1. INTRODUCTION

As indicated in Annex II of EU Regulation 2017/745 (hereinafter MDR), "*The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex*".

The requirements for the technical documentation, compared to Directive 93/42/EEC, both in terms of content and in terms of "structure", have been increased to ensure a correct and immediate understanding of all the elements supporting the conformity to the requirements.

Technical documentation must be kept up to date during the life cycle of the device, in order to ensure that it accurately reflects the specifications/manufacturing processes of the device.

Technical documentation content is under the manufacturer's responsibility. This guidance is intended to provide practical advices on how to manage and organize the documentation but it does not represent an exhaustive list of evidence needed in order to fulfil MDR requirements.

This guidance is based on Annexes II and III of the MDR.

2. SUBMISSION

The technical documentation must be sent to ITALCERT together with the certification application.

In case of extension of the certification or changes to the technical documentation (e.g., new validations, design changes, new production and/or control processes, etc ...), a review document is mandatory (this document must identify and clarify the changes, the reason for these changes and a reference to the documentation where the change is described). It is also necessary to highlight the modified parts in the text of the document. Without such information, ITALCERT will not start the evaluation. For example, the manufacturer should submit a table, preferably as a part of the index, that describes for each section of the documentation at least the following information (even in the case of first submission):

- Reference to the section/chapter of the documentation
- Indication if the specific section has been modified or not, or if it is the first issue
- Brief description of the change (if any) introduced in the specific section
- If the change does not affect the specific section, provide a justification

The above information may be reported in a format similar to the following:

Ref. Technical documentation	Changed / Not changed / First emission	Change description	Reason for not updating
--	--	--	--

In the case of first certification, acceptance of a specific offer issued by ITALCERT is mandatory.

In case of certification extension/changes, MDR rate table generally apply. However, ITALCERT reserves the right to issue a specific offer.

3. SENDING THE DOCUMENTATION

The technical documentation can be sent to ITALCERT through a proprietary or non-proprietary file sharing system (eg Dropbox, Wetransfer or similar). In the latter case, responsibilities related to the transmission of information (e.g., confidential information) through third party systems are in charge of the manufacturer.

The documentation can also be provided through the ITALCERT's cloud space, based upon agreements with the Technical Secretariat. In this case, ITALCERT will share with the manufacturer a specific 5 days validity folder in the cloud space.

Physical copies (e.g., USB memory stick and/or CD/DVD and/or paper copies) are not accepted.

3.1 Language requirements

The technical documentation must be exclusively in Italian or in English.

Supporting documents, such as process validation reports, pre-clinical validation reports (biocompatibility, tests, tests, etc.) and scientific articles, must be provided in Italian or English. Any translations from the original language must meet the requirement below.

If translated copies to languages different than English are included in the technical documentation (eg IFU, labels, marketing material, SSCP, etc ...), evidence of proper translation must be provided. Specific QMS procedure can be provided for this scope (as an external controlled documentation).

3.2 Formats and structure

Electronic documents must be provided in a non-editable and searchable format (pdf). Appropriate "bookmarks" within the files should be used in order to make easier the documents consultation.

File names and/or folder names must be clear, intuitive and must allow an easy identification of their contents. File names consisting exclusively of alphanumeric codes will not accepted.

The documentation must be structured as defined in Annex II of MDR; it is necessary to generate pdf files, or folders containing the relevant files, following a structure similar to the following:

Document / Folder		MDR
1.	Device description and specification, including accessories and variants	Annex II sec. 1
2.	Information to be supplied by the manufacturer	Annex II sez. 2
3.	Design information	Annex II sez. 3
4.	Manufacturing information	Annex II sez. 3
5.	General safety and performance requirements	Annex II sez. 4
6.	Benefit-risk analysis and risk management	Annex II sez. 5
7.	Product verification and validation *Pre-clinical and clinical data*	Annex II sec. 6.1.a, 6.1.b
	Product verification and validation *Additional information required in specific cases*	Annex II sec. 6.2.a, 6.2.b, 6.2.c, 6.2.d, 6.2.g, 6.2.f
	Sterilization	Annex II sec. 6.2.e
	Clinical evaluation, PMS and PMCF	Annex II sec. 6.1.c, 6.1.d Annex III
8.	Declaration of Conformity	Annex IV

Each section must be identified by specific ID and revision.

