GUIDE

CLINICAL EVALUATION
SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP) REGULATION (EU) 2017/745

DECEMBER 2023 EDITION

GMED
LNE GROUP

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CONTENTS

REFERENCE DOCUMENTS

ORIGIN	REFERENCE	TITLE
European Union	Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
European Union	Implementing Regulation (EU) 2022/2346	Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices
European Union	Implementing Regulation (EU) 2022/2347	Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose
European Union	MEDDEV 2.7/1 rev4	Evaluation of clinical data: a guide for manufacturers and notified bodies
European Union	MEDDEV 2.12/2 rev2	Guidelines on post-market clinical follow-up studies
CEN - ISO	NF EN ISO 13485:2016	Medical devices Quality management systems – Requirements for regulatory purposes
CEN - ISO	NF EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
CEN - ISO	NF EN ISO 14155:2020	Clinical investigation of medical devices for human subjects
GHTF	SG5/N1R8 (2007)	Clinical Evidence - Key definitions and concepts
GHTF	SG5/N2R8 (2007)	Clinical Evaluation
MDCG	MDCG 2019-9 rev 1	Summary of safety and clinical performance A guide for manufacturers and notified bodies
MDCG	MDCG 2020-1	Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software
MDCG	MDCG 2020-5	Clinical evaluation - Equivalence A guide for manufacturers and notified bodies
MDCG	MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies

REFERENCE DOCUMENTS

MDCG	MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
MDCG	MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
MDCG	MDCG 2020-13	Clinical evaluation assessment report template
MDCG	MDCG 2021-20	Instructions for generating CIV-ID for MDR Clinical Investigations
MDCG	MDCG 2021-28	Substantial modification of clinical investigation under Medical Device Regulation
MDCG	MDCG 2020-10/1 rev 1	Guidance on safety reporting in clinical investigations
MDCG	MDCG 2020-10/2 rev 1	Appendix: Clinical investigation summary safety report form

NOTE

The texts of the European regulation and implementing regulations are published in the Official Journal of the European Union.
MEDDEV guidelines are available on the European Commission website:
https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en
MDCG guidelines are available on the European Commission website:
https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
Standards are available at AFNOR: www.afnor.org
GHTF (Global Harmonization Task Force) guidelines are available on the following website:
http://www.imdrf.org/documents/documents.asp

II DEFINITIONS

Bias: Bias is a systematic deviation of an outcome measure from its true value, leading to either an overestimation or underestimation of a treatment's effect. It can originate from, for example, the way patients are allocated to treatment, the way treatment outcomes are measured and interpreted, and the way data are recorded and reported.
[Adapted from GHTF SG5/N2R8:2007]

Clinical benefit: The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.
[Regulation (EU) 2017/745]

Clinical data: Information concerning safety or performance that is generated from the use of a device and is sourced from the following:

- Clinical investigation(s) of the device concerned;
- Clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated;
- Reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated;
- Clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up.

[Regulation (EU) 2017/745]

Clinical evaluation: A systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.
[Regulation (EU) 2017/745]

Clinical evidence: Clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer.
[Regulation (EU) 2017/745]

Clinical investigation: Any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.
[Regulation (EU) 2017/745]

Clinical Investigation Plan: A document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organization and conduct of a clinical investigation.
[Regulation (EU) 2017/745]

Clinical performance: The ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.
[Regulation (EU) 2017/745]

Clinical safety: Freedom from unacceptable clinical risks, when using the device according to the manufacturer's Instructions for Use.
[MEDDEV 2.7/2 revision 2]
Note: In exceptional cases where the instruction for use are not required, collection, analysis and assessment are carried out taking into account generally recognized terms of use.

Consumer: A natural person on whom a product without an intended medical purpose is intended to be used.
[Implementing Regulation (EU) 2022/2346]

Equivalent device: A device for which equivalence to the device in question can be demonstrated *(See the explanation in this guidance document).*

Feasibility study: A clinical investigation that is commonly used to capture preliminary information on a medical device (at an early stage of product design) to adequately plan further steps of device development, including needs for design modifications or parameters for a pivotal study.
[MEDDEV 2.7/2 revision 2]

Generic device group: A 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.
[Regulation (EU) 2017/745]

Indication/Indication for use: Refers to the clinical condition that is to be diagnosed, prevented, monitored, treated, alleviated, compensated for, replaced, modified or controlled by the medical device. It should be distinguished from 'intended purpose/intended use', which describes the effect of a device. All devices have an intended purpose/intended use, but not all devices have an indication (e.g. medical devices with an intended purpose of disinfection or sterilisation of devices).
[MDCG 2020-6]

Intended purpose: The use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.
[Regulation (EU) 2017/745]

Performance: The ability of a device to achieve its intended purpose as stated by the manufacturer.
[Regulation (EU) 2017/745]

Post-market clinical follow-up (PMCF): A continuous process that updates the clinical evaluation addressed in the manufacturer's post-market surveillance plan.
[Regulation (EU) 2017/745]

Post-market clinical follow-up study: A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e., residual risks) of a device when used in accordance with its approved labelling.
[MEDDEV 2.12/2 rev.2]

Post-market surveillance: All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.
[Regulation (EU) 2017/745]

Similar device: Device belonging to the same generic device group.
[MDCG 2020-6]

Sufficient clinical evidence: An amount and quality of clinical evidence to guarantee the scientific validity of the conclusions.
[MEDDEV 2.7/1 revision 4]

III PART A: CLINICAL EVALUATION

Confirmation of conformity with applicable relevant general safety and performance requirements to Regulation (EU) 2017/745, under the normal conditions of the device intended use, as well as the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk ratio are based on clinical data providing sufficient clinical evidence.

It is the manufacturer's responsibility to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers plan, perform and document a clinical evaluation.

The purpose of this section, to the attention of device manufacturers, is to describe the different elements to be included in:

- The clinical evaluation plan;
- The clinical evaluation report;
- The post-market surveillance plan including the post-market clinical follow-up (PMCF) plan;
- The PMCF evaluation report.

All these documents are part of the technical documentation that the manufacturer must establish to demonstrate the conformity of its device with the relevant provisions of Regulation (EU) 2017/745.

Preamble:

- In case of the devices concerning by the specific procedure of Article 54 of Regulation (EU) 2017/745, namely class III implantable devices and class IIb active devices intended to administer in the organism and/or remove a medicinal product, the manufacturer is requested to send the clinical evaluation report in duplicate and in English;
- In case of devices that have used the provisions of Article 61, paragraph 2, of Regulation (EU) 2017/745, namely a prior consultation with a group of experts, the manufacturer is requested to transmit the opinion issued by the group of experts, as part of the clinical data evaluation;
- In case of medical device software, the manufacturer is requested to use the MDCG 2020-1 guide: "Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software" in order to carry out the evaluation of clinical data.

1 → Principles of clinical evaluation

1.1 What is a clinical evaluation?

Clinical evaluation is a methodologically sound ongoing procedure to collect, appraise and analyse clinical data pertaining to a device and to analyse whether there is sufficient clinical evidence to confirm compliance with relevant general safety and performance requirements when using the device according to the manufacturer's instructions for use.

Clinical evaluation is a requirement of Regulation (EU) 2017/745 which applies to all classes and types of devices, including devices for which demonstration of conformity with the general safety and performance requirements based on clinical data is not deemed appropriate as well as device without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745. The evaluation should be appropriate to the device assessed, its specific properties, and its intended purpose.

Please note that the Article 61, paragraph 10, of Regulation (EU) 2017/745 which allows the use of non-clinical data to demonstrate the conformity with the general safety and performance requirements does not apply to implantable devices or class III devices.

Conformity to the general safety and performance requirements can only be assumed when the following items are aligned with each other:

1. The information supplied by the manufacturer (the labelling, instructions for use, available promotional materials, including accompanying documents foreseen by the manufacturer);
2. The clinical evaluation (the device description used for the clinical evaluation, results of clinical investigations, publications, post-market clinical studies, other content of the clinical evaluation report);
3. The risk management file;
4. The usability demonstration.

1.2. When clinical evaluation is to be performed?

Clinical evaluation is conducted throughout the life cycle of a device, as an ongoing process.
Usually, it is first performed during the development of a device in order to identify data that need to be generated for market access. Clinical evaluation is mandatory to obtain CE marking and it must be actively updated thereafter.
As reminder, it addresses the section 7.3.7 of the ISO 13485 standard, current version.

