MDCG 2020-13

Clinical evaluation assessment report template

July 2020

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List of acronyms

CEAR	Clinical Evaluation Assessment Report
CECP	Clinical Evaluation Consultation Procedure
CER	Clinical Evaluation Report
CIP	Clinical Investigation Plan
EUDAMED	European Databank on Medical Devices
IFU	Instructions for Use
MDR	Medical Device Regulation (Regulation (EU) 2017/745 on medical devices)
PMCF	Post-Market Clinical Follow-up
PMS	Post-Market Surveillance
PSUR	Post-Market Surveillance Update Report
SRN	Single Registration Number
SSCP	Summary of Safety and Clinical Performance
TDAR	Technical Documentation Assessment Report
UDI-DI	Unique Device Identification Device Identifier

Introduction

A clinical evaluation assessment report (CEAR) is a report used by the notified body to clearly document the conclusions of its assessment of the clinical evidence presented by the manufacturer in the clinical evaluation report (CER) and the related clinical evaluation that was conducted – a core requirement of the Medical Device Regulation (EU) 2017/745 (MDR).

The clinical evaluation must be a part of the manufacturer's quality management. It should also be aligned with and reflected in other aspects of the technical documentation, such as:

- The interface of the clinical evaluation with the risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation and their relevance for the demonstration of conformity with the relevant requirements in Annex I.[1]
- Post-market surveillance including any corrective and preventive actions involving the device.
- Post-market clinical follow-up plan and where appropriate the post-market clinical follow-up report.
- Instructions for use, which provide adequate information on intended purpose, proper use and warnings about risks to patients and healthcare practitioners.

As part of its conformity assessment activities the notified body shall examine, validate and verify that manufacturers' procedures and documentation adequately address the requirements relating to the technical documentation[2] and clearly document its assessment[3].

The notified body shall review the clinical evidence presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted, which includes[4]:

- Assessing the suitability of using data from claimed equivalent devices, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess to what extent specific claims are supported by specific pre-clinical and clinical data and risk analysis.
- Verifying that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMCF plan proposed, where applicable.
- Considering the clinical evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMCF data.

The outcome of this assessment must be clearly documented in the CEAR.[5] A harmonised CEAR template provides a standardised method for documenting the notified body's assessment of the manufacturer's clinical evaluation and related documents. CEARs in this format will also support **specific additional requirements** such as the clinical evaluation consultation procedure[6] and reviews by designating authorities.[7]

Scope

This template applies to MDR Annexes IX section 4 and Annex X section 3. It also applies to assessments of technical documentations on a sampling basis for class IIa/IIb devices in accordance with Annex IX sections 2.3 and 3.5 and

[1] MDR, Annex VII Section 4.5.1 and 4.5.5
[2] MDR, Annexes II and III
[3] MDR Annex VII Section 4.5.5 and 4.6
[4] MDR, Annex IX Sections 4.4 to 4.7
[5] MDR, Annex IX 4.8
[6] MDR, Article 54
[7] MDR, Article 45

Section 10 of Annex XI(A).[8] Aspects related to the clinical evaluation assessment are also laid down in Section 4.5.5 and other relevant sections of Annex VII. It also applies to medical devices for which clinical data is not deemed appropriate,[9] to demonstrate conformity with Annex I, and the demonstration of an adequate justification for this.[10]

Approach to Template

Please note that the explanatory text under each heading provides brief descriptions of the type of information which will be included by the notified body, however it is not an all-inclusive list and further detail may be required depending upon the device or the intended purpose for which it will be used. This template represents **the minimum content** for a CEAR and needs to be incorporated into the process and procedures of the notified body.[11] The CEAR shall also make a recommendation to support a final review and a final decision to be taken by the notified body.

Any non-compliances identified during the assessment of the aspects described in the relevant sections of the template, as well as the appropriate follow up actions taken by the manufacturer to close them need to be documented. This template may be used by the notified body to document the non-compliance/deficiencies and queries raised during the assessment and the assessment of responses received. It is important to note that the completed CEAR may not necessarily contain comprehensive information regarding the non-compliance/deficiencies, which were raised by the notified body during the course of the assessment. The CEAR shall document the outcome[12] and the conclusions[13] of the assessment.

Designating authorities shall assess whether the clinical evaluation assessment was conducted appropriately, considering the assessment, procedures, associated documentation and the conclusions;[14] Designating authorities will have access to the complete 'audit trail' of the notified body.

Expert panels who are conducting a clinical evaluation consultation procedure shall assess the CEAR, however they may not have access to the complete conformity assessment for the device and associated procedures and documentation. To enable the expert panel work, the CEAR shall provide sufficient information with respect to the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan.[15] Expert panels may also request the notified body to present its conclusions regarding the clinical evaluation assessment report.[16]

It is only once all the non-compliances have been closed out that the relevant tick-box should be completed to signal that the assessment is positive. In the