Documents must be dated and signed. Both digitally signed documents or scanned signature pages are allowed.

In case of revision of documents during the evaluation process, the revised document must necessarily have a new revision index (with date updated accordingly) or a new issue date. In response to the comments/non conformities issued by ITALCERT during the evaluation process, it is possible to provide only the modified documents along with a document that describes the changes, preferably according to the following format:

Ref. Technical documentation	Ref. to ITALCERT's NC	Change description
--	--	--

The modified parts in the documents must be highlighted.

Once the evaluation process has been successfully completed, the manufacturer must provide the whole documentation in the revision status approved by ITALCERT.

3.3 Change management

As required by Article 10 of MDR, the manufacturer should define procedures for device change management and for quality management system change management, in order to establish if the change must be considered significant and if it must be subjected to approval by the notified body prior to its implementation.

As defined in the certification regulation R013, any changes to the technical documentation must be communicated to ITALCERT.
However, the manufacturer should contact ITALCERT technical secretariat in order to evaluate the proper management methods for specific changes.

4. TECHNICAL DOCUMENTATION

Note regarding the applicable standards: the manufacturer should apply the relevant harmonized standards (or existing Common Specifications) in order to comply with specific requirements. During the transition period from MDD to MDR, in the absence of harmonized standards for MDR, harmonized standards for MDD are considered applicable.

The manufacturer must maintain its competence and knowledge about the standards development and it is committed to apply the relevant standards accordingly.

When standards, Directives, Regulations and guidelines are cited, the revision of the document must be specified.

Any change to the standards or to the CS used for the demonstration of the conformity must be promptly taken into due consideration by the manufacturer.

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING ACCESSORIES AND VARIANTS

1.1 Device description and specification

1.1.1 - General description

General description: device name, trade name (s), operating principles, mechanism of action, rationale for qualification as a medical device.

Provide extensive information on the manufacturer (company name, addresses of the headquarter(s) – description of the specific activity carried out in each headquarter).

Device description must allow a clear understanding of the device and how it is supplied to the market (variants, packaging, supplied sterile or not, etc.).

Variants (including any free samples) must be clearly identified by an adequate description. Any difference between variants must be fully identified, also in terms of performance and/or operating principle (if applicable).

The mode of action must be described, where appropriate and applicable, on the basis of scientific evidence and, if relevant, through supporting tests.

If applicable, provide a description of the functional elements, including the qualitative and quantitative formulation and composition.

Provide, if deemed necessary for a complete understanding of the device, images, diagrams, photos, along with an exhaustive explanation for their understanding.

It is necessary to describe the qualification of the product as medical device under the MDR, Article 2 or as a product without an intended medical purpose (Annex XVI).

1.1.2 - Basic UDI-DI, EMDN code, identification of the device(s)

Provide information about the basic UDI-DI and about the relevant EMDN codes (European Medical Device Nomenclature).

Provide the complete list of devices covered by the documentation.

It is strongly suggested to refer to the relevant MDCG guidelines.

1.1.3 – Accessories

If applicable, describe the accessories (including Class I devices) required for the proper use and functioning of the device or which are expected to be used with the device.

Provide reference to the technical documentation for each accessory (identification, revision date).

If the accessory is supplied with the device, provide all relevant information (packaging, bearing or not its own CE mark, etc ...).

For each accessory (whether it is included with the device or not included) the compatibility with the device in question must be demonstrated. Specific reference to the relevant sections of the technical documentation is allowed.

1.1.4 – Intended use

Provide details about the clinical conditions that the device is intended to treat/monitor, the intended patient population, intended users, indications and contraindications.

Indications and contraindications must be supported by evidence, possibly linked to the risk analysis and clinical documentation.

All claims (both in the IFU and in the marketing documentation) about the intended use and the mode of action must be demonstrated from a scientific point of view.

1.1.5 – Users

Specify in detail the expected users (eg. Professional doctor, nurse, surgeon, lay user, etc ...) and define, if necessary, the necessary training for the use of the device.

