TECHNICAL MEMO

TECHNICAL DOCUMENTATION
INFORMATION TO BE PROVIDED FOR ASSESSMENT

TYPE OF ASSESSMENT: INITIAL | MODIFICATION | EXTENSION | RENEWAL

REGULATION (EU) 2017/745

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GMED
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→ RECOMMENDATIONS ON THE FORMAT OF THE TECHNICAL DOCUMENTATION SUBMITTED FOR ASSESSMENT

1 Approach

The Technical Documentation assessment requires the precise and comprehensive analysis of documents that may contain a significant number of pages in total. The variable form and quality of these files (printing, dividers, binders, plastic sleeves, non-searchable PDFs, etc.) impact the internal organization.
The first part of this recommendation is essentially a guide on the form of the Technical Documentation to be assessed and submitted to our departments. It therefore gives instructions for preparing the Technical Documentation solely in terms of their form.

This approach complies with the direction set out in the new Regulation (EU) 2017/745 which specifies the following in Annex II - Technical Documentation: ***"The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, readily searchable and unambiguous manner [...]."***

Important note: As part of a conformity assessment on the basis of the EU type-examination according to Annex X of Regulation (EU) 2017/745, the Technical Documentation must be accompanied by a representative sample of the devices produced envisaged ("Type") as well as evidence demonstrating that the type was manufactured in accordance with the Technical Documentation concerned.

2 Technical Documentation structure

a → Composition content

Technical Documentation includes the following as a minimum:
- A printed copy **(paper file),**
- The identical copy in electronic format **(electronic file).**

These two files must have absolutely identical contents, and are both essential for conducting the device conformity assessment. These files must be submitted in full to GMED at once. The submission of additional documents during the assessment (annexes, amendments, corrections, or otherwise) will not be accepted and will not be taken into consideration.
The file must be written in either French or in English (English only for customers managed by GMED North America). GMED assessment report will be written in the language of the Technical Documentation submitted.
In the event that the assessment process requires third party consultation (such as: Competent Authorities, EMEA, expert panel, etc.) the Technical Documentation relevant sections must be provided in the language required by the consulted parties.

Submission to GMED of the following additional information is highly recommended:
- Relevant pictures of the device and its commercial packaging, together with identification of labels positions and accompanying documents,
- Wherever possible, a sample in its commercial packaging (as it is intended to be put on the market), and clearly identified as such.

b → Consistency of the terminology

In general terms, the terminology used must be strictly consistent throughout the file.
Thus, where the name of the device has evolved (or changed) during the design process and its previous names appear in the supporting evidence document (for example), this historical information must be clearly specified in the introduction to the Technical Documentation. Omitting this information can potentially result in non-admissibility of the supporting evidence documents concerned (for example).
Similarly, the given names in the Technical Documentation for example to raw materials, packaging and other elements must be consistent with those used in the supporting evidence document. Where this is not the case, the information must be explained in the Technical Documentation for the product reviewer to accept the document as effective.

c → Overall structure of paper and electronic files

I. Initial notification, renewal or modification file

In general terms, it is important to remember that the Technical Documentation must be structured in accordance with the framework of GMED's report and specific reports. These GMED documents differ depending on the type of medical devices (combined products, packaging, sterilizations, etc.).

In this context, it is recommended that the introduction to the Technical Documentation makes clear:

- **The purpose of submitting the file** and **the required assessment scope** (especially if the Technical Documentation relates to several devices),
- An **explanatory letter specifying, for each of the points** (set out in Part 2 of this document), **the answers given and links to the corresponding Technical Documentation** or the rationale for the non-applicability or the lack of impact of the modification on the specific point set out in the report.

II. File for additional information request

On completion of Technical Documentation assessment, there may be a number of outstanding questions that become the subject of Non-Conformity(ies) addressed to the manufacturer. In that case, the manufacturer is notified of the Non-Conformity(ies) and will receive a NC form(s).
The recommendation is to answer the Non-Conformity(ies) in the requested order. It will be expected to have for each Non-Conformity, the answers given and the links to the corresponding Technical Documentation (or the rationale for the non-applicability or the lack of impact of the modification) specifically identified in a document. This document should be included in the introduction to the additional information file.

d → Technical Documentation content

The Technical Documentation includes **a table of contents covering every part of the Technical Documentation.** These tables of contents detail and specify (non-exhaustive):

- Document titles,
- Document number (reference, version and effective date) and the name and location of the electronic file,
- Chapter number,
- Annex number,
- The precise pagination,
- The table of contents for each annex.

