguous, and should be readily translatable into verification acceptance criteria. NOTE: See EN 62304 Clause 5.2.2 for generally expected categories that should be covered in the software requirements specification.			
	- Software architectural design Include the software architectural design (SAD). The SAD is generally represented graphically (e.g. class diagrams, block diagrams, etc.) and shows how the software requirements per 6.3.3 are allocated to the SOFTWARE ITEMS that comprise the overall SOFTWARE SYSTEM. The following major areas should be addressed in the software architectural design: (1) Internal and external interfaces of the software; (2) Inclusion of any Software of Unknown Provenance (SOUP); (3) Segregation measures that may be necessary for risk control purposes.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 4. Intend	- Software detailed design For EN 62304 Software Safety Class ‘B’ and ‘C’ software, include the software detailed design (SDD). The software detailed design (SDD) represents a further refinement of the software architecture described in 6.3.4. The SDD should clearly identify the SOFTWARE UNITS that are derived from the SOFTWARE ITEMS specified in the software architecture. The SDD should provide details regarding the function and expected inputs and outputs of the SOFTWARE UNITS. In general, the SDD should provide enough detail to allow correct implementation of the SOFTWARE UNITS and their expected interfaces.			
	- Software unit implementation and verification For EN 62304 Software Safety Class ‘B’ and ‘C’ software, include evidence of SOFTWARE UNIT verification. These may include unit test protocols/scripts and associated reports. Note that this type of testing is usually considered “white box” testing in that detailed knowledge of the underlying software code is usually required to properly design the unit verification tests. Where automated testing has been used to perform verification activities, include the test scripts and the test log results in the submission documentation.			
Annex II, Section 6.1 b), 4. intend	- Software integration and integration testing For EN 62304 Software Safety Class ‘B’ and ‘C’ software, include evidence that software integration testing has been performed. Please note that this testing should be aimed at showing how the SOFTWARE ITEMS (which are internal to the SOFTWARE SYSTEM) function as expected when integrated together. Areas to investigate can include, for example, expected timing, functioning of internal and external interfaces, and testing under abnormal conditions/foreseeable misuse. This testing is typically not conducted on the final, compiled code and will normally make use of a test/simulation environment where various combinations of SOFTWARE ITEMS can be tested in isolation. It is permissible to combine software integration testing with software system testing (per 6.3.8 below). Where this strategy has been employed to cover the requirement to perform software integration testing, this should be clearly explained in the submission documentation. Where automated testing has been used to perform verification activities, include the test scripts and the test log results in the submission documentation.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 4. intend	- Software systems testing Include the software system test protocol(s) and report(s). This testing should demonstrate that each of the software requirements (per 6.3.3) have been verified. It is expected that traceability between the software requirements and the software test cases/test procedures should be established. This testing is typically conducted on the final, compiled SOFTWARE SYSTEM. Input stimuli, expected outcomes, pass/fail criteria, and test procedures should be clearly established in the test documentation. Where test failures or deviations have been encountered, these should be clearly documented and justified in the provided reports. Where automated testing has been used to perform verification activities, include the test scripts and the test log results in the submission documentation.			
Annex II, Section 6.1 b), 4. intend	- SW-Release Include the list of known residual anomalies. The following information on each remaining anomaly should be included: • Unique Identifier • Brief description of the issue • Severity/Risk Level • Justification for why it is acceptable to release the software with the anomaly Also include documentation showing how the released software was created (e.g. procedure and environment used create the released software). The final released software version number should be identified in this documentation. Documentation explaining how the released software is archived and how it can be reliably delivered (e.g. to the manufacturing environment or to the user of the software) should be included.			