1.1.6 – Classification

Provide the classification of the device in accordance with Annex VIII, specifying the rule and, if applicable, the specific indent. It is always necessary to provide a rationale that considers all the indents of a rule.

If the device is considered to be characterized by well-established technologies (Article 52 (4) and 52 (5)) it is necessary to provide a justification.

1.1.7 – Explanation of any new features

If applicable, describe the innovations and how these affect safety and performance of the device (see points below).

1.1.8 – Materials

Description of the raw materials contained in the main functional elements and in those that directly or indirectly come into contact with the human body.

Identify all the materials used in the key functional elements, including information on coatings or treatments that are critical to the functionality and the safety of the device. For each material, the nature of the contact with the body must be identified.

Regarding substances and medical devices that are composed of substances or combinations of substances, it must be considered that certain raw materials are made available in the form of mixtures and not as pure substances.

Provide detailed information about the use of tissues / cells and nanomaterials and provide statements in this regard (presence / absence).

Provide statements regarding the presence or absence of substances that can be considered a medicinal product derived from human blood or plasma pursuant to art. 1 point 10, Dir. 2001/83/EC.

Provide statements regarding the presence or absence of substances that can be considered a medic medicinal product pursuant to art. 1 point 2, Dir. 2001/83/EC.

The list of materials (bill of materials) must be provided, together with the relevant technical information (e.g., safety data sheets, certificates of analysis, technical data sheets, etc ...).

1.2 Reference to previous and similar generations of the device

1.2.1 – State of the art

Presentation of the previous generation or generations of the device produced by the manufacturer, if such devices exist.

At each submission of the documentation to ITALCERT (initial certification, renewal, extension, etc…), the "history" of the device must be defined with a description of the evolutions/changes and reasons thereof.

If the device is a new one and never manufactured (for the manufacturer in question, not in general), it must be clearly specified

If the device already exists and the application relates to extensions/changes, it is necessary to provide:

- the "history" of the device (see above), also considering the certification history (certificate numbers, dates of issue and the ON that issued them)
- evidence of the approvals by ITALCERT (or other ON) in relation to previous revisions of the documentation
- if the device was previously certified under the MDD (legacy device), provide a description of any changes made compared to the MDD certified version of the device, or a declaration that nothing is changed
- provide information on the sales volumes of the device, in the form of a trend, possibly for all the interested geographical area

1.2.2 – Similar devices

Presentation of identified similar devices available on the Union or international market, if such devices exist.

Provide an overview of the “similar” devices available on the market, where “similar” means belonging to the same generic device group. [1]

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

2.1 Labeling

Label or labels affixed to the device and packaging, such as unit packaging, commercial packaging, transport packaging in case of specific handling conditions, in the languages accepted in the Member States where the device is intended to be sold.

Copies of labels of all applicable levels must be provided (e.g., secondary packaging, primary packaging, marketing packaging, etc.), representative of the final layout and size.

If applicable, provide drawings/diagrams that show where the labels are placed on the packaging/product.

If the device is sterile packed, the label must be clearly identified this.

2.2 Instructions for Use (IFU) / User manual

All information referred to the General Safety and Performance Requirement (GSPR) No. 23 must be considered.

2.3 Information for the patient

[1] set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics. Generic device group is to be understood as the 4th level of the European Nomenclature on Medical Devices (EMDN)

If applicable, provide additional patient-specific information that may be found in specific manuals or documents.

2.4 Information for users

Provide all information for users not included in the IFU, such as surgical techniques.

2.5 Information relating to the Implant Card

If applicable, provide the information required by Article 18 of the MDR and an indication of where the card is physically positioned, in the packaging.

Consider the relevant MDCG guidelines.

2.6 Electronic IFU

If electronic instructions are used, compliance with Regulation 2021/2226 must be demonstrated. It is necessary to provide the web address (URL) at which the information referred to in GSPR No. 23.1 can be found.

3. DESIGN INFORMATION

3.1 – Design Phases

Information needed for understand the design phases of the device.

Provide a description of the design process, throughout its history, highlighting any significant changes.

It is important to highlight, in the case of legacy devices, any differences between the design approved under the MDD and what is submitted for the MDR certification.