3 The paper file

a → Materials to be used

The various documents included in the paper file are to be spiral bound, their front cover protected by a transparent sheet and a cardboard sheet used for their back cover.
Naturally, GMED expects two-sided, high-quality print, color diagrams and the inclusion of high-resolution documents (where scanning cannot be avoided).

b → Visual references to file structure

Comprehensive and detailed tables of contents are required (for the main body of the document and its annexes). This goes with a clear and precise identification of individual documents, chapters, paragraphs, annexes and pages.

It is therefore essential that the introductory page for each document to display the title and number of that document and to provide a reference to the tree structure of the corresponding table of contents.

Each of documents will be organized using **visual and clear dividers**. The different items should be legibly referenced in these tables of contents, even when this document is closed.
Lastly, the pagination, paragraph, chapter and document numbers will be shown on the header or footer of each page.

c → Submitting the paper file to GMED

A printed copy of each Technical Documentation must be submitted to GMED. It should be marked for the attention of your Certification Project Manager and the Certification Assistant (Operations Coordinator at GMED NA).
For clear identification of paper files received, please **include the GMED project number** in the covering letter, for example. This number is usually provided before the paper file is submitted.

4 The electronic file

a → Electronic files in PDF format

The electronic file includes multiple electronic documents. These documents must be **in Portable Document Format (PDF)**. It must be possible to conduct an active (searchable) word search within each PDF file for **the entirety of the documents**.
Filenames must provide a quick and clear link to the table of contents of the file. However, for technical reasons, **the path to the file are limited to 40 characters and must not contain any special characters** (_ @ - [], etc.).
The recommendation is that the **diagrams, illustrations and photos included in files remain in their original colors and resolutions**.
Lastly, the inclusion of several small files is preferable to a single file with a large number of pages.

b → The use of bookmarks and pagination

The PDF format offers **the use of bookmarks (within a tree structure)** as electronic dividers to structure the document and enable browsing on the basis of this organizational structure. It is essential to use these bookmarks for each document contained in the electronic file. Naturally, each bookmark should refer consistently to the electronic file table of contents (or the contents of the corresponding annex).
Lastly, the pagination, paragraph, chapter and document numbers will be shown on the header or footer of each page.

c → Submitting the electronic file to GMED

Each Technical Documentation must be sent in an electronic copy to GMED via a download platform of your choice. The link to initiate the download is to be sent to the attention of your Certification Project Manager and the Certification Assistant (Operations Coordinator at GMED NA).
For easy identification of the electronic file, please indicate the GMED project number in the subject of the email.

In case of difficulty to transmit your Technical Documentation in electronic format, please reach out your designated GMED contact.

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT

This list of information to be provided for the Technical Documentation assessment by GMED has been compiled in accordance with the requirements set out in Annex II to Regulation (EU) 2017/745.
As part of the assessment activities conducted by GMED, the Technical Documentation is subject to a preliminary review to verify that the Technical Documentation submitted is complete, and to identify, when necessary, any points where additional information is required before the assessment process begins.
The assessment is then planned based on the results of this review.

I – GENERAL INFORMATION	1	**LEGAL MANUFACTURER**
		The name, registered trade name or registered trade mark and full address of the manufacturer as defined in the Regulation **Note 1:** The legal entity responsible for placing the medical device on the market must be specifically and consistently stated throughout the Technical Documentation and all information provided by the manufacturer (instructions, user manual, labeling, brochure, catalog and similar publications, etc.)
	2	**AUTHORIZED REPRESENTATIVE IN THE EUROPEAN UNION (WHERE APPLICABLE)**
		Name or registered trade name and address of the authorized representative in the European Union
	3	**TRADE NAME OF THE MD**
		3.1. Identification of the device, its various configurations/variants, with their commercial references 3.2. Identification of the Member States in which it is planned to sell the product or in which the product is already marketed
	4	**EXISTING CERTIFICATION**
		4.1. Identification of the EC Quality System Certificate covering the device (Annexe IX section 1 of the Regulation) 4.2. Identification of the Certificate of Conformity where applicable in Annex IX section 2 of the Regulation) 4.3. Has the device been the subject of a conformity assessment under another statute, or been registered outside the EU?