- **During device development**

Typically, manufacturers carry out clinical evaluations to:

1. Define needs regarding clinical safety and clinical performance (including clinical benefit) of the device;
2. In case of possible equivalence to an existing device, evaluate if there are clinical data available and determine equivalence;
3. Carry out a gap analysis and define which data still need to be generated for the device under assessment, whether clinical investigations are necessary and if so, to define the study.

- **Clinical evaluation for CE marking**

Clinical evaluation is required to be carried out for the conformity assessment process leading to the CE marking and placing on the market of a device. The purpose is to:

1. Document that there is sufficient clinical evidence to demonstrate conformity with the relevant general safety and performance requirements;
2. Identify aspects that need to be systematically addressed during post-market surveillance, e.g., the required post-market clinical follow-up (PMCF) studies. Typically, these aspects include estimation of residual risks and uncertainties or unanswered questions (such as rare complications, uncertainties regarding long-term performance, safety under wide-spread use).

- **Updating the clinical evaluation: frequency and consideration**

The manufacturer should define and justify the frequency at which the clinical evaluation needs to be actively updated.

It should ensure that the clinical evaluation and the documentation relating thereto are updated throughout the life cycle of the device concerned using clinical data obtained following the application of its post-market surveillance plan, including the PMCF plan.

For class III devices and implantable devices, the PMCF evaluation report and, where applicable, the summary of safety and clinical performance, are updated at least annually by adding the relevant data.

Please note that for each update of the summary of safety and clinical performance, the manufacturer must send the summary to GMED for validation and upload of the summary in the European database on medical devices (EUDAMED) as soon as EUDAMED will be fully functional.

At the end of the conformity assessment process, GMED decides a specific frequency for review the updated clinical evaluation. The frequency at which the clinical evaluation will be updated by the manufacturer must be coordinated with the timeline set by GMED.

1.3. Clinical investigation in the case of implantable devices and class III devices

As a general rule, in case of implantable devices and class III devices, clinical investigations shall be performed.

However, there is no need to conduct clinical investigations in the following cases:

Case 1:
- The device has been designed by modifications of a device already marketed by the same manufacturer;
- The manufacturer has demonstrated that the modified device is equivalent (see part IV) to the device marketed, and this demonstration has been approved by GMED;
- The clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

Case 2:
- The manufacturer has demonstrated that its device is equivalent to a device already on the market and not manufactured by itself;
- The two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis;
- The original clinical evaluation has been performed in compliance with the requirements of the Regulation (EU) 2017/745;
- The manufacturer of the second device provides clear evidence thereof to GMED;
- The device claimed to be equivalent is already CE marked under Regulation (EU) 2017/745.

Case 3:
- The device has been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC;
- The clinical evaluation is based on sufficient clinical data;
- The clinical evaluation complies with the relevant product-specific common specification (CS) for the clinical evaluation of that type of device, where such CS is available.

Case 4:
- The device belongs to the following list: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors;
- The clinical evaluation is based on sufficient clinical data;
- The clinical evaluation complies with the relevant product-specific CS for the clinical evaluation of that kind of device, where such CS is available.

In cases 1 and 2, GMED verifies that the PMCF plan is appropriate and includes post-market studies to demonstrate the safety and performance of the device.

In all cases, the manufacturer justifies its decision not to conduct clinical investigations in the clinical evaluation report. GMED shall assess this justification in the clinical evaluation report assessment.

1.4. How is clinical evaluation performed?

There are distinct stages in performing a clinical evaluation:

- **Preliminary stage -** Clinical evaluation planning:
  - Establishes the clinical evaluation plan.

- **Stage 0 -** Scope of clinical evaluation:
  - Explains the scope and context of the evaluation, including which products/models/sizes/settings are covered by the clinical evaluation report, and the technology on which the medical device is based.

- **Stage 1 -** Identification of pertinent data:
  - Describes the literature search strategy;
  - Presents the nature and extent of the clinical data and relevant pre-clinical data that have been identified.

- **Stage 2 -** Appraisal of pertinent data:
  - Evaluates the clinical data identified in the previous step, their methodological quality, their scientific validity, the relevance for the evaluation, the weighting attributed to the evidence, and any limitations.

  The clinical data sets should be subject to an appraisal with respect to their relative contribution to the overall clinical evaluation. It is important to perform analysis of the methodological quality of data obtained from different sources to identify and assess the level of evidence, bias, other inherent weaknesses, or other possible shortcomings. Indeed, clinical investigations, scientific literature, post-market clinical data and other sources of clinical data can be of variable methodological quality and therefore an appraisal of the design of these studies is important.

  Clinical data appraisal should be conducted using verified/validated assessment tools. Among these methodological quality assessment tools, we find the tools described in Appendix F of IMDRF MDCE WG/N56 on Clinical Evaluation, Cochrane Collaboration's tool for Randomized Controlled Trials (RTC), MINORS (Methodological Index for Non-Randomized Studies), Reisch tool (for non-randomized interventional studies), Newcastle-Ottawa Scale (NOS) for assessing the quality of non-randomised studies in meta-analyses. This list is not exhaustive. Additional verified/validated assessment tools may be used.

  - Presents justifications for rejecting certain data or documents.

- **Stage 3 -** Summary and analysis of data:
  - Summarizes the relevant data provided;
  - Analyses relevant data provided to demonstrate:
    - The conformity to the safety requirements;
    - The conformity to the performance and clinical benefit requirements;
    - The conformity to the requirement related to acceptable benefit-risk, including acceptability of undesirable side-effects.

It is noted that the utilization of post-market surveillance data, such as data from customer complaints, vigilance, incidence report or any other vigilance, for the purpose of conformity assessment cannot always provide reliable data with respect to the incidence of risks due to limitations of complaints reporting, misuse, etc. Therefore, the use of ratio [number of incidents or complaints] / [number of device sales] cannot be considered sufficient to provide proof of device safety. Its use should be limited to cases where data from pre-market or post-market clinical investigations are not deemed appropriate.

- **Stage 4 -** Finalisation of the clinical evaluation report:
  - Provides clear statement concerning compliance to general safety and performance requirements;
  - Takes into account the opinion of the expert group, when applicable;
  - Justifies the acceptability of the benefit-risk profile according to current knowledge / the state of the art in the medical fields concerned and according to available medical alternatives;
  - Declares suitability of the device, including its IFU, for the intended users and usability aspects; discrepancies;
  - Evaluates if there is consistency between the clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under assessment; discrepancies.

1.5. What is the post-market surveillance plan?

The post-market surveillance plan relates to the collection and usage of available information, in particular:

- Records referring to serious incidents, including information from Periodic Safety Updated Reports (PSUR), and field safety corrective actions;
- Records referring to serious incidents and data on any undesirable side-effects;
- Information from trend reporting;
- Relevant specialist or technical literature, databases and/or registries;
- Information, including feedbacks and complaints, provided by users, distributors and importers;
- Publicly available information about similar medical devices.

1.6. What is the post-market clinical follow-up plan?

The PMCF plan specifies the methods and procedures for proactively collecting and evaluating clinical data with the aim of:

- Confirming the safety and performance of the device throughout its expected lifetime;
- Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications;
- Identifying and analysing emergent risks on the basis of factual evidence;
- Ensuring the continued acceptability of the benefit-risk ratio referred to in Annex I, sections 1 and 9 of Regulation (EU) 2017/745;
- Identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

The MDCG 2020-7 "Post-market clinical follow-up (PMCF) Plan Template – A guide for manufacturers and notified bodies" provides a PMCF plan template to meet the requirement of Regulation (EU) 2017/745. GMED advises the manufacturer to use this template to build the PMCF plan.

1.7. Who should perform a clinical evaluation?

The clinical evaluation should be conducted by a suitably qualified individual or a team.

The manufacturer should take the following aspects into consideration:

1. The manufacturer defines requirements for the product reviewers that are in line with the nature of the device under evaluation and its clinical performance and risks;
2. The manufacturer should be able to justify the choice of the product reviewers through reference to their qualifications and documented experience, and to present a declaration of interest for each product reviewer.

As a general principle, the product reviewers should possess knowledge of the following:

1. Research methodology (including clinical investigation design and biostatistics);
2. Information management (e.g., scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline);
3. Regulatory requirements;
4. Medical writing (e.g., post-graduate experience in a relevant science or in medicine, training and experience in medical writing, systematic review and clinical data appraisal).