3.2 – Product and project specifications

Complete information and specifications, including manufacturing processes and their validation, monitoring and testing of the finished device. The data must be fully reported in the technical documentation.

3.2.1 – Design process

Design specifications and device specifications (materials, packaging, etc ...) must comply with the intended use, the applicable GSPRs, the risk assessment and any applicable standards/CS.

It is possible to generate references to the appropriate sections of the technical documentation.

3.2.2 – Manufacturing process

It is necessary to provide a complete and exhaustive description of the production process, including suppliers and sub-suppliers. All manufacturing processes must be identified.

The whole production chain must be fully identified (e.g., name and address of the suppliers).

If the design, or part of it, is carried out by a third party, this must be identified and a description of the process must be provided (for example, engineering and design transfer).

3.2.3 – Manufacturing processes validation

All manufacturing processes subjected to validation must be identified.

A Validation Master Plan should be provided.

It is necessary to provide protocols, plans and reports for the validation and/or verification of each identified process. The data must be fully reported in the technical documentation.

3.2.4 – Monitoring and control

Accordingly with point 4.5.3 of Annex VII (“assessment shall include examination of the implementation by manufacturers of incoming, in-process and final checks and the results thereof”), it is necessary to provide:

- description of the acceptance criteria of raw materials and of all components/assemblies necessary for the realization of the device (considering the critical ones). Provide evidence of the checks carried out on an example batch;
- description of the in-process control criteria of the verified processes. Provide evidence of the checks carried out on an example batch;
- description of the criteria for final inspection and product release. Provide evidence of the checks carried out on an example batch;
- if the controls, as well as the final inspection, are made by a supplier, a description of the criteria adopted by the supplier must be provided and the name of the involved supplier must be identified. Provide evidence of the checks carried out on an example batch.

3.2.5 – Installation

If the device requires installation, provide all the specifications relating to the tests that must be carried out for the release of the installation. If a supplier is envolved, specify the method(s) adopted and the name of the involved supplier.

4. MANUFACTURING INFORMATION

4.1 – Manufacturing information

Identification of all sites, including those of suppliers and subcontractors, where design and manufacturing activities take place.

All the operating units must be clearly identified (also physical locations – addresses) in relation to:

- Manufacturer
- EU REP, if applicable
- Where is located the design process
- Where is located the sterilization process
- Outsourcers and critical suppliers, including all critical sub-suppliers. Certifications must also be provided. In the absence of ISO 13485 certificates, an audit by ITALCERT may be required. The manufacturer must have in place appropriate quality contracts/agreements with outsourcers and critical suppliers, which must be sent to ITALCERT, also as external documentation. The manufacturer must ensure that the presence of sub-suppliers is adequately defined in the agreements. Moreover, the manufacturer must ensure the proper management of the sub-suppliers (e.g., qualification and monitoring) by its outsourcer or critical supplier.

It should be noted that where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted to EUDAMED database (Article 10 (15) of MDR). This information must be aligned with the technical documentation.

5. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

5.1 – General Safety and Performance Requirements (GSPR) Checklist

- **All GSPRs must be identified**. If some of these may be deemed not applicable, an explanation must be provided
- Description of how compliance with the specific GSPR is guaranteed must be provided.
- Standards and Common Specifications applied to demonstrate compliance with the requirement must be identified (with also the specific edition). If compliance with the requirement is demonstrated by applying only part of a standard or CS, the specific section must necessarily be identified.
- The sections of the technical documentation or of other documentation proving conformity to the requirements must be identified (identification must be as “Document ID, section, point, page”).

If the device is also a machine, if applicable, provide demonstration of compliance with the additional Essential Requirements of Directive 2006/42/EEC.

5.2 – List of applicable standards

A list of applicable standards, Common Specifications, guidelines and all applicable legislative and regulatory acts (Directives and / or Regulations) must be provided, including local legislation, if applicable. It is acceptable to refer to an external controlled document.

6. RISK AND BENEFIT ANALYSIS AND RISK MANAGEMENT

6.1 – Benefits and risks analysis

Analysis of the risks and benefits referred to in Annex I, points 1 and 8.