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(Afterpart)

		STATEMENTS
I – GENERAL INFORMATION	5	5.1. A statement indicating whether or not a product of animal origin is used in the manufacture of the device ***See Technical memo: Materials of Animal Origin - Information to be provided*** **Note 5.1.1:** A derived product is a material or substance obtained from a tissue of animal origin by means of a manufacturing process (e.g. collagen, gelatin, enzymes, etc.) **Note 5.1.2:** For example, the reagents of biological origin used in the medical device manufacturing process may be peptones of bovine origin, amino acids of porcine origin, murine monoclonal antibodies or fetal calf serum (used in cell cultures) **Note 5.1.3:** Where the assessment relates to the modification of a MD using a material of animal origin (or the introduction of a variant of an existing product or extension of the range), the absence of any impact on viral safety and reduction in TSE risk (where applicable) as a result of the modification must be documented **Note 5.1.4:** Tallow derivatives are addressed in section 18.3 of this technical memo 5.2. A statement indicating whether or not the device incorporates a substance considered to be a medicinal product (with reference to Annex I section 12.1 of Regulation (EU) 2017/745) ***See Technical memo: Medical device incorporating a medicinal substance as an integral part - Information to be provided*** 5.3. A statement indicating whether or not the device incorporates a substance derived from human blood 5.4. A statement indicating whether or not the device is composed of a substance or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by it or locally dispersed in the human body (with reference to Annex I, section 12.2 of Regulation (EU) 2017/745) ***See Technical memo: Assessment of the quality and safety of a medical device composed of a substance or of combinations of substances that are absorbed by the human body or locally dispersed in it - Information to be provided***

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

II – DESCRIPTION AND SPECIFICATION OF THE MD	6	**CLASS AND RATIONALE**
		6.1. Rationale for the qualification of the product as a medical device 6.2. Classification according to Annex VIII of the Regulation: Classification rule applied and justification for the classification
	7	**DESCRIPTION OF THE DEVICE**
		7.1. Unique Device Identifier (UDI-DI) 7.2. EMDN (or GMDN) code 7.3. Where applicable, a description of the accessories, other devices and products that are not devices which are intended to be used in combination with the device (including those **covered and not covered** by the assessment) 7.4. Where applicable, identification and description of the various configurations/variants of the device 7.5. Where applicable, identification and description of the associated software program(s) 7.6. A description of the commercial presentation (the device in its packaging), including detailed photos
	8	**DESCRIPTION OF THE CLAIMED USE**
		8.1. Intended medical purpose 8.2. The device's intended users 8.3. The indications and the instructions for use related to the disease, pathology and/or disability treated, the patient target group and patient selection criteria 8.4. Principle of operation of the device and its mode of action, including the use of accessories that are not assessed as part of this assessment, where applicable 8.5. The clinical performances claimed for the intended use relative to the disease, pathology and/or disability treated **Note 8.5:** For joint replacements, please specify the functional performances claimed (e.g. minimum and maximum relative angular movements facilitated between the parts of the skeleton to which the joint replacements relate, assumed wear of the joint surfaces, etc.) 8.6. Intended clinical benefits 8.7. Any contra-indications, side-effects and warning 8.8. Lifecycle of the device (the period over which it continues to deliver its clinical performance under normal conditions of use): depending on the MD concerned, it is important to be precise , for example, by making a distinction between the period of time during which the MD remains effective, and the length of time that the MD remains in the human body, but is no longer effective 8.9. Intended expiry date

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

II – DESCRIPTION AND SPECIFICATION OF THE MD

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CHARACTERISTICS OF THE COMPONENTS, FINISHED PRODUCT AND ACCESSORIES COVERED BY THE ASSESSMENT

9.1. General description of key functional elements, such as parts or components (formulation, composition and functionality)

Note 9.1: For medical devices containing particles smaller than 100 nm, the documentation provided by the manufacturer must provide characteristics such as: agglomeration/aggregation status, composition (e.g. chemical composition and structure), particle size and distribution, purity/impurity, shape, solubility (hydrophobicity, lip solubility or water solubility), stability, surface area, surface chemistry, surface load, coating characteristics, etc.

