The clinical evaluation report must include:

- **Administrative particulars**

  ☐ Medical device name model and type.
  ☐ Basic UDI-DI(s) (if available).
  ☐ Certificate number (if applicable).
  ☐ Project number.
  ☐ Risk Class.
  ☐ Applicable code(s) per Commission Implementing Regulation (EU) 2017/2185.
  ☐ Manufacturer(s) name and SRN.
  ☐ Authorized representative (if applicable) name and SRN.
  ☐ Type of assessment (initial conformity assessment, or assessment of changes and update of the clinical evaluation, or re-certification assessment, or assessment of technical documentation for class IIa/ IIb devices on a sampling basis).
  ☐ Intended purpose.
  ☐ CER is dated and signed.
  ☐ Udated CVs of CER author(s) are provided.
  ☐ CER authors have full range of required expertise represented (e.g. research methods, information management, regulatory requirements, device technology, diagnosis and management of conditions to be treated).
  ☐ Title, version number/reference and date of clinical evaluation report, clinical investigation plan, clinical investigation report, ethics committee approval, Competent Authority approval, post market surveillance data, publications, etc.. are provided.

- **Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, common specifications and harmonised standards applied, equivalence and state of the art.**

  - The device description includes:
    ☐ The intended patient population and medical conditions to be diagnosed, treated and/or monitored.
    ☐ 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.

    ☐ The classification includes the applicable classification rule(s) and indents.

  - Device configurations/variants includes:
    ☐ Description of the sizes, differences in design features, different configurations etc.
    ☐ An image of the device where possible.
    ☐ If applicable, the description of the device history and/or changes in the device since its last assessment.

☒ Where relevant, the description of the reason for differences in design variants with illustrative images where possible.

- The description of accessories or compatible devices includes:
  - ☐ Component devices in case of system/procedure pack.
  - ☐ 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.
  - ☐ If it is necessary to understand the usage of the device, include images or other relevant information such as diagrams.

- The description of previous generations of the device and similar devices includes (if applicable):
  - ☐ An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist.
  - ☐ An overview of identified similar devices available on the Union or international markets, where such devices exist, including length of time on the market, sales volume etc.

- The clinical evaluation plan includes:
  - ☐ 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 contraindications.
  - ☐ A detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters.
  - ☐ 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 on how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are addressed.
  - ☐ 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 as referred to in Part B of Annex XIV of MDR, with an indication of milestones and a description of potential acceptance criteria.

☐ The clinical performance summarises the clinical data to demonstrate the ability of the device, resulting from any direct or indirect medical effect which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed, thereby leading to a clinical benefit for patients, when used as intended. Moreover, it describes the clinical benefits.

☐ Safety is adequately addressed in the clinical evaluation, in particular the qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and undesirable side effects and the confirmation of the relevant safety and performance requirements. A summary of clinical data regarding safety, describing residual risks and any undesirable side-effects is provided. The methods to be used for examination of qualitative and quantitative aspects of clinical safety are specified with clear reference to the determination of residual risks and undesirable side-effects. If relevant, significant complaint, trends or vigilance issues associated with earlier device iterations, which may be equivalent or similar devices, are summarized and it is explained whether or not they have any impact on the clinical evaluation assessment.

☐ Harmonised standards relevant to the clinical evaluation of the device under evaluation are listed and it is indicated which ones have been applied. The most up-to-date revision is used. If they are partially applied, the justification is added and it is ensured that the level of safety and performance required by the Regulation (EU) 2017/745 is maintained. Deviations are explained also how these might affect the validity of the clinical evaluation and its conclusions, and any equivalence claims. If standards, guidance or other solutions have been applied, they are described with a justification.

- The demonstration of equivalence includes:
  - ☐ The specification if the clinical evaluation is based upon clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated.
  - ☐The device(s) to which equivalence has been claimed.
  - ☐ The specification if the clinical evaluation is based upon reports published in peer reviewed scientific literature on a device for which equivalence to the device in question can be demonstrated.
  - ☐ The specification of which devices are/are not equivalent, and the confirmation that data relating to devices which are not equivalent have been excluded from the analysis of clinical data for the purposes for demonstrating safety and performance.
  - ☐ A demonstration of equivalence for each single device (if equivalence has been claimed to more than one device) including the identification of any difference in technical, biological and clinical characteristics and the verification of why these are not expected to adversely affect the safety and performance of the medical device under evaluation.
  - ☐ The access to data should be described in a way that it is possible to assess that this is sufficient to provide 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
  - ☐ For implantable and Class III devices, if equivalence is claimed with a device marketed by another manufacturer, a clear indication that there is a current valid contract between the two manufacturers allowing ongoing access to the technical documentation in accordance with Article 61 (5) of the MDR.

☐ State of the art describes the alternative available treatment options which could offer comparable safety and performance for the same treatment indications / patient populations, etc. It also describes 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 or registry analysis); if individual devices are selected as benchmarks for safety and performance, a suitable rationale is provided. The state of the art is based upon an appropriate literature search. The state of the art confirms that the identified performance and safety endpoints are appropriated, clinically relevant and justifiable in light of the outcomes achievable with benchmark products and other treatment options. Moreover, it adequately supports the acceptability of the benefit/risk ratio for the various indications and for the intended purpose or purposes of the device.

☐ Explanation of any novel features of the device and/or the related clinical procedures and their purpose with the possible clinical or health impact in terms of benefit/risk.

- **Clinical literature review**

☐ All device sizes, variants, model and accessories and clinical condition(s) are addressed.