With respect to the particular device under evaluation, the product reviewers should in addition have knowledge of:

1. The device technology and its application;
2. The diagnosis and management of the conditions for which the device is intended to be used, knowledge of medical alternatives, treatment standards and technology (e.g., specialist clinical expertise in the relevant medical specialty).

The product reviewers should have at least the following training and experience in the relevant field:

1. A degree from higher education in the relevant field and 5 years of documented professional experience, or;
2. 10 years of documented professional experience if a degree is not a prerequisite for a given task, related to the clinical evaluation.

There may be circumstances where the level of product reviewer expertise may be less or different; this should be documented and duly justified. It is understood that the competences can be shared on a team, knowing that the plan and the report need to be signed by all the members of the team.

2. → Equivalence

Clinical, technical and biological characteristics shall be taken into consideration for the demonstration of equivalence:

- Clinical, the device shall be:
  - Used for the same clinical condition or purpose, including similar severity and stage of disease;
  - Used at the same site in the body;
  - Used in a similar population, including as regards age, gender, anatomy, physiology, possibly other aspects;
  - Used by the same kind of user;
  - Have similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.
- Technical, the device shall:
  - Be of similar design;
  - Use under similar conditions of use;
  - Have similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms;
  - Use similar deployment methods, where relevant;
  - Have similar principles of operation and critical performance requirements.
- Biological, the device shall:
  - Use the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables.

Different aspects of equivalence and conformity of different general safety and performance requirements can be affected by materials. Product reviewers should consider biological safety (e.g., in compliance to ISO 10993) as well as other aspects necessary for a comprehensive demonstration of equivalence. A justification explaining the situation should be provided for any differences.

For assuming equivalence:

- Equivalence can only be based on a single device;
- All three characteristics (clinical, technical, biological) need to be fulfilled;
- Similar means that no clinically significant difference in the performance and safety of the device would be triggered by the differences between the device under evaluation and the device presumed to be equivalent;
- The differences between the device under evaluation and the device presumed to be equivalent need to be identified, fully disclosed, and evaluated; explanations should be given why the differences are not expected to significantly affect the clinical performance and clinical safety of the device under evaluation;

- The manufacturer should investigate if the medical device presumed to be equivalent has been manufactured via a special treatment (e.g., a surface modification, a process that modifies material characteristics); if this is the case, the treatment could cause differences in respect to technical and biological characteristics, and this should be taken into account for the demonstration of equivalence and documented in the clinical evaluation report;

- If measurements are possible, clinically relevant specifications and properties should be measured both in the device under evaluation and the device presumed to be equivalent, and presented in comparative tabulations;

- Comparative drawings or pictures should be included in order to compare shapes and sizes of elements that are in contact with the body;

- The manufacturer is expected to:
  - Include the supporting non-clinical information (e.g., pre-clinical study reports) in the technical documentation of the device;
  - In the clinical evaluation report, summarise the information and cite its location in the technical documentation.

- For the evaluation of the technical characteristics:
  - Devices that achieve the same therapeutic result by different means cannot be considered equivalent.

- For the evaluation of the biological characteristics:
  - When a detailed chemical characterisation of materials in contact with the body is needed, ISO 10993-18 Annex C can be used to show toxicological equivalence, but this is just one part of the evaluation of the biological criteria;
  - Sourcing and manufacturing procedures may adversely affect impurity profiles; analytical methods chosen to characterise medical devices should appropriately take into consideration knowledge concerning expected impurity profiles (tests may have to be repeated when production methods or sourcing are modified);
  - It may be necessary to show from histopathological studies that the same host response is achieved in vivo in the intended application and the intended duration of contact;
  - For animal tests, differences between species may limit the predictive value of the test; the choice of the test and its predictive value should be justified;
  - Abrasion, if relevant, and host response to particles may also need to be considered.

- For the clinical characteristics evaluation:
  - The only clinical data that are considered relevant are the data obtained when the equivalent device is a CE marked device used in accordance with its intended purpose as documented in the Instructions For Use (IFU).

- For implantable devices and class III devices:
  - When the equivalence concerns implantable devices and class III devices already marketed and not manufactured by the manufacturer itself and this equivalence allows the manufacturer to not conduct clinical investigations, the manufacturer must provide a contract concluded between the two manufacturers who explicitly allows the manufacturer of the device under clinical evaluation full access to the technical documentation on an ongoing basis as well as clear evidence that the original clinical evaluation has been performed in accordance with the requirements of Regulation (EU) 2017/745 and the device claimed to be equivalent is already CE marked under Regulation (EU) 2017/745.

- For devices other than implantable devices and class III devices:
  - When the equivalence concerns devices other than implantable devices and class III devices already marketed and not manufactured by the manufacturer itself and this equivalence allows the manufacturer to not conduct clinical investigations, Regulation (EU) 2017/745 does not require a contract between the two manufacturers allowing full access to the technical documentation. However, the manufacturer must have a sufficient level of access to data relating to the devices with which it claims equivalence and document this access.

- **Note :** Exceptions can be considered for devices other than implantable devices and class III devices:

  a) When the equivalent device is not a CE marked device (the device has an active regulatory status other than CE marking or has had a regulatory status other than CE marking which is no longer active), and the following conditions are met:
  - The manufacturer must have a sufficient level of access to data relating to the device with which it claims equivalence;
  - Clinical investigations have been conducted in accordance with current international guidelines;
  - Clinical data meets the requirements of Regulation (EU) 2017/745 and it is justified that the clinical data is transferable to the European population;
  - The regulatory status of the device claimed to be equivalent must be indicated as well as the reason why this regulatory status is no longer active, where applicable.

  b) When the device has had a CE marking, which is no longer active at the time of assessment, and the following conditions are met:
  - The manufacturer must have a sufficient level of access to data relating to the device with which it claims equivalence;
  - Clinical investigations have been conducted in accordance with current international guidelines;
  - Clinical data meets the requirements of Regulation (EU) 2017/745;
  - The manufacturer must justify the reason why the CE marking is no longer active.

- For devices without an intended medical purpose:
  - In the case of devices without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, clinical evaluation may be based on clinical data from an equivalent device without an intended medical purpose or an analogous device with a medical purpose.

    An analogous device with a medical purpose shall be understood as the same device with a medical purpose or a medical device for which equivalence to the same device with a medical purpose has been demonstrated by the manufacturer in accordance with section 3 of Annex XIV to Regulation (EU) 2017/745, as specified in section 2.3 of Annex I of Implementing Regulation (EU) 2022/2346.

    As it is not possible to demonstrate clinical equivalence between a medical device and a device without an intended medical purpose, where all available results on clinical investigation relate only to medical devices for their intended medical indications, clinical investigations should be performed for devices without an intended medical purpose.

3. → Clinical evaluation plan

The manufacturer must establish a clinical evaluation plan which, at least:

- Identifies the general safety and performance requirements that require support from relevant clinical data;
- Specifies the intended purpose of the device;
- Specifies clearly the intended target groups with clear indications and contra-indications;
- Describes in detail the intended clinical benefits to patients with relevant and specified clinical outcome parameters;
- Specifies the methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;
- Provides an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;
- Indicates how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed;
- Includes a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF with an indication of milestones and a description of potential acceptance criteria.

The clinical evaluation plan must be systematically attached to the clinical evaluation report.

Note that for the devices covered by a CE marking certificate under Directive 93/42/EEC or 90/385/EEC (legacy devices), the content of the clinical evaluation plan can be adapted to this type of device.

Consequently, the clinical evaluation plan expected for this type of device should include at least:

- An identification of the general safety and performance requirements that require support from relevant clinical data;
- A specification of the intended purpose of the device;
- A clear specification of intended target groups with clear indications and contra-indications;
- A detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;
- A strategy to identify, analyse and assess alternative treatments;
- A specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;
- An indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;
- An indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed;
- A strategy and methodology to identify, analyse and assess all relevant available clinical data in light of the changed definition for clinical data;
- Evidence for equivalence, if clinical data from an equivalent device is included in the clinical evaluation;
- A definition of the required level of clinical evidence, which shall be appropriate in view of the characteristics of the device and its intended purpose;
- A strategy and methodology to systematically collect, summarise and assess post-market surveillance data to demonstrate continuing safety and performance, and to what extent complaints with regards to safety and performance have been observed with the legacy devices.

4. → Clinical evaluation report (CER)

The elements of the clinical evaluation report are records of the process that the manufacturer applies to the identification, selection, evaluation and critical analysis of clinical data in order to meet the relevant provisions of Regulation (EU) 2017/745.