9.2. Raw material specifications (see note 9.4.1 below): physical, chemical, biological, etc., together with their references, revision number and revision date

9.3. Specifications of additives, contaminants and residues from the manufacturing process: Physical, chemical, biological, etc. together with their references, version number and revision date

9.4. Specifications of primary packaging (the packaging in direct contact with the MD), together with its reference, version number and revision date

Note 9.4.1: Raw materials, additives, manufacturing process contaminants or residues and primary packaging, where any change could potentially compromise compliance with the Safety and Performance parameters set out in the General Requirements

Note 9.4.2: The list of specifications required in the previous points must be provided in the following format, as well as in a reproducible electronic format ***(Annex 1 of this Technical memo)***

Raw materials, additives, manufacturing process contaminants and residues and primary packaging	Specifications Physical, surface, chemical composition, size, etc. characteristics	Supplier / Address	Distributor / Address

9.5. Identification of materials in contact with the patient (when implanted or otherwise), and/or the user, regardless of whether contact with the human body is direct or indirect

9.6. Specifications of the finished product: all technical specifications, such as device characteristics, dimensions and all variants/configurations

9.7. Where applicable, full technical specifications of accessories, including accessory characteristics, dimensions and all variants/configurations

9.8. Where applicable, plans and diagrams together with their references, version numbers and revision dates and a photograph

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

II – DESCRIPTION AND SPECIFICATION OF THE MD	10	**REFERENCE TO PREVIOUS AND SIMILAR GENERATIONS OF THE DEVICE** 10.1. Changes in a MD already CE marked by the manufacturer (provide a general overview of the previous generation(s) of the device produced by the manufacturer, if any) 10.2. Development basis of similar MD based on a competitor device (provide a general overview of similar devices identified available on the EU or international markets, if any) 10.3. Totally new MD 10.4. Explanation of any new features Whether the device is innovative or not must be specified and further explained if applicable. To do so, the degree to which the device is innovative must be defined on the basis of the criteria given in the ANSM 'Degrees of novelty card', the link to which is given below: https://ansm.sante.fr/var/ansm_site/storage/original/application/569e94a19945e1f0eb6e6d0d0fff8c21.pdf
	11	**HISTORY OF CHANGES (NOT APPLICABLE IN CASE OF INITIAL ASSESSMENT)** 11.1. Changes made to the device since its initial market introduction (specify the date of market introduction) 11.2. Identification of modifications not yet notified 11.3. Regulatory, standards or state of the art changes

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

III - INFORMATION PROVIDED BY THE MANUFACTURER	12	**SUPPORTING DOCUMENTS** 12.1. Instructions for use: • The contents of the instructions for use or user manual (or draft manual) specific to the device in the languages accepted in the Member States where the device is intended to be sold • Where applicable, other documents for users or patients, where these are referred to in the instructions for use (e.g. surgical technique, implant card, brochure, etc.) **Note 12.1.1:** When instructions for use in electronic form is implemented, conformity with Regulation (EU) No 207/2012 will be assessed. In this context, the Technical Documentation shall include the impact analysis of the instructions for use in electronic form, especially in relation to the following information: • Characteristics of the components, finished product and accessories covered by the assessment (***See section 9***) • Description of the supporting documents • Demonstration of conformity with applicable requirements of the Regulation (EU) No 207/2012 shall be documented. It is recommended to use a Summary Table format. • Risk Management File (***See section 17***) • Usability engineering (***See section 18.9***) • Impact analysis on the special process validations (e.g. Packaging, sterilization processes, etc.) • Requirements Summary Table in Annex I (GSPR) (***See section 15***) **Note 12.1.2:** Please note that the Regulation (EU) No 207/2012 also establishes certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form relating to their contents and websites. 12.2. Labeling: • The label(s) on the device and on its packaging, such as single unit packaging, sales packaging and/or transportation packaging in case of specific management conditions, in the languages accepted in the Member States where the device is intended to be sold • The text and graphic elements of the commercial packaging (mockup), in the languages accepted in the Member States where the device is intended to be sold 12.3. Other supporting documents (e.g. Surgical Technique, user manual, maintenance manual, calibration manual, brochure, catalog and similar publications, etc.) **Note 12.2:** Refer to the requirements of Annex I section 23 of Regulation (EU) 2017/745, product standards, EN ISO 15223-1, etc.