☐ Selection criteria of the literature review are related to the device under evaluation or to a device demonstrated to be equivalent, and the state of the art or alternative available treatment option.

☐ Selection criteria are clearly described with respect to the regulatory purpose to which it will apply.

☐ Search terms in the literature search protocol are adequate (i.e. be sufficiently broad to establish benchmarks, determine the general state of the art, determine potential risk, adverse events, undesirable side-effects, etc.)

  - Literature search protocol includes:
    ☐ Databases used (to minimize bias multiple databases should be used).
    ☐Acceptability of inclusion and exclusion criteria.
    ☐ Both favourable and unfavourable data.
    ☐ Strategies for avoiding duplication of data (for example, across different publications or between manufacturer and published data).
    ☐ Literature search and review protocol (i.e. how did the manufacturer test this protocol to ensure comprehensive identification of relevant data / demonstrate that all relevant data has been retrieved).
    ☐ Any deviations.
    ☐ Overall conclusions regarding the adequacy of search methods, likelihood of having retrieved all relevant data, and methods used to avoid bias.
    ☐ Systematic search and review methods (such as PICO (patient characteristics, type of intervention, control, and outcome queries), Cochrane Handbook for Systematic Reviews of Interventions, PRISMA (The Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement, MOOSE Proposal (Meta-analysis Of Observational Studies in Epidemiology).

☐ Literature search reports.

☐ Full list of retrieved articles.

☐ Full list of excluded articles with reasons for exclusion.

☐ Full text copies of relevant documents.

☐ The search protocol must document the planning of the search before execution.

☐ Literature search is documented to such degree that the methods can be appraised critically, the results can be verified, and the search reproduced if necessary.

☐ The literature search protocol(s), the literature search report(s), and full text copies of relevant documents using URL links, become part of the clinical evidence and, in turn, the technical documentation for the medical device.

☐ Data appraisal methods for study design, sources of bias, peer review, relevance to subject device, etc. are disclosed. Retrieved studies and data sets are weighted on the basis of scientific quality and relevance to the scope and objectives of the clinical evaluation for the subject devices.

- **Clinical investigations and related documentation.**

☐ Pre-market or post-market clinical investigation(s) are reported with details, or the rationale why clinical investigation(s) has not be conducted.

☐ A copy of all clinical investigation reports is provided.

☐ Clinical investigations are publicly registered (those conducted with respect to Regulation (EU) 745/2017 must be publicly registered on EUDAMED: in this case the EUDAMED single registration number should be provided).

☐ The clinical investigation report reflects the results of clinical investigation(s) or other studies reported in scientific literature, or reports published in peer reviewed scientific literature on other clinical experience, or differences are justified.

☐ Competent/Regulatory Authority correspondence (from all countries, including outside of EU) is provided.

☐ Clinical Investigation Plan (CIP) reference is provided.

☐ CIP complies with MDR, Annex XV, and EN ISO 14155 Annex A.

☐ Adequacy of CIP for demonstration of safety, performance and benefit risk of subject devices, including: study design, devices identified, patient population, patient numbers, objectives and endpoints, length of follow up and intervals, study locations, overall conclusions.

- **PMS, PMCF and the plan for updates**

  ☐ The following documents are included and referenced: PMS Plan, PMS Report (where relevant), PMCF Plan, PMCF Report (where relevant), PSUR.

  ☐ How it is verified 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 post market clinical follow-up is described.

  ☐ In case of an implantable or class III device for which clinical investigations have not been performed in accordance with Article 61(4), the PMCF plan includes post market clinical studies to demonstrate the safety and performance of the device.

  ☐ If no PMCF is planned, an acceptable justification for not conducting it is provided.

  ☐ Clinical evaluation updates are indicated.

- **IFU, SSCP, labelling and other information supplied with the device**

  ☐ Clinical evidence supports the intended purpose.

  ☐ The intended patient population is indicated, it is supported by the clinical evidence, and all the appropriate/relevant restrictions, warnings or contraindications are in place.

  ☐ The intended users (healthcare professionals or lay users) are indicated; the IFU provides all the appropriate/relevant information for the intended user; the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users) are taken into account; if training of the user is not required as a risk control measure, it is justified with respect to the risk management file and the clinical evaluation.

  ☐ The limitations for the device use are adequately/clearly described.

  ☐ The contraindications are adequately/clearly described.

  ☐ Warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety are adequately descried.

  ☐ The safety and performance information relevant to the user, or any other person, as appropriate/relevant is adequately/clearly provided.

  ☐ The estimation of associated risks and residual risk are adequate.

  ☐ The information provided to the end user is written in a clear and understandable way (instructions of use, indications, and warnings).

☐ The IFU and other information materials are aligned with the other parts of the technical documentation (including in particular, the clinical evaluation, the available clinical data, PMS report or PSUR, and the risk management file).

☐ **Safety data**

☐ **Performance data**

☐ **Clinical data with sufficient clinical evidence**

☐ **Clinical benefits are described also in relation to the meaningful and measurable patient relevant clinical outcomes, including outcome(s) related to diagnosis, and to their positive impact on patient management or public health.**

☐ **The risks with clinical relevance (e.g. incidence, severity, duration, vulnerable patient subgroups, dose-response relationship where relevant, etc), including the impact of risks in relation to the clinical benefits taking into account in particular the uncertainties in relation to available clinical data.**

☐ **Clinical evaluation is aligned with the risk management.**
☐ **How the clinical benefits outweigh the risks also considering the current state of the art.**

☐ **Deficiencies/non-compliances are satisfactorily addressed and it is possible to follow the changes that have been made to address them.**