4.1. Clinical evaluation report for devices with a medical purpose

The table below gives an example of the clinical evaluation report possible content for devices with a medical purpose. It is recommended that the manufacturer follows this template.

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
	• **Device name, model, and type;** • **Risk class;** • **Applicable code(s) to the device per Commission Implementing Regulation (EU) 2017/2185;** • **Basic UDI-DI** (if available); • **EMDN** (European Medical Device Nomenclature) **code corresponding to the device;** • **For non-implantable class IIb and implantable class IIb devices** (limited to sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors), **generic group corresponding to the device;** • **For class IIa devices, category corresponding to the device;** • **Certificate number** (if applicable); • **Project number of the device assigned as part of its design and development.**
	• **Manufacturer name and SRN;** • **If applicable, authorized representative name and SRN.**
Section 1: *Administrative particulars (manufacturer, product and clinical evaluation report reference)*	• **Type of conformity assessment:** - Initial conformity assessment, or; - Assessment of changes and update of the clinical evaluation, or; - Re-certification assessment, or; - Assessment limited to clinical evaluation for class IIb active devices intended to administer and/or remove a medicinal product not selected within the framework of the sampling plan established prior the issuance of the certificate, or; - Assessment of technical documentation for class IIa / IIb devices on a sampling basis. • **Conformity assessment procedure under Regulation (EU) 2017/745:** - Annex IX Chapters I, II and III, or; - Annex X + Annex XI Part A, or; - Annex X + Annex XI Part B, or; - Annex IX Chapters I and III with sampling of technical documentation assessment as specified in section 4 of Annex IX, or; - Annex IX Chapters I and III, or; - Annex XI Part A - Including section 10, or; - Annex XI Part B - Including section 18.
	• **Technical documentation identification number**
	• **Device intended purpose**

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 1: *Administrative particulars (manufacturer, product and clinical evaluation report reference)*	• **Type of clinical data used for clinical evaluation of the device:** - Data from clinical investigation of the device concerned; - Data from clinical investigation of a device for which equivalence to the device concerned can be demonstrated; - Bibliographic data from scientific literature of the device concerned; - Bibliographic data from scientific literature of a device for which equivalence to the device concerned can be demonstrated; - Data from post-market surveillance of the device concerned; - Clinical data is not deemed appropriate according to Article 61(10) of Regulation (EU) 2017/745.
	• **CVs of CER author(s)**
Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**1. Device description:** Describe the device and comment on the intended use, including: • The intended purpose; • Indication(s) and contra-indication(s); • Adverse effects; • The intended patient population and medical conditions to be diagnosed, treated and/or monitored; • Target user group; • A general description of the key functional elements: its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition; • The principles of operation of the device and its mode of action; explanation of any novel features; • Intended application of the device: single-use/reusable, invasive/non-invasive, implantable; • The duration of use or contact with the body, the maximum number of repeated applications; • The identification of organs, tissues or bodily fluids in contact with the device; • The claims on clinical performance and clinical safety foreseen by the manufacturer; • The clinical benefits sought for the patients, using relevant and precise parameters in terms of clinical results. **2. Classification** Applicable classification rule(s), specify the corresponding indent. **3. Device configurations/variants:** • Description of the different sizes, differences in design features, different configurations, etc.; • Image of the device where possible; • Whether the device is already CE marked or already on the market, specify the date since which the device has been CE marked or the date since the device has been on the market and the regions in which the device is available and the sales volumes; • If applicable, description of the device history and/or changes in the device, including the date and reason of these changes; • Where relevant, description of the reason for differences in design features between variants of the device with photographs or diagrams where possible. **4. Accessories or compatible devices:** • Description, images, or other relevant information such as diagrams, if necessary, of any accessories or compatible devices, including components of the device in case of system/procedure pack; • Identification if the use of accessories or compatible devices has an impact on clinical safety or performance or the scope or validity of the clinical evaluation.

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**5. Previous generations of the device and similar devices (if applicable):** • An overview of the previous generation(s) of the device produced by the manufacturer, where such devices exist; • An overview of identified similar devices available in the European Union or international markets, where such devices exist, including length of time on the market, sales volume, etc. **6. Clinical evaluation plan:** *See Part A section 3 of this guide.* **7. Common specifications and harmonized standards applied:** • List of common specifications relevant to the device applied and respected; • In the event that common specifications specific to the device exist and they are not applied, precise and detailed presentation of the alternative and equivalent solutions retained and applied to the device; • List of relevant harmonized standards related to the device with their revision; • In case of partial application of a relevant harmonized standard relating to the device, justification for the partial application of the corresponding harmonized standard; • In the event that the relevant harmonized standard(s) relating to the device is (or are) not applied, precise and detailed presentation of the alternative and equivalent solutions retained and applied to the device; • List, description, and justification for other solutions retained and applied (e.g., standards, directives, etc.). **8. Demonstration of equivalence:** a) Indicate if: • The clinical evaluation is based upon clinical investigations or other studies reported in scientific literature of a device for which equivalence to the device in question can be demonstrated; or/and • The clinical evaluation is based upon reports published in peer reviewed scientific literature on other clinical experience of a device for which equivalence to the device in question can be demonstrated. b) Device(s) to which equivalence has been claimed: • Identification of the equivalent device(s) and its manufacturer: - Exact name, models, sizes, software versions, accessories, etc.; - Name of the manufacturer; - Relationship to the device under evaluation (predecessor/successor, others). If the device is not CE marked, justification for the use of the data, based on the other regulatory status; - Device with which equivalence is most relevant. c) Equivalence: • Comparative tables for device(s) under evaluation compared to the equivalent device showing the parameters relating to the evaluation of the three characteristics in accordance with Annex XIV, section 3, of Regulation (EU) 2017/745; • Justification of equivalence in accordance with section 3 of Annex XIV, description of relevant clinical, biological and technical characteristics that affect clinical properties of the device. Comparative diagrams or photos of the device and equivalent device(s) showing the elements in contact with the body; • Conclusions whether equivalence is demonstrated or not; if it is demonstrated, confirmation that the differences between the devices are not expected to affect the clinical performance and clinical safety of the device under evaluation; description of any limitations and gaps of equivalence, where applicable.

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**9. Access to data:** For implantable and class III devices, if equivalence is claimed with a device already marketed by another manufacturer: • Provide evidence that the device claimed to be equivalent is already CE marked under Regulation (EU) 2017/745; • Provide the current valid contract between the two manufacturers that explicitly allows the manufacturer of the device under clinical evaluation full access to the technical documentation on an ongoing basis in accordance with Article 61(5) of Regulation (EU) 2017/745; • Provide evidence that access to data is sufficient to provide the manufacturer with enough information about the equivalent devices to support equivalence claims, including any testing which may have been undertaken to confirm equivalence of specifications/performance/etc. **10. State of the art:** a) Clinical context: • Identification of medical fields concerned/relevant medical conditions; • Description, natural course and consequences of the medical conditions concerned; whether there are different clinical forms, stages and severities of the conditions; frequency in the general population, by age group, gender, ethnicity, familiar predispositions, genetic aspects. b) Literature search: • A brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/the state of the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent; • Justification concerning the choice of data bases used; • Literature search documentation to provide: - Literature search protocol available; - Literature search report available; - Full list of retrieved articles; - Full list of excluded articles, with reasons for exclusion; - Full text copies of relevant documents available. c) Benchmark devices, state of the art and other available treatment options: • Description of available therapeutic/management/diagnostic options, historical context and developments, summary of advantages and disadvantages of the different options, benefit-risk profiles and limitations in relation to the different clinical forms, stages, and severities of the medical conditions, and relation to different target populations. Description of the advantages and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects, and other risks (including the nature, severity, probability, and duration of acceptable harm); • Description how benchmarks for safety and performance have been identified in terms of the state of the art. Benchmarks will normally be based on aggregate data from several devices considered to have acceptable performance (e.g., systematic reviews of registry or analysis); if individual devices are selected as benchmarks for safety and performance, a suitable rationale is to be provided. d) Safety, performance and risk-benefit claims/requirements in terms of the state of the art: • Performance, safety, and clinical benefits endpoints identified by the manufacturer; • Outcomes achievable with benchmark devices and other treatment options; • Justification of the performance, safety, and clinical benefits endpoints retained; • Description of an indicative list and specification of parameters used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the device's intended purpose(s).