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

IV – DESIGN AND MANUFACTURING INFORMATION

13	**DESIGN INFORMATION (IF APPLICABLE)** 13.1. The final version of the design project plan making clear the individual stages of the product design process 13.2. Identification of design verification outputs 13.3. Records of the results and conclusions of the design and development transfer process 13.4. Reports of all design reviews conducted during the project implementation
14	**MANUFACTURING** 14.1. Name and address of Suppliers / Distributors of raw materials, additives, manufacturing process contaminants and residues **Note 14.1.1:** These are the main components such as: raw materials, additives, manufacturing process contaminants or residues and primary packaging, where any change could potentially compromise compliance with the General Safety and Performance Requirements **Note 14.1.2:** The identification of suppliers and distributors is to be transmitted ***(Annex 1 of this Technical memo)*** 14.2. The manufacturing flowchart (identifying the processes implemented and specifying whether they are validated or verified, together with the in-process and final controls performed), including where these stages are subcontracted **Note 14.2.1:** This document must also be provided in a reproducible electronic format ***(Annex 2 of this Technical memo)*** **Note 14.2.2:** Any intermediate cleaning stage(s) must also be specified 14.3. Description of the manufacturing methods used and controls applied, including where these stages are subcontracted **Note 14.3:** Details must be provided of the in-process controls and controls applied to the final product. The control criteria on the critical characteristics of the device, including where these are subcontracted, must also be provided 14.4. A description of the validated manufacturing process(es) and Validation report(s) (OQ and PQ), including where these processes are subcontracted **Note 14.4.1:** This must at least identify the following information: • Description of the validated process with the precise identification of the equipment concerned • Identification of associated validation reports (OQ / PQ) with their reference, revision number and revision date • Identification of critical process parameters as well as validated tolerance intervals (Mini / Maxi) **Note 14.4.2:** The list of processes must also be transmitted in a reproducible electronic format ***(Annex 3 of this Technical memo)*** 14.5. Description of the manufacturing environment(s), including their corresponding classification 14.6. Identification of the manufacturing sites, the subcontractors' QMS certifications (if any), Certification Bodies and validity of the current certificates (if any) Where a process has been the subject of a previous GMED assessment in the context of Regulation (EU) 2017/745 in a Master-File format (validation of a process covering several devices covered by different Technical Documentations and / or dependent on different categories and / or generic groups): 14.6.1. Identification of the process(es) concerned 14.6.2. Identification of the number and date of GMED assessment report, with a satisfactory outcome 14.6.3. Rationale for the proposed inclusion of the device which is subject of the assessment, in the validation of the process previously assessed (inclusion of the product within a defined family without challenging the worst-case scenario)

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
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V – GENERAL REQUIREMENTS SAFETY AND PERFORMANCE	15	**REQUIREMENTS SUMMARY TABLE IN ANNEX I OF THE REGULATION (EU) 2017/745 (GSPR)** 15.1. The General Safety and Performance Requirements that apply to the device and an explanation as to why others do not apply 15.2. The method(s) used to demonstrate conformity with each applicable General Safety and Performance Requirement 15.3. The harmonized standards, Common Specifications or other solutions applied **Note 15.3:** The list of standards and documents applied must also be provided in a reproducible electronic format ***(Annex 4 of this Technical memo)*** 15.4. The precise identification of the controlled documents providing evidence of conformity to each harmonized standard, common specification or other method applied to demonstrate conformity with the General Safety and Performance Requirements. The location of controlled documents within the Technical Documentation and, where applicable, the Technical Documentation summary is to be provided
VI – BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT	16	**THE BENEFIT-RISK ANALYSIS REFERRED TO IN ANNEX I OF THE REGULATION (EU) 2017/745** The manufacturer's benefit-risk analysis is conducted using data from the clinical data evaluation, the PSUR and PMS conclusions and risk management outcomes
	17	**RISK MANAGEMENT FILE** 17.1. Description of the methods used for risk analysis, risk control and identification of the relevant standard (e.g.: NF EN ISO 14971, current version) 17.2. Definition of the lifecycle of the device(s): e.g. Design,..., aging disposal., etc. 17.3. The complete risk management file including (in accordance with EN ISO 14971, current version): 17.3.1 Risk Management Plan 17.3.2 Summary of the stages of risk management: Risk analysis, risk evaluation, implementation and verification of the measures for risk control and evaluation of any residual risk acceptability, including overall residual risk 17.3.3 Report (review of the risk management process) **Note 17:** • The risks associated with all phases of the MD lifecycle (e.g. design, manufacture, utilization, aging, disposal) are to be evaluated and controlled • It is important to clearly identify, document and justify the decision-making criteria whose application has resulted in demonstrating that the risks identified are acceptable in light of the anticipated benefits to patients • All known and foreseeable hazards and hazardous situations (combinations or sequences of events) must be identified • The level of acceptability of the risk under specific conditions must be considered with reference to the "generally recognized state of the art" • Residual risks and their processing operations must be identified. A decision must be made regarding the acceptability of overall residual risk. Mention should be made where the medical benefits outweigh the residual risk
	18.1	**PRE-CLINICAL DATA: DEMONSTRATION THAT CHARACTERISTICS OF THE DEVICE CONFORM WITH THE STANDARDS, REFERENCE DOCUMENTS AND/OR APPLIED STATE OF THE ART IN ORDER TO DEMONSTRATE THE PRE-CLINICAL SAFETY OF THE DEVICE AND ITS COMPLIANCE WITH THE SPECIFICATIONS** • Discussion on the use of alternative materials or substances • Rationale behind the choice of materials or substances relative to the available alternatives