Annex II, Section 6.1 b), 4. intend	- Software risk assessment Include software risk assessment documentation (e.g. software hazard analysis, software failure mode and effects analysis, fault tree analysis, traceability). Note: Some documentation may or may not be required per the standards based on software system/module/item risk classification.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 4. intend	- Cybersecurity documentation Include documentation related to the design and maintenance of the cybersecurity features of the medical device. Documentation should include the security risk management plan, security risk assessment, and verification/validation evidence for the identified security risk controls. Threats and the associated protections needed to ensure the confidentiality, integrity, and availability of the data, function and services of the medical device should be considered. Documentation showing how cybersecurity threats are monitored and responded to as part of the post-market surveillance of the device should also be provided. NOTE: See MDCG 2019-16 Guidance on Cybersecurity for medical devices.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 5. intend	Stability/shelf-life validation protocols (to include both device and packaging performance) • Shelf life is normally considered to be the time the device can be kept in the packaging prior to its first use. This is not the same as “Lifetime”. • Shelf-life testing is not restricted to the packaging. The device itself should be subject to shelf life testing, or a rationale provided to demonstrate why its characteristics are not expected to degrade over the claimed shelf life. • If shelf life testing is based on accelerated age testing, this should be accompanied by a plan for real time testing. Real time testing should be underway by the time documentation is submitted for review. • Extensions to shelf life for Class III devices and Class IIb implantable devices (non-WET) must be reported to DQS-Med for review and certificate re-issue. Shelf Life Validation should include: • Protocol (with acceptance criteria for each test performed) and appropriate test references; • A clear statement of the intended shelf life; • A clear statement defining the sterilisation status of the test samples (1X, 2X sterilised); • A summary of the accelerated aging parameters (temperature and humidity) and how the aging times were calculated; • A statement covering Real Time Aging plans; • A clear delineation of statistically significant sample quantities; • Actual physical/microbiological test data reports supporting the expiration date, or post aging, claim (peel testing, burst testing, dye testing, etc.); • A summary of the ship testing/transit simulation testing conducted and applicable test reports.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 6. intend	Performance and Safety – Design Verification and Validations A design verification / validation strategy document and / or summary of the outcomes should be provided. Verification / validation results should be provided for each design requirement. If compliance has been demonstrated without testing, an appropriate rationale should be provided. For legacy products refer also to Section “Annex II, Section 3 a)”			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 b), 6. Anstrich	Test reports should document objectives, acceptance criteria, materials & methods, results, protocol deviations, and conclusions. If test results are considered representative for a group of devices (i.e. worst-case devices or comparative devices), then a justification for leveraging protocol(s) and report(s) should be provided. Similarly, if testing has been undertaken on prototypes, previous generations of a device, or devices that otherwise do not represent the finished goods, a justification for the adequacy of this testing should be provided. If multiple design verification / validation studies were conducted, please provide a flow chart or table that shows how the studies were conducted and highlight which study ultimately demonstrates that the design meets the product performance specifications. For line extensions or devices based on “existing” devices, it may be possible to leverage data from testing undertaken on the existing devices. In this case, a rationale for the use of existing data must be provided, including: • Evidence of equivalence to the comparative devices – a table showing the similarities and differences greatly speeds the review process. Key things to consider include (but may not be limited to): - Materials of construction - Indications for use - Methods of manufacturing - Key design features • An evaluation of the impact of any differences on clinical safety, performance, and testing undertaken. The evaluation should support the conclusion that the new devices do not represent a worst case in terms of testing as compared to the devices tested. Please provide the protocols and results for design validation studies.			
Annex II, Section 6.1 b), 6. Anstrich	Please provide the protocols and results for usability studies.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
	The lifetime of the device should be defined and considered relative to other parts of the dossier (e.g. risk management, clinical evaluation, PMS). Product lifetime is normally considered as the time from first use until the device ceases to fulfil its intended use. This is not the same as “Shelf Life”.			
	Please clearly define how sample sizes have been determined and the rationale/ justification for the sample sizes. If the rationale is documented in a procedure provide the relevant procedure.			