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**11. Novelty:** • Identification of the degree of novelty of the device according to the matrix in Annex 1 of this guide; • Explanation of any novel features of the device and/or the related clinical procedures and their purpose; • Detail on possible clinical or health impact in terms of benefit-risk.
Section 3: *Clinical literature review*	**12. Literature search protocol:** • Provide a brief summary and rationale for the literature search strategy including sources used, search questions, search terms, selection criteria applied to the search result, quality control measures, results, number, and type of literature found to be pertinent; • Justification concerning the choice of databases used. **13. Literature search documentation to provide:** • Literature search protocol available; • Literature search report available; • Full list of retrieved articles; • Full list of excluded articles, with reasons for exclusion; • Full text copies of relevant documents available. **14. Data relevance:** • Provide a summary of the data relevance appraisal methods applied (i.e., whether the data from a given study or other source of data is of sufficient quality and relevance to be included in the clinical evaluation. This includes evaluation of criteria including study design, sources of bias, peer review, relevance to subject device, etc.).
Section 4: *Clinical investigations and related documentation*	**15. Pre-market or post-market clinical investigations:** • If pre-market or post-market clinical investigations were conducted, provide the following elements: - Copy of all clinical investigation reports; - Information on publicly registration of clinical investigations; - Information on publicly registration on EUDAMED of clinical investigations conducted with respect to Regulation (EU) 2017/745, including EUDAMED single registration number, where available; - Information on publication in a scientific journal; - All competent/regulatory authority correspondence (from all countries, including outside of EU); - A rationale if clinical investigations not performed under Regulation (EU) 2017/745 were not publicly registered or published; - Clinical Investigation Plan (CIP). • If any pre-market or post-market clinical investigations were not conducted, provide a rationale.

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 5: *Post-market surveillance and post-market clinical follow-up*	**16. Post-Market Surveillance (PMS) and Post-Market Clinical Follow-up (PMCF):** • PMS plan; • PMS report (where relevant); • PMCF plan; • PMCF report (where relevant); • Periodic Safety Update Report (PSUR) (if available). ***Please, note that the MDCG 2020-7 "Post-market clinical follow-up (PMCF) Plan Template – A guide for manufacturers and notified bodies" provides a PMCF plan template to meet the requirement of Regulation (EU) 2017/745. GMED advises the manufacturer to use this template to build the PMCF plan.*** ***Please, note that the MDCG 2020-8 "Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies" provides a PMCF evaluation report template to meet the requirement of Regulation (EU) 2017/745. GMED advises the manufacturer to use this template to build the PMCF evaluation report.*** • If no PMCF plan is planned, provide a justification. **17. Demonstration of equivalence and link to post-market clinical follow-up:** • Description of the means implemented to verify the presumption that there would be no clinically significant difference in the safety and clinical performance of the device under evaluation compared with the equivalent device by post-market surveillance or PMCF. **18. Clinical evaluation updates:** • Define the frequency of the CER update
Section 6: *Instructions for use, summary of safety and clinical performance, labelling, and other information supplied with the device*	**19. Information as provided in the Instruction For Use (IFU) and all information materials supplied with the device:** • Intended purpose; • Intended patient population; • Intended users; • Indications; • Limitations; • Contraindications; • Undesirable effects and side-effects; • Warnings and precautions.
Section 7 : *Summary of all available data and conclusion*	**20.Summary of pre-clinical data:** • Provide a summary of the relevant pre-clinical data in relation to the claims in terms of clinical safety and performance of the device. Data should be appropriately summarized, analyzed, assessed, and referenced. **21. Summary of safety data:** • Summary of safety data (with reference to the relevant section of the CER and the PMCF evaluation report). The qualitative and quantitative aspects of clinical safety should be addressed with clear reference to the determination of residual risks and undesirable side-effects and the confirmation of the relevant safety and performance requirements provided for in Annex I of Regulation (EU) 2017/745; • Summary of clinical data regarding safety, and also residual risks and any undesirable side-effects. The methods to be used for examination of qualitative and quantitative aspects of clinical safety should be specified with clear reference to the determination of residual risks and undesirable side-effects; • If relevant, summary of any significant complaint, trends or vigilance issues associated with earlier device iterations, which may be equivalent or similar devices, and an explanation whether or not they have any impact on the clinical evaluation assessment.

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 7 : *Summary of all available data and conclusion*	**22. Summary of performance data:** • Summary of performance data (with reference to the relevant section of the CER and the PMCF evaluation report); • Summary of clinical data to demonstrate the ability of the device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer. **23. Justification that the clinical data provide sufficient clinical evidence:** • To demonstrate compliance with the relevant general safety and performance requirements; • To support the intended use, the claims, and the information in the IFU, and summary of safety and clinical performance (SSCP). **24. Identification of unanswered questions regarding the device under evaluation and description of means put in place during the PMS and PMCF to follow these questions.**
Overall conclusion	**25. Summary of clinical benefits:** • Describe the clinical benefits in relation to the meaningful and measurable patient relevant clinical outcomes, including outcomes related to diagnosis. Describe their positive impact on patient management or public health. **26. Summary and description of risks in relation with clinical aspects:** • Information on uncertainties or limitations of clinical data, undesirable side-effects, potential for misuse, etc.; • Information on incidence, severity, duration, vulnerable patient subgroups, dose-response relationship where relevant, etc. **27. Discussion on the impact of risks (as described above) in relation to the clinical benefits taking into account the factors described and in particular the uncertainties in relation to available clinical data.** **28. Information on consistency or discrepancies between the clinical data, the information materials supplied by the manufacturer and the risk management documentation for the device.** **29. Conclusion on the benefit-risk ratio related to clinic, considering in particular the current state of the art.**
Specific sections	

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 8: *Clinical evaluation consultation procedure for certain class III and class IIb devices (Article 54 of Regulation (EU) 2017/745)*	The clinical evaluation consultation procedure (CECP), in accordance with Article 54 of Regulation (EU) 2017/745, applies, regardless of the conformity assessment procedure chosen by the manufacturer, for the following devices: • Class III implantable devices; • Class IIb active devices intended to administer and/or remove a medicinal product. In accordance with section 2 of Article 54 of Regulation (EU) 2017/745 and MDCG 2019-3, the clinical evaluation consultation procedure is not required in the following cases: a) In the case of renewal of an EU technical documentation assessment certificate, relating to the device, issued under Regulation (EU) 2017/745; b) Where the device has been designed by modifying a device already marketed by the same manufacturer, for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device. **For devices already marketed under Directives 93/42/EEC or 90/385/EEC, provide:** • A statement that the manufacturer has marketed the device in question for the same intended purpose in accordance with the requirements of Directive 93/42/EEC or 90/385/EEC; • A copy of the latest certificate issued under Directive 93/42/EEC or 90/385/EEC with its certificate history; • A description of the modifications made to the device marketed under the directives as part of its transition to the regulation (the description of the modifications must not be limited to the modifications made to the device to meet the requirements of the regulation); • A rationale demonstrating that the modifications do not adversely affect the benefit-risk ratio. **For devices already marketed under Regulation (EU) 2017/745, provide:** • A copy of the latest certificate issued under Regulation (EU) 2017/745 with its certificate history; • A summary of the modifications that have been made to the device; • A rationale demonstrating that the modifications do not adversely affect the benefit-risk ratio. c) Where the principles of clinical evaluation of the device type or category have been addressed in a common specification referred to in Article 9 of Regulation (EU) 2017/745 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant common specification for clinical evaluation of that type of device.
Section 9: *Where demonstration of conformity based on clinical data is not deemed appropriate (Article 61(10) of Regulation (EU) 2017/745*	If the demonstration of conformity with general safety and performance requirements, based on clinical data is not deemed appropriate, adequate justification based on evidence should be given in accordance with Article 61(10) of Regulation (EU) 2017/745. ***It should be noted that in this case, a clinical evaluation is still required, and the evidence-based justification shall be presented in the clinical evaluation report.*** **The justification that the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate should be based on:** • Any clinical data available on the device or an equivalent device; • Clinical data available for similar devices if these provide relevant information to the safety and performance of the device under evaluation; • The results of the manufacturer's risk management; • Consideration of the specificities of the interaction between the device and the human body; • The clinical performance intended; • The claims of the manufacturer. **After this justification, the demonstration of conformity with general safety and performance requirements should be documented. This demonstration should be based on:** • Results of non-clinical test methods, such as performance evaluation; • Bench testing; • Pre-clinical evaluation.