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
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VI – BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT	18.2	**PRESENCE WITHIN THE DEVICE OF SUBSTANCES IN CONCENTRATIONS GREATER THAN 0.1% WEIGHT BY WEIGHT (w/w) (WHERE APPLICABLE)** Information regarding whether the device(s) which is(are) the subject of this assessment, or parts of devices or materials used are: • Invasive and come into direct contact with the human body, or • Intended to (re)administer medicines, body fluids or other substances, including gases, to/from the body, or • Intended to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body Where the answer to one or more of these questions is yes: • Indicate whether category 1A and 1B substances which are carcinogenic, mutagenic or toxic to reproduction are present in concentrations greater than 0.1% weight by weight or substances having endocrine disrupting properties (as referred to in section 10.4.1 of Annex I of Regulation (EU) 2017/745) / Identification of the substance(s) concerned and the quantity present • Rationale behind the presence of carcinogenic, mutagenic or toxic to reproduction and/or endocrine disrupting substances. This rationale shall be based on: o An analysis and estimation of potential patient or user exposure to the substance, accompanied by details of the weight by weight concentration o An analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees if available and an analysis of the availability of such alternatives o Argumentation as to why possible alternative substances and/or materials, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratio of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials o Where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4. of Regulation (EU) 2017/745
VII – PRODUCT VERIFICATION AND VALIDATION	18.3	**PRESENCE OF ANIMAL TALLOW DERIVATIVES** Information regarding whether the device(s) which is(are) the subject of this assessment, or parts of devices or materials used are: • Intended to come into contact with the human body or non-intact skin If yes: • Indicate the presence of animal tallow derivatives that may have been used particularly in the processing of plastics and/or packaging materials used for these medical devices **Note 18.3.1:** Tallow is fat from animal tissue, including subcutaneous, abdominal and intermuscular areas and bones • List of components and raw materials whose manufacturing processes involve the use of materials of animal origin, together with the identities of their suppliers (specific information regarding contact or lack of contact with the patient and/or user is also required) • Copies of supplier certificates, including information relating to the parameters applied to the manufacture of tallow derivatives, to enable assessment of whether or not Regulation (EU) No 722/2012 applies (i.e. identification of the plastics and/or packaging materials concerned, and the conditions under which tallow derivatives have been manufactured) • Documented rationale regarding the applicability or otherwise of Regulation (EU) No 722/2012 on the basis of certificates provided by suppliers **Note 18.3.2:** Additional regulatory proceedings may need to be carried out in the event that Regulation (EU) No 722/2012 becomes applicable

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VII – PRODUCT VERIFICATION AND VALIDATION

18.4

PRE-CLINICAL DATA: MECHANICAL, PHYSICAL, CHEMICAL, ELECTRICAL AND OTHER EVALUATION

Reports relating to the tests conducted, including the certificate from the laboratory which conducted the tests (e.g. 17025 accreditation) and rationale in the absence of pre-clinical testing

Note 18.4.1: When the device is designed to be used sterile, the testing should be performed on the sterile device

Furthermore, whenever an assessment refers to an evaluation report or any company document more than 5 years old, the corresponding data must be provided, including a rationale explaining why it remains applicable

Note 18.4.2: The results should preferably be presented in the form of a table

Standard / Document / State of the Art	Characteristic / Specification	Requirements / Acceptance criteria	Method used to demonstrate compliance with the requirement (Testing and rationale)	Laboratory name and address Accreditation identification & expiry date	Report reference	Worst case justification	Compliance outcome