Provide documentation that clearly demonstrates that the benefits arising from the use of the device outweigh the associated risks, when used according to the intended intended use.

6.2 – Risk management

Solutions adopted and the results of the risk management referred to in Annex I, point 3.

6.2.1 – Risk management procedure

It is necessary to provide procedures for risk management. In particular, evidence of the "life-cycle management" concept must be provided, i.e., the analysis must be performed throughout the life cycle of the device, from design to disposal, considering all the appropriate PMS data. The link between risk management process and data from pre-clinical evaluations (product verification and validation) and clinical evaluation must be clear and noticeable.

Information must be provided about the adopted methods of evaluation, including the evaluation criteria for acceptability.

Provide the qualification (resumes) of the risk assessment team and explain why the manufacturer deems its the competence appropriate.

6.2.2 – Risk management plan

Provide the specific risk management plan for the device.

6.2.3 – Risk management report

Provide the specific risk management report for the device.

7. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

Non-exhaustive list of the documentation required for product verification and validation is provided below. For each item a brief description is proposed. It is not the purpose of this document to provide complete indications about the specific points, as the requirements are strictly related to the specific device.

However, the manufacturer is responsible for defining which analyses and evaluations are necessary for the demonstration of safety and performance of the specific device. For each aspect treated, a test protocol and appropriate reports must be provided.

7.1 – Biocompatibility

Biological risk assessment

This analysis can also be part of the risk assessment. However, the biological risk assessment must takes into account the specific GSPRs

Materials Characterization

Provide the data about the materials used and their characterization, in accordance with the requirements of Annex I.

We recommend to carry out appropriate tests, where appropriate and applicable (e.g., it is not considered strictly essential to provide evidence of laboratory tests for materials considered standard and regulated by specific standards as ISO 5832 series).

Biocompatibility protocols, tests and reports

Biocompatibility must be evaluated on the finished product. Biological risk assessment cannot be based exclusively on considerations about raw materials. All transformation processes, including sterilization, must be included in the analysis.

When possible, for devices characterized by well-established technologies (Art. 52 (5)), a demonstration of biocompatibility based on literature is allowed.

Provide the qualification (CVs) of the team responsible of the biological risk assessment.

In principle, harmonized standards and the applicable Common Specifications apply. In the transition period from MDD to MDR, in the absence of harmonized standards under the MDR, ISO 10993 series are considered applicable. If other standards or other non-standard methodologies are used, it is mandatory to provide a gap analysis.

7.2 – Microbiological characterization

Characterization studies must be representative of the production process.

Following every variation to the production process, appropriate considerations must be made.

7.3 – Electromagnetic compatibility (ECM) and electrical safety

Provide protocols and test reports relating to electrical safety and electromagnetic compatibility.

The documentation must be aligned with the risk management plan for the device

7.4 – Software verification and validation

Provide a description of the design and development process for both software-as-medical-device or software integrated into a medical device, in relation to the specific applicable GSPRs.

It is requested to consider the life cycle requirements of the software for medical devices as defined in the applicable harmonized standards.

Manufacturer should consider all the applicable MDCG guidelines.

7.5 – Stability, shelf-life, packaging

Validation must be supported by protocols, with acceptability criteria for each test performed.

If the tests are based on accelerated stability data, a real-time test plan must be provided as well as a specific plan for aging, which includes the method of calculating the aging conditions.

If special conditions are defined for the conservation of the device, it is necessary to provide the results of specific tests in order to demonstrate that the characteristics of the device are not altered during transport, in accordance with the applicable GSPRs.

7.6 – Sterilization

For devices that are intended to be sterilized by the user and that require specific procedures for cleaning, decontamination and sterilization, refer to the requirements of point 6.9 – Reusable surgical instruments, as applicable.

In case of devices placed on the market in a sterile condition or in a given microbiological condition, provide a description of the environmental conditions related to the relevant manufacturing steps. If devices are placed on the market in a sterile condition, provide a description of the methods used, including packaging, sterilization and sterility maintenance reports. The validation report regards the determination of the microbial state (bioburden), pyrogens tests and, where applicable, the tests for the determination of sterilizing agent residues.

7.7 – Performance and safety studies

Design verification and validation tests, such as mechanical tests or simulations, must be provided (if applicable). In case of a device group or family, a worst-case rationale must be provided.