4.1. Clinical evaluation report for devices with a medical purpose (afterparts)

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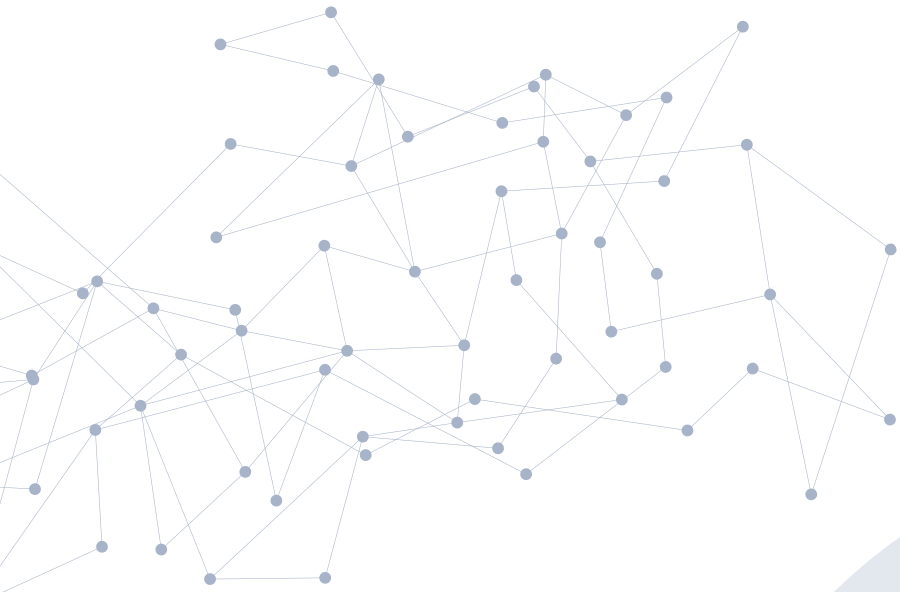
Section 10: *Voluntary clinical consultation on the clinical development strategy (Article 61(2) of Regulation (EU) 2017/745)*	• Expert panel consultation reference; • Expert panel recommendation; • Expert panel recommendation in the clinical evaluation report.



4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745

The table below gives an example of the clinical evaluation report possible content for products without a medical purpose. It is recommended that the manufacturer follows this template.

In the case of devices intended both for a medical and non-medical purpose, it is recommended that the manufacturer establishes a clinical evaluation report for each purpose (a first clinical evaluation report for the medical purpose and a second clinical evaluation report for the non-medical purpose).

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 1: *Administrative particulars (manufacturer, product and clinical evaluation report reference)*	• **Device name, model, and type;** • **Risk class;** • **Applicable code(s) to the device per Commission Implementing Regulation (EU) 2017/2185**; • **Basic UDI-DI** (if available); • **EMDN** (European Medical Device Nomenclature) **code corresponding to the device;** • **For non-implantable class IIb and implantable class IIb devices** (limited to sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors), **generic group corresponding to the device;** • **For class IIa devices, category corresponding to the device;** • **Certificate number** (if applicable); • **Project number of the device assigned as part of its design and development.**
	• **Manufacturer name and SRN;** • **If applicable, authorized representative name and SRN.**
	• **Type of conformity assessment:** - Initial conformity assessment, or; - Assessment of changes and update of the clinical evaluation, or; - Re-certification assessment, or; - Assessment limited to clinical evaluation for class IIb active devices intended to administer and/or remove a medicinal product not selected within the framework of the sampling plan established prior the issuance of the certificate, or; - Assessment of technical documentation for class IIa / IIb devices on a sampling basis. • **Conformity assessment procedure under Regulation (EU) 2017/745:** - Annex IX Chapters I, II and III, or; - Annex X + Annex XI Part A, or; - Annex X + Annex XI Part B, or; - Annex IX Chapters I and III with sampling of technical documentation assessment as specified in section 4 of Annex IX, or; - Annex IX Chapters I and III, or; - Annex XI Part A - Including section 10, or; - Annex XI Part B - Including section 18.
	• **Technical documentation identification number**
	• **Device intended purpose** In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the intended purpose is not medical.

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 1: *Administrative particulars (manufacturer, product and clinical evaluation report reference)*	• **Type of clinical data used for clinical evaluation of the device:** - Data from clinical investigation of the device concerned; - Data from clinical investigation of a device for which equivalence/analogy to the device concerned can be demonstrated; - Bibliographic data from scientific literature of the device concerned; - Bibliographic data from scientific literature of a device for which equivalence/analogy to the device concerned can be demonstrated; - Data from post-market surveillance of the device concerned; - Clinical data is not deemed appropriate according to Article 61(10) of Regulation (EU) 2017/745.
	• **CVs of CER author(s)**
Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**1. Device description:** Describe the device and comment on the intended use, including: • The intended purpose; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the intended purpose is not medical. • Contra-indication(s); • Adverse effects; • The intended user and/or consumer population; A "consumer" shall be understood as a natural person on whom a product without an intended medical purpose is intended to be used, as specified in Implementing Regulation (EU) 2022/2346. • Target user group; • A general description of the key functional elements: its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition; • The principles of operation of the device and its mode of action; explanation of any novel features; • Intended application of the device: single-use/reusable, invasive/non-invasive, implantable; • The duration of use or contact with the body, the maximum number of repeated applications; • The identification of organs, tissues or bodily fluids in contact with the device; • The claims on clinical performance limited to the ability of the device to achieve its intended purpose and clinical safety foreseen by the manufacturer. In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the claimed performances are the performances of the product for the intended use and the requirement to demonstrate a clinical benefit shall be understood as a requirement to demonstrate the performance of the product, as specified in section 9 of Article 61 of Regulation (EU) 2017/745. **2. Classification** Applicable classification rule(s), specify the corresponding indent. In the case of groups of certain active products without a medical purpose, refer to the reclassification rules of Implementing Regulation (EU) 2022/2347. **3. Device configurations/variants:** • Description of the different sizes, differences in design features, different configurations, etc.; • Image of the device where possible; • Whether the device is already CE marked or already on the market, specify the date since which the device has been CE marked or the date since the device has been on the market and the regions in which the device is available and the sales volumes; • If applicable, description of the device history and/or changes in the device, including the date and reason of these changes; • Where relevant, description of the reason for differences in design features between variants of the device with photographs or diagrams where possible.

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**4. Accessories or compatible devices:** • Description, images, or other relevant information such as diagrams, if necessary, of any accessories or compatible devices, including components of the device in case of system/procedure pack; • Identification if the use of accessories or compatible devices has an impact on clinical safety or performance or the scope or validity of the clinical evaluation. **5. Previous generations of the device and similar devices (if applicable):** • An overview of the previous generation(s) of the device produced by the manufacturer, where such devices exist; • An overview of identified similar devices available in the European Union or international markets, where such devices exist, including length of time on the market, sales volume, etc. **6. Clinical evaluation plan:** In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the following clarifications have been provided to the provisions presented in Part A section 3 of this guide. The manufacturer must establish a clinical evaluation plan which, at least: • Identifies the general safety and performance requirements that require support from relevant clinical data; • Specifies the intended purpose of the device; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the intended purpose is not medical. • Specifies clearly the intended target groups with clear indications and contra-indications; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, there are no indications. • Describes in detail the intended clinical benefits to patients with relevant and specified clinical outcome parameters; Non-applicable in the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745. • Specifies the methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects; • Provides an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, specification of parameters to be used to demonstrate, based on the state of art, that the product does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use. • Indicates how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the term "benefit-risk" is to be replaced by the term "risk". • Includes a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF with an indication of milestones and a description of potential acceptance criteria.