Definitions:
o Characteristic: intrinsic property of the MD
o Specification: document stating the requirements applying to a characteristic
o Requirement: expressed expectation, whether implied or mandatory
o Compliance: fulfillment of a requirement

Note 18.4.3: Where tests have not been conducted in accordance with the provisions set out in the applicable standards or reference documents, the manufacturer must demonstrate the equivalence of the solutions adopted in documentary form

Note 18.4.4: Where calculations (including finite element analysis) and simulations fail to demonstrate achievement of the performances claimed by the manufacturer, and - where applicable - the compliance of the device with the applicable standards or reference documents, the manufacturer must consider the desirability of confirming these simulations and calculations by means of testing

Note 18.4.5: Justification must be provided where no pre-clinical data is available. Furthermore, whenever an assessment refers to an evaluation report or any company document more than 5 years old, the corresponding data must be provided, accompanied by a rationale explaining why it remains applicable

Note 18.4.6: The safety of devices emitting ionizing radiation and electrical devices in relation to these characteristics must be taken into account

Note 18.4.7: Where studies have been conducted using animal models, detailed information must be provided, specifically regarding the purpose of research, the methodology used, results, analyses, and conclusions, accompanied by the rationale and limitations governing selection of the model(s) used

Note 18.4.8: Where simulated use testing has been conducted, the manufacturer must supply detailed information

Note 18.4.9: Where the manufacturer conducts pre-clinical tests in-house or in a laboratory without 17025 accreditation, GMED reserves the right to request validations of the testing methods used

Note 18.4.10: Where an EU type-examination, this section should be completed jointly with the EU type-examination report

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VII – PRODUCT VERIFICATION AND VALIDATION	18.5	**WHERE DEVICES WITH A MEASURING FUNCTION ARE PLACED ON THE MARKET**
		Description of the methods used to ensure the accuracy indicated in the specifications
	18.6	**IF THE DEVICE IS TO BE CONNECTED TO OTHER DEVICE(S) IN ORDER TO OPERATE AS INTENDED**
		18.6.1. A description of this combination/configuration must be provided 18.6.2. This description must include proof that it conforms to the General Safety and Performance Requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer
	18.7	**DEMONSTRATION THAT CHARACTERISTICS ARE MAINTAINED**
		18.7.1. As part of the stability study to justify the shelf life of the device 18.7.2. During the device lifetime claimed by the manufacturer 18.7.3. Validation of device reprocessing, where applicable
	18.8	**PRE-CLINICAL DATA: CONCLUSION OF THE MANUFACTURER**
		Conclusion of the manufacturer taking account of the considerations around the use of alternative materials or substances
	18.9	**USABILITY ENGINEERING**
		Report on usability, including the identification of the reference standard (e.g. IEC 62366-1, current version)

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

VIII – POST-MARKET SURVEILLANCE	19	**DESCRIPTION OF THE PROVISIONS MADE FOR POST-MARKET SURVEILLANCE OF THE DEVICE, INCLUDING THE POST-MARKET CLINICAL FOLLOW-UP (PMCF) PLAN**
		19.1 The Post-Market Follow-up plan prepared in accordance with Annex III section 1.1 of Regulation (EU) 2017/745
		19.2 The Post-Market Clinical Follow-up plan
		19.3 The Periodic Safety Update Report (PSUR) prepared in accordance with article 86 of Regulation (EU) 2017/745
		19.4 The Post-Market Follow-up report prepared in accordance with article 85 of Regulation (EU) 2017/745
		19.5 The PMCF evaluation report
		19.6 Changes in provisions and reasons for modifications made to provisions
	20	**POST-MARKET DATA**
		20.1 Date of placing on the market
		20.2 Number of products sold inside and outside Europe
		20.3 Estimated population using the device (population size and characteristics)
		20.4 Number and type of complaints about technical characteristics, clinical performance and fitness for purpose of the device received since the initial market placement or CE marking
		20.5 Number and type of medical device vigilance reports received since the initial market placement or CE marking
		20.6 Data from clinical studies, including Post-Market clinical follow-up and registries
		20.7 Modifications made and/or corrective actions taken following the incidents reported and revisions made to the risk management file