If the studies are not considered necessary, for example in the case of extensions of the certification or in the case of minor changes to the device, a justification must be provided.

Usability studies must also be included.

7.8 – Reusable surgical instruments

The information provided regarding cleaning, disinfection and sterilization must be supported by specific validations. Reference to procedures or good practices generally applied by final users (e.g., hospital's sterilization unit) cannot be considered sufficient.

Protocols and reports must be provided for each process listed in the IFU.

Maintenance process must be described in the IFU and in the technical documentation. Provide information about the device performance evaluation, i.e., functional tests carried out in order to confirm compliance with safety and performance requirements.

Maximum number of reuses must be supported by tests and validations. If the manufacturer does not consider appropriate to declare a maximum number of re-uses, justification must be provided.

7.9 – Devices with measurement function

Provide a description of the methods (protocols and reports) used to ensure precision and accuracy of the measures, as declared in the device technical specifications. Provide details about calibration of the device.

7.10 – Dispositivi destinati ad essere connessi ad altri dispositivi

Devono essere forniti i protocolli, i test e i rapporti a supporto della garanzia della sicurezza e prestazione della combinazione dei dispositivi, in particolare in relazione al rispetto dei GSPR.

7.11 – Devices incorporating a medicinal substance

Dossier of the medicinal product must be provided, as a separate document.

7.12 – Devices manufactured utilising tissues or cells of human or animal origin

Certification application must specify whether the device incorporates tissues or cells of animal origin. A declaration must be present in the technical documentation, also in case the device does not incorporate any tissue.

Compliance with ISO 22442 must be demonstrated.

It should be noted that ITALCERT is not authorized for the evaluation of devices referred to in EU Reg. 722/2012.

It should be noted that ITALCERT is not authorized for the evaluation of devices incorporate tissues or cells of human origin.

7.13 – Devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body

Manufacturer must consider the requirements of Directive 2001/83/EC regarding the assessment of absorption, distribution, metabolism and excretion (ADME), local tolerance, toxicity and interaction with other devices, medicinal substances or other substances, potential adverse reactions.

In general, for devices consisting of substances in relation to Rule 21, tests for product characterization, for proper qualification as a medical device (mechanism of action) and for establish the right classification according to Rule 21 are deemed necessary.

If the manufacturer does not conduct specific tests, data from scientific literature can be used, along with a supporting rationale.

7.14 – Devices containing CMR or endocrine-disrupting substances

Provide evidences to support compliance with GSPR requirements 10.4.1 - 10.4.5.

If the manufacturer does not conduct specific tests, data from scientific literature can be used, along with a supporting rationale.

7.15 – Clinical evaluation

Fill and provide the ITALCERT's MDR34 form.

In general, the following information must be provided:

- Clinical evaluation plan, as per Annex XIV, Part A, letter a) of MDR
- Clinical assessment report
- Evaluator's resume and signed declaration of interest (resume must be signed and refer to Reg. UE 2016/679, as applicable)
- Clinical investigations, if applicable
- SSCP (Article 32 of MDR) - if applicable. Consider the relevant MDCG guidelines.

7.16 PMS – PMCF

Fill and provide the ITALCERT MDR34 form.

Refer to Annex III and Annex XIV Part B of MDR. Consider the relevant MDCG guidelines.

8. DECLARATION OF CONFORMITY

Declaration of Conformity must include the information required by Annex IV of MDR.

9. RE-CERTIFICATION

In case of certificate renewal provide a summary of changes and scientific findings for the device (Annex VII, point 4.11) including:

a) all changes to the originally approved device, including changes not yet notified
b) experience gained from post-market surveillance
c) experience from risk management

d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I
e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF
f) changes to the requirements, to components of the device or to the scientific or regulatory environment
g) changes to applied or new harmonised standards, CS or equivalent documents
h) changes in medical, scientific and technical knowledge, such as:
    a. new treatments
    b. changes in test methods
    c. new scientific findings on materials and components, including findings on their biocompatibility
    d. experience from studies on comparable devices
    e. data from registers and registries
    f. experience from clinical investigations with comparable devices.