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**7. Common specifications and harmonized standards applied:** • List of common specifications relevant to the device applied and respected; • List of relevant harmonized standards related to the device with their revision; • In case of partial application of a relevant harmonized standard relating to the device, justification for the partial application of the corresponding harmonized standard; • In the event that the relevant harmonized standard(s) relating to the device is (or are) not applied, precise and detailed presentation of the alternative and equivalent solutions retained and applied to the device; • List, description, and justification for other solutions retained and applied (e.g., standards, directives, etc.). **8. Demonstration of equivalence/analogy:** a) Indicate if: • The clinical evaluation is based upon clinical investigations or other studies reported in scientific literature of a device without a medical purpose for which equivalence to the device in question can be demonstrated or of an analogous device with a medical purpose; or/and • The clinical evaluation is based upon reports published in peer reviewed scientific literature on other clinical experience of a device without a medical purpose for which equivalence to the device in question can be demonstrated or of an analogous device with a medical purpose. b) Device(s) without a medical purpose to which equivalence has been claimed: • Identification of the equivalent device(s) and its manufacturer: - Exact name, models, sizes, software versions, accessories, etc.; - Name of the manufacturer; - Relationship to the device under evaluation (predecessor/successor, others). If the device is not CE marked, justification for the use of the data, based on the other regulatory status; - Device with which equivalence is most relevant. c) Device(s) with a medical purpose claimed as analogous: • Identification of the analogous device(s) and its manufacturer: - Exact name, models, sizes, software versions, accessories, etc.; - Name of the manufacturer; - Relationship to the device under evaluation (predecessor/successor, others). If the device is not CE marked, justification for the use of the data, based on the other regulatory status. d) Equivalence/analogy: • Comparative tables for device(s) under evaluation compared to the equivalent/analogous device showing the parameters relating to the evaluation of the three characteristics in accordance with Annex XIV, section 3, of Regulation (EU) 2017/745; • Justification of equivalence/analogy in accordance with section 3 of Annex XIV, description of relevant clinical, biological and technical characteristics that affect clinical properties of the device. Comparative diagrams or photos of the device and equivalent/analogous device(s) showing the elements in contact with the body; • Conclusions whether equivalence/analogy is demonstrated or not; if it is demonstrated, confirmation that the differences between the devices are not expected to affect the clinical performance limited to the ability of the device to achieve its intended purpose and clinical safety of the device under evaluation; description of any limitations and gaps of equivalence/analogy, where applicable.

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

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Section 2: *Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, manufacturer's claim, common specifications, and harmonized standards applied, equivalence, and state of the art*	**9. Access to data:** For implantable and class III devices, if equivalence/analogy is claimed with a device already marketed by another manufacturer: • Provide evidence that the device claimed to be equivalent/analogous is already CE marked under Regulation (EU) 2017/745; • Provide the current valid contract between the two manufacturers that explicitly allows the manufacturer of the device under clinical evaluation full access to the technical documentation on an ongoing basis in accordance with Article 61(5) of Regulation (EU) 2017/745; • Provide evidence that access to data is sufficient to provide the manufacturer with enough information about the equivalent/analogous devices to support equivalence/analogy claims, including any testing which may have been undertaken to confirm equivalence/analogy of specifications/performance/etc. **10. State of the art:** a) Literature search: • A brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/the state of the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent; • Justification concerning the choice of databases used; • Literature search documentation to provide: - Literature search protocol available; - Literature search report available; - Full list of retrieved articles; - Full list of excluded articles, with reasons for exclusion; - Full text copies of relevant documents available. b) Benchmark devices, state of the art and other available options: • Description of available options, historical context and developments, summary of advantages and disadvantages of the different options, and relation to different target populations. Description of the advantages and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects, and other risks (including the nature, severity, probability, and duration of acceptable harm); In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the available options are not medical. • Description how benchmarks for safety and performance have been identified in terms of the state of the art. Benchmarks will normally be based on aggregate data from several devices considered to have acceptable performance (e.g., systematic reviews of registry or analysis); if individual devices are selected as benchmarks for safety and performance, a suitable rationale is to be provided. c) Safety, performance and risk claims / requirements in terms of the state of the art: • Performance and safety endpoints identified by the manufacturer; • Outcomes achievable with benchmark devices and other options; • Justification of the performance and safety endpoints retained; • Description of parameters to be used to demonstrate, based on the state of the art, that the product does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use. **11. Novelty:** • Identification of the degree of novelty of the device according to the matrix in Annex 1 of this guide; • Explanation of any novel features of the device and/or the related clinical procedures and their purpose; • Detail on possible clinical or health impact in terms of risk.

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

TABLE OF CONTENTS	EXAMPLE OF CONTENTS
Section 3: *Clinical literature review*	**12. Literature search protocol:** • Provide a brief summary and rationale for the literature search strategy including sources used, search questions, search terms, selection criteria applied to the search result, quality control measures, results, number, and type of literature found to be pertinent; • Justification concerning the choice of databases used. **13. Literature search documentation to provide:** • Literature search protocol available; • Literature search report available; • Full list of retrieved articles; • Full list of excluded articles, with reasons for exclusion; • Full text copies of relevant documents available. **14. Data relevance:** • Provide a summary of the data relevance appraisal methods applied (i.e., whether the data from a given study or other source of data is of sufficient quality and relevance to be included in the clinical evaluation. This includes evaluation of criteria including study design, sources of bias, peer review, relevance to subject device, etc.).
Section 4: *Clinical investigations and related documentation*	As it is not possible to demonstrate clinical equivalence between a medical device and a product without an intended medical purpose, where all available results on clinical investigation relate only to medical devices for their intended medical indications, clinical investigations should be performed for products without an intended medical purpose. **15. Pre-market or post-market clinical investigations:** • If pre-market or post-market clinical investigations were conducted, provide the following elements: - Copy of all clinical investigation reports; - Information on publicly registration of clinical investigations; - Information on publicly registration on EUDAMED of clinical investigations conducted with respect to Regulation (EU) 2017/745, including EUDAMED single registration number, where available; - Information on publication in a scientific journal; - All competent/regulatory authority correspondence (from all countries, including outside of EU); - A rationale if clinical investigations not performed under Regulation (EU) 2017/745 were not publicly registered or published; - Clinical Investigation Plan (CIP). • If any pre-market or post-market clinical investigations were not conducted, provide a rationale.
Section 5: *Post-market surveillance and post-market clinical follow-up*	**16. Post-Market Surveillance (PMS) and Post-Market Clinical Follow-up (PMCF):** • PMS plan; • PMS report (where relevant); • PMCF plan; • PMCF report (where relevant); • Periodic Safety Update Report (PSUR) (if available). ***Please, note that the MDCG 2020-7 "Post-market clinical follow-up (PMCF) Plan Template – A guide for manufacturers and notified bodies" provides a PMCF plan template to meet the requirement of Regulation (EU) 2017/745. GMED advises the manufacturer to use this template to build the PMCF plan.***

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

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Section 5: *Post-market surveillance and post-market clinical follow-up*	***Please, note that the MDCG 2020-8 "Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies" provides a PMCF evaluation report template to meet the requirement of Regulation (EU) 2017/745. GMED advises the manufacturer to use this template to build the PMCF evaluation report.*** • If no PMCF plan is planned, provide a justification. **17. Demonstration of equivalence/analogy and link to post-market clinical follow-up:** • Description of the means implemented to verify the presumption that there would be no clinically significant difference in the safety and performance of the device under evaluation compared with the equivalent device or with an analogous device by post-market surveillance or PMCF. **18. Clinical evaluation updates:** • Define the frequency of the CER update.
Section 6: *Instructions for use, summary of safety and clinical performance, labelling, and other information supplied with the device*	**19. Information as provided in the Instruction For Use (IFU) and all information materials supplied with the device:** In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, information supplied with the product shall not bear any clinical benefit claim or statement. Refer to the applicable annexes of Implementing Regulation (EU) 2022/2346 which list the content of the specific instructions for use and label for these products. • Intended purpose; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the intended purpose is not medical. • Intended user and/or consumer population; • Intended users and/or consumers; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, manufacturers must take into account the different degree of understanding of users and consumers (see section 9 of Annex I of Implementing Regulation (EU) 2022/2346) and specify on the labels and IFU the information regarding the categories of users and consumers (see sections 11.2.a) and 12.1.a) of Annex I of Implementing Regulation (EU) 2022/2346). • Indications; In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, there are no indications. • Limitations; • Contraindications; • Undesirable effects and side-effects; • Warnings and precautions.
Section 7: *Summary of all available data and conclusion*	**20. Summary of pre-clinical data:** • Provide a summary of the relevant pre-clinical data in relation to the claims in terms of clinical safety and performance of the device. Data should be appropriately summarized, analyzed, assessed, and referenced. **21. Summary of safety data:** • Summary of safety data (with reference to the relevant section of the CER and the PMCF evaluation report). The qualitative and quantitative aspects of clinical safety should be addressed with clear reference to the determination of residual risks and undesirable side-effects and the confirmation of the relevant safety and performance requirements provided for in Annex I of Regulation (EU) 2017/745; • Summary of clinical data regarding safety, and also residual risks and any undesirable side-effects. The methods to be used for examination of qualitative and quantitative aspects of clinical safety should be specified with clear reference to the determination of residual risks and undesirable side-effects; • If relevant, summary of any significant complaint, trends or vigilance issues associated with earlier device iterations, which may be equivalent or analogous or similar devices, and an explanation whether or not they have any impact on the clinical evaluation assessment.