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

MANDATORY ANNEXES

1 IDENTIFICATION OF RAW MATERIALS, ADDITIVES, MANUFACTURING PROCESS CONTAMINANTS OR RESIDUES AND PRIMARY PACKAGING ITEMS

1. Raw material specifications: Physical, chemical, biological, etc., together with their references, version number and version date
2. Specifications of additives, contaminants and residues from the manufacturing process: physical, chemical, biological, etc., together with their references, version number and version date
3. Specifications for primary packaging (in direct contact with the MD), together with its reference, version number and version date

Note: Raw materials, additives, contaminants and residues from the manufacturing process and primary packaging, changes to which may call into question compliance with General Safety and Performance Requirements

Note: The list of specifications required in the previous points must be provided in the following format, as well as in a reproducible electronic format:

Raw materials, additives, manufacturing process contaminants and residues and primary packaging	Specifications Physical, surface, chemical composition, size, characteristics etc.	Supplier / Address	Distributor / Address

2 FLOWCHART OF MANUFACTURING PROCESSES AND CONTROLS

The manufacturing flowchart (identifying the processes implemented and specifying whether they are validated or verified, together with the in-process and final controls performed), including where these stages are subcontracted

3 IDENTIFICATION OF VALIDATED PROCESSES

The list of validated processes must be transmitted. This must at least identify the following information:

1. Description of the validated process with the precise identification of the equipment concerned
2. Identification of associated validation reports (OQ / PQ) with their reference, revision number and revision date
3. Identification of critical process parameters as well as validated tolerance intervals (Mini / Maxi)

Note: The list of validated processes is to be transmitted in the following format, also in a reproducible electronic format:

Description of the validated process	Equipment identification	Validation reports (OQ / PQ) (Ref. / Rev. / Date)	Critical parameters and validated tolerance intervals (Mini / Maxi)
Process	*Equipment*	*Report Ref. Rev. Date*	*Critical parameters 1 ± X*
			Critical parameters 2 ± X
			Critical parameters 3 ± X

4 LIST OF STANDARDS AND DOCUMENTS APPLIED

List of Common Specifications, standards, whether harmonized or non-harmonized, and other documents (e.g. European Pharmacopoeia monographs) applied

Where harmonized standards are not used, the solutions implemented must be equivalent and the equivalence documented

Note: This document is also to be provided in a reproducible electronic format

II INFORMATION TO BE PROVIDED IN THE CONTEXT OF THE ASSESSMENT
(afterpart)

ADDITIONAL ANNEXES	1	CLINICAL DATA EVALUATION
		See Guide: Clinical Evaluation - Summary of safety and clinical performance - Regulation (EU) 2017/745
	2	BIOLOGICAL EVALUATION
		See Guide: Biological assessment according to ISO 10993-1 standard *See Technical memo: Biological evaluation report assessment - Information to be provided*
	3	PROCESS VALIDATION: CLEANING AND DISINFECTION
		See Technical memo: Cleaning process assessment - Information to be provided
	4	PROCESS VALIDATION: PACKAGING (CONDITIONING)
		See Technical memo: Packaging (conditioning) process for terminally sterilized MDs - Information to be provided
	5	PROCESS VALIDATION: STERILIZATION
		See Technical memos: • *Irradiation sterilization process assessment - Information to be provided* • *Ethylene Oxide sterilization process assessment - Information to be provided* • *Moist heat sterilization process assessment - Information to be provided*
	6	USE OF MATERIALS OF ANIMAL ORIGIN
		See Technical memo: Materials of Animal Origin - Information to be provided
	7	DEVICE INCORPORATING A MEDICINAL PRODUCT
		See Technical memo: Medical device incorporating a medicinal substance as an integral part - Information to be provided
	8	SUBSTANCES OR COMBINATIONS OF SUBSTANCES THAT ARE ABSORBED BY, OR LOCALLY DISPERSED IN, THE HUMAN BODY
		See Technical memo: Assessment of the quality and safety of a medical device composed of a substance or of combinations of substances that are absorbed by the human body or locally dispersed in it - Information to be provided
	9	SOFTWARE VALIDATION
		Technical memo: Software security assessment - Information to be provided
	10	TYPE-EXAMINATION ASSESSMENT REPORT AND ASSOCIATED TEST PROGRAM
	11	EXPERT REPORT(S)
	12	NOTIFIED BODY ASSESSMENT REPORT PERIODIC SAFETY UPDATE REPORT (PSUR)

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