Annex II, Section 6.1 c) Article 61, Absatz 12 Annex XIV, Part A	Please explain the clinical development strategy for the device. This stragedy must enclose (at least) the informationen, statet in VO2017/75, Annex XIV, Part A, Section 1 a) final intended. Clinical evaluations are required for all medical devices. Representative clinical data must be provided for all indications and variants. Justifications for why one group of data is representative of another must be clearly substantiated. If no clinical investigation data are available for the subject device and the Clinical Evaluation relies on a justification of equivalence of comparative devices, the justification must identify and discuss the potential clinical impact of all differences between the subject and comparable devices relative to intended use, technical, or biological factors (MDR Annex XIV Sec. 3). In the context of equivalence, Manufacturers should also include any additional information necessary to show compliance with the requirements of MDR Article 61.5 for implantable devices and Class III devices. If the device is a system with multiple components, the clinical evaluation must consider all the components of the device. Similarly, the clinical evaluation must give due consideration to the accessories associated with the device. A justification should be provided (with appropriate evidence) to substantiate the qualifications of individual(s) conducting / approving the clinical evaluation.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.1 c) Article 61, Absatz 12 Annex XIV, Part A	For devices without suitable equivalents and / or insufficient data in the literature, pre-market clinical investigation may be required. In addition, for Class III devices and Class IIb implantable devices, pre-market clinical investigation will be required unless: • The device is demonstrated to be equivalent to another of the manufacturer's own devices with sufficient clinical data available demonstrating conformity with the relevant GSPRs • The device is demonstrated to be equivalent to an already marketed device of another manufacturer and a contract is in place explicitly allowing ongoing access to that manufacturer's Technical Documentation • For listed device types where the clinical evaluation is based on sufficient data and in compliance with relevant CS • The device had been lawfully placed on the market or put into service per Directives 90/385/EEC or 93/42/EEC, where the clinical evaluation is based on sufficient clinical data and is in compliance with any relevant CS; • Annex XIV and XV describe Clinical Evaluation and Clinical Investigations, respectively. Guidance is also available in EN-ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice If a pre-market clinical investigation has been conducted, please ensure: • appropriate documentation (CIP, letter of "no objection" from the Competent Authority, evidence of Ethics approval, final report, etc.) is provided; • the final clinical trial protocol agrees with that submitted to the Competent Authority, and evidence that any deviations have been agreed with the CA has been provided; • the final report demonstrates that requirements for all safety and performance endpoints have been met; • there are no open clinical investigations relevant to your devices with endpoints related to safety or performance claims. A clear description must be provided of the statistical tools, techniques, analyses used in the design and conduct of clinical investigations, and analysis of clinical data within the overall clinical evaluation. A copy of all literature articles selected and analysed within the clinical evaluation report should be included in the Technical Documentation.			

Annex II, Section 6.1 c) Annex XIV, Part A	For Class III and implantable devices other than custom-made or investigational devices, a Summary of Safety & Clinical Performance (SSCP) per Article 32 must be provided in the Technical Documentation. • The SSCP should be written clearly and understandable to the intended user and patient (if relevant) and should contain all the elements listed in MDR Article 32, Sec 2. • Please consult current available guidance for SSCP content and format as per MDCG 2019-9. • A draft SSCP in English is acceptable at the time of initial submission. • Once the SSCP has been finalised based on DQS-Med review, Manufacturers should submit the final version of the English SSCP, which is in pdf format and is printable, searchable before a certificate recommendation can be made. • The SSCP should be updated annually (as per Article 61), if indicated, over the lifetime of the device as needed, and updates should be defined in the Post-Market Surveillance Plan. For Class IIa implantable and Class IIb implantable WET (Well-Established Technologies) devices, MDR allows NBs to choose representative devices from each device category or generic device group respectively for the assessment of Technical Documentation. The SSCPs for such devices chosen as the representative samples will be validated by the NB as part of the Technical Documentation assessment for those devices. The MDCG document 2019-9 requires that NBs also upload the unvalidated SSCPs of the devices that were not chosen as representative devices (but are part of the same device categories or generic device groups) to EUDAMED. Hence Manufacturers may submit these unvalidated SSCPs at any time during the certification process to DQS-Med, but before a DQS-Med Certifier prepares and makes a recommendation for certification based on the completion of all the required conformity assessments (including Technical Documentation assessment) for the relevant device categories or generic device groups. (The MDCG guidance on SSCPs, MDCG 2019-9, also includes several requirements related to languages, translations of SSCPs depending on the Member State requirements related to languages and the availability of translated SSCPs on EUDAMED prior to placing affected devices on the market within these Member States. Manufacturer's processes/procedures related to making the translated SSCPs available to DQS-Med (for the NB to upload these to EUDAMED) and ensuring that they are available on EUDAMED			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
	prior to placing the devices on the market within these Member States will be audited as part of the DQS-Med QMS audits)			
Annex II, Section 6.1 d) Article 61 Annex XIV, Part B	Please provide a PMCF plan including all necessary elements outlined per Part B of MDR Annex XIV and any applicable MDCG guidance documents. If the PMCF plan includes a PMCF study, include the study protocol. Include any information and reports from PMCF activities previously carried out. This should clearly identify the PMCF study, which products are included and the applicable indication of use. In cases with multiple products and studies a table is preferable. The Notified Body may be required to periodically review results from ongoing or completed PMCF studies following CE mark certification, including a specialised clinical evaluator in some cases.			