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

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Section 7: *Summary of all available data and conclusion*	**22. Summary of performance data:** • Summary of performance data (with reference to the relevant section of the CER and the PMCF evaluation report). In the case of products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745, the claimed performances are the performances of the product for the intended use and the requirement to demonstrate a clinical benefit shall be understood as a requirement to demonstrate the performance of the product, as specified in section 9 of Article 61 of Regulation (EU) 2017/745. **23. Justification that the clinical data provide sufficient clinical evidence:** • To demonstrate compliance with the relevant general safety and performance requirements; • To support the intended use, the claims, and the information in the IFU, and summary of safety and clinical performance (SSCP). **24. Identification of unanswered questions regarding the device under evaluation and description of means put in place during the PMS and PMCF to follow these questions.**
Overall conclusion	**25. Summary and description of risks in relation with clinical aspects:** • Information on uncertainties or limitations of clinical data, undesirable side-effects, potential for misuse, etc.; • Information on incidence, severity, duration, vulnerable user and/or consumer subgroups, dose-response relationship where relevant, etc. **26. Discussion on the fact that the product, when used under the conditions and for the purposes intended, is to present no risk at all or present a risk that is no more than the maximum acceptable risk related to the product's use.** **27. Information on consistency or discrepancies between the clinical data, the information materials supplied by the manufacturer and the risk management documentation for the device.**
Specific sections	
Section 8: *Clinical evaluation consultation procedure for certain class III and class IIb devices (Article 54 of Regulation (EU) 2017/745)*	The clinical evaluation consultation procedure (CECP), in accordance with Article 54 of Regulation (EU) 2017/745, applies, regardless of the conformity assessment procedure chosen by the manufacturer, for the following devices: • Class III implantable devices; • Class IIb active devices intended to administer and/or remove a medicinal product. In particular, products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 meeting the criteria set out above are also concerned. In accordance with section 2 of Article 54 of Regulation (EU) 2017/745 and MDCG 2019-3, the clinical evaluation consultation procedure is not required in the following cases: a) In the case of renewal of an EU technical documentation assessment certificate, relating to the device, issued under Regulation (EU) 2017/745; b) Where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the risks of the device.

4.2. Clinical evaluation report for products without a medical purpose listed in Annex XVI of Regulation (EU) 2017/745 (afterparts)

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Section 8: *Clinical evaluation consultation procedure for certain class III and class IIb devices (Article 54 of Regulation (EU) 2017/745)*	**For devices already marketed under Directives 93/42/EEC or 90/385/EEC, provide:** • A statement that the manufacturer has marketed the device in question for the same intended purpose in accordance with the requirements of Directive 93/42/EEC or 90/385/EEC; • A copy of the latest certificate issued under Directive 93/42/EEC or 90/385/EEC with its certificate history; • A description of the modifications made to the device marketed under the directives as part of its transition to the regulation (the description of the modifications must not be limited to the modifications made to the device to meet the requirements of the regulation); • A rationale demonstrating that the modifications do not adversely affect the risks. **For devices already marketed under Regulation (EU) 2017/745, provide:** • A copy of the latest certificate issued under Regulation (EU) 2017/745 with its certificate history; • A summary of the modifications that have been made to the device; • A rationale demonstrating that the modifications do not adversely affect the risks. c) Where the principles of clinical evaluation of the device type or category have been addressed in a common specification referred to in Article 9 of Regulation (EU) 2017/745 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant common specification for clinical evaluation of that type of device.
Section 9: *Where demonstration of conformity based on clinical data is not deemed appropriate (Article 61(10) of Regulation (EU) 2017/745*	If the demonstration of conformity with general safety and performance requirements, based on clinical data is not deemed appropriate, adequate justification based on evidence should be given in accordance with Article 61(10) of Regulation (EU) 2017/745. ***It should be noted that in this case, a clinical evaluation is still required, and the evidence-based justification shall be presented in the clinical evaluation report.*** **The justification that the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate should be based on:** • Any clinical data available on the device or an equivalent/analogous device; • Clinical data available for similar devices if these provide relevant information to the safety and performance of the device under evaluation; • The results of the manufacturer's risk management; • Consideration of the specificities of the interaction between the device and the human body; • The performance intended; • The claims of the manufacturer. **After this justification, the demonstration of conformity with general safety and performance requirements should be documented. This demonstration should be based on:** • Results of non-clinical test methods, such as performance evaluation; • Bench testing; • Pre-clinical evaluation.
Section 10: *Voluntary clinical consultation on the clinical development strategy (Article 61(2) of Regulation (EU) 2017/745)*	• Expert panel consultation reference; • Expert panel recommendation; • Expert panel recommendation in the clinical evaluation report.

IV PART B: SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Article 32 of Regulation (EU) 2017/745 requires manufacturers to establish a summary of the safety and clinical performance for implantable devices and class III devices other than custom-made devices or devices subject to an investigation.

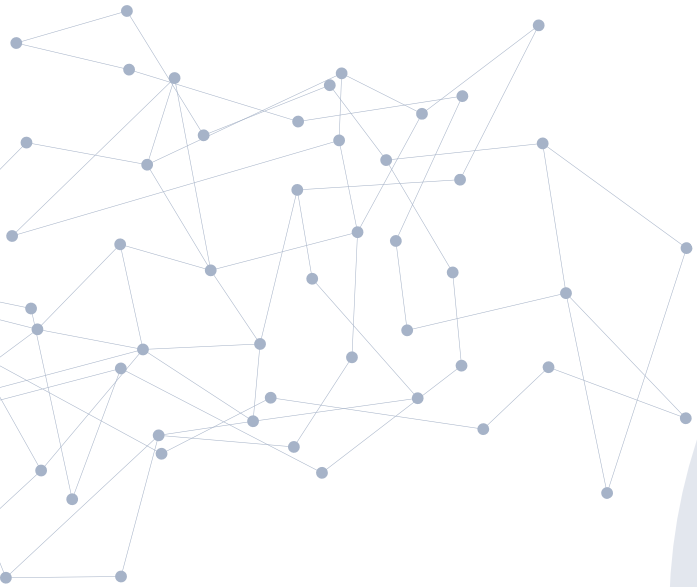
The minimum content of the summary of safety and clinical performance is defined in Article 32(2) of Regulation (EU) 2017/745.

The MDCG has published a guide for manufacturers and notified bodies on the summary of safety and clinical performance: MDCG 2019-9 "Summary of safety and clinical performance - A guide for manufacturers and notified bodies."

This guide provides recommendations for the structure and content of the summary of safety and clinical performance. GMED recommends that the manufacturer follow the recommendations of the MDCG 2019-9 guide for the establishment of the summary of safety and clinical performance.

The MDCG 2019-9 guide will be used by GMED as a reference document when validating the summary of safety and clinical performance.

In the case of devices intended both for a medical and non-medical purpose, it is recommended that the manufacturer establishes a summary of safety and clinical performance for each purpose (a first summary of safety and clinical performance for the medical purpose and a second summary of safety and clinical performance for the non-medical purpose).



ANNEX 1

Degrees of novelty for a device

DEGREE OF NOVELTY	TYPE OF NOVELTY	INNOVATION WHERE THE DOMINANT IS:		
		TECHNOLOGICAL		CLINICAL
5	Major innovation	Breaking technology	and	Strong clinical impact
4	Innovation (Innovative device)	Breaking technology	or	Strong clinical impact
3	Substantial novelty	Incremental technology	and	Moderate clinical impact
2	Moderate novelty	Incremental technology	or	Moderate clinical impact
1	Lacking or minor novelty	Known technology	and	Unchanged clinical impact

Breaking technology: Device that disrupts technologies in healthcare and could replace it definitely.

Incremental technology: Device including a technological breakthrough in comparison to another device.

Strong clinical impact: Device which presents a major interest for healthcare especially by improving very statistically the clinical practice, and/or the patient's condition, and/or providing a new diagnostic strategy in a clinical field.

Moderate clinical impact: Device which presents a new interest for healthcare especially by improving the clinical practice, and/or the patient's condition, and/or providing a diagnostic alternative.

Lacking or minor novelty: Device with no or negligible modification compared to a similar device already on the market (like aesthetic modification).

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