Annex II, Section 6.2 a)	Devices incorporating medicinal substances The Medicinal dossier provided should comply to MEDDEV 2.1/3 and follow CTD headings in a bookmarked format. The Medicinal dossier will be a standalone dossier to the Technical Documentation as it may be sent to a Competent Authority for further assessment. The submission should clearly indicate whether the device utilises, or is used in conjunction with, any medicinal substances or substances absorbed by or locally dispersed in the human body. If the device is a system and includes multiple components, then identify the components which incorporate these medicinal substances. Devices which incorporate medicinal substances or substances absorbed or locally dispersed may be subject to requirements of additional European Directives / regulations. Additional review resources may be required, including external independent reviewers and/or Competent Authority consultation and/or a European Agency for the Evaluation of Medicinal Products (EMA). Some EU Competent Authorities require that the IFU and labels are included in the CTD format Medicinal dossier that is submitted to them for carrying out the consultation process. Please include a copy of the device labels and IFU within the Medicinal dossier.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.2 b) Annex I, Section 13.3 Annex I, Section 23.3, 23.4	Devices utilising tissue and cells of human or animal origin or their derivatives or other non-viable biological substances (as per GSPR 13.3) The submission should clearly indicate whether the device utilises or contains any human or animal- based products or other non-viable biological substances. If the device is a system and includes multiple components, then identify the components which incorporate these substances. Manufacturing subcontractors should be consulted if appropriate to establish if any such substances are used during manufacture, even if they do not feature in the final device (e.g., lubricants or mould release agents which may use animal derived substances). The manufacturer should request evidence of compliance to ISO 22442 or EU 722/2012 or for any applicable exclusions (e.g., tallow species and processing method utilised) from the subcontractor. If in doubt, speak with your Scheme Manager before submitting a dossier. Devices which incorporate human or animal-derived substances may be subject to requirements of additional European Directives / Regulations. Additional review resources may be required, including external independent reviewers and/or Competent Authority consultation and/or a European Agency for the Evaluation of Medicinal Products (EMA). Manufacturers must ensure that the labels and IFU submitted in Section 2 above include relevant information related to the human or animal tissues or cells or derivatives utilised or contained in the device as per GSPR 23.2 and GSPR 23.4.s.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.2 c) Annex VIII, Rule 21 Annex I, Section 12.2	Devices composed of substances that are absorbed by or locally dispersed in the human body (Rule 21 devices) GSPR 12.2 requires that for devices that are composed of substances that are absorbed by or locally dispersed in the human body (as per Rule 21 of MDR Annex VIII) manufacturers consider the relevant requirements of Directive 2001/83/EC in relation to absorption, distribution, metabolism, excretion (commonly referred to as ADME profile), local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions. Information and/or test data related to these requirements should be included in the Technical Documentation. If evidence is based on published literature, manufacturers should rationalise the applicability of such literature data to their own device considering the nature of their device, intended purpose, contact with various body tissues and other substances etc.			
Annex II, Section 6.2 d) Annex I, Section 10.4.1 – 10.4.5	Devices containing CMR or endocrine-disrupting substances referred to in GSPR 10.4.1 of Annex I of MDR GSPRs 10.4.1 - 10.4.5 describe specific requirements for devices that contain substances which are carcinogenic, mutagenic or toxic to reproduction and substances having endocrine-disrupting properties. Information and/or test data related to these requirements should be included in the Technical Documentation. This information may be provided either as a stand-alone section or incorporated into other relevant sections such as biocompatibility, labelling etc. If evidence is based on published literature, manufacturers should rationalise the applicability of such literature data to their own device considering the nature of their device, intended purpose, contact with various body tissues and other substances etc.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.2 e)	Products that are placed on the market in sterile condition or with a defined microbiological status: • Appropriate rationales are required if sterilisation validation is by adoption into an existing family or sterilisation validation. • Devices for End-User-Sterilisation also require review of cleaning and sterilisation validation / adoption with respect to parameters recommended in the IFU. • Documents should describe: - use of “State of the art” process validation methods - the bioburden controls and monitoring - the product qualification (Dose verification, BI suitability testing, SAL calculations) - the process qualification (Performance qualification, Dose Map, BI Inactivations) Additional guidance relating to specific document types is provided below: **Sterilization Validation – Radiation should include:** • Protocol • Dosimetry mapping data (typically from the sterilization contractor) • Validation of bioburden testing method & test report • Bioburden determination & test reports • Calculation or determination of verification dose and full dose • Validation of product sterility testing method & test report • Sterility testing of verification dose samples & test report **Sterilisation Validation – Ethylene Oxide should include:** • Protocol • Summaries regarding commissioning of the sterilisation equipment • Validation of bioburden testing method & test report • Bioburden determination and test reports • Biological indicator data • All cycle data and test reports (fractional, half, full) • Validation of product sterility testing method & test report • Product sterility testing & test report • Sterilant residual analysis reports			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.2 e)	aa) Packaging of equipment delivered sterile Descriptions of the packaging of the sterile goods, enclosing the structure (primary and secondary packaging) as well as the labeling must be submitted. In addition, descriptions of the packaging process, the validation of the used machinery, packaging tests, life tests with regard to sterility, etc. must submitted. b) End User Sterilisation Product documentation should include: • Instructions for use that detail the validated sterilisation and cleaning parameters. Please be aware that reference to “standard hospital practice” is insufficient • Validation protocol and report for the sterilisation parameters listed in the IFU • Validation protocol and report for the cleaning parameters listing in the IFU • All cycle data and test reports (fractional, half or full cycle) • Validate the product sterility test method and test report • Product sterility test and test report • Sterility testing of verification dose samples and test reports • Instructions for use, in which the validated sterilization parameters are listed. Please note that the reference to "standard hospital practice" is insufficient • Validation protocol and report for the sterilization parameters listed in the instructions for use			
Annex II, Section 6.2 f)	Devices with a measuring or diagnostic function If the device has a measuring function or diagnostic function, include test protocols and reports used for verifying or establishing the device limits of accuracy, precision, calibration etc. Refer to MEDDEV 2.1/5 for guidance on criteria that qualify a device as having a measuring function.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex II, Section 6.2 g)	Devices intended to be connected to other devices to operate as intended If the device is intended to be connected to other devices to operate as intended, include test protocols and reports that establish the safety and performance of the combination of devices including addressing their interoperability and any usability elements.			
Annex III	TECHNISCHE DOKUMENTATION ÜBER DIE ÜBERWACHUNG NACH DEM INVERKEHRBRINGEN			
Annex III, Section 1.1 Article, 83 - 86	A Post-Market Surveillance Plan (PMS Plan) commensurate with the product risk, lifetime, and available clinical data should be provided for each device / device family. • Ensure that the PMS plan adequately justifies the monitoring of the safety and intended performance of the device. • If Post-Market Clinical Follow-up (PMCF) is not part of the PMS Plan, please ensure that adequate justification is provided, based on the risk and clinical data available for the device. • A copy of the Post Market Surveillance procedure should also be provided. Please note that the procedure is not the same as the Plan – the former refers to the manufacturer's quality system requirements and is generic to all devices marketed by a manufacturer, whereas the latter is specific to the subject device, and can only be generated in light of data from the clinical evaluation and risk evaluation for that device.			

Requirement / Reference (VO 2017/745)	Content / Guide	Applicability / Compliance shown in	Document evidence	Remark / Comment
Annex III, Section 1.1 Article, 83 - 86	Please provide sales, complaints and vigilance data for the last 5 years for your device, • Sales and complaints data should include sales outside of the EU. A breakdown should be provided to enable evaluation of sales and complaints by region. • Complaints data should be evaluated rather than just listed. For example, why is the complaints rate considered acceptable? Have any trends been analysed and noted, or corrective actions taken? What is the status of these actions? Has a comparison of PMS data been made to the expected occurrence in the risk assessment? Full details of vigilance issues should be provided, including the status of any Field Safety Corrective Actions or Notices, the associated CAPAs and patient outcomes. This data should include FSCA or FSN outside the EU, if related to a device which is sold in the EU. • Ensure that the PMS data submitted at the time of the submission is up to date.			
Annex III, Section 1.2 Article, 85 - 86	For Class III, IIb, and IIa devices, manufacturers must prepare a periodic safety update report (“PSUR”) for each device or group of devices summarising results and conclusions of post-market surveillance data analysis as a result of the PMS plan described above. The PSUR should contain all the elements outlined in MDR Article 86 and any applicable MDCG guidance documents. Any PSURs the manufacturers may have issued by the time of submission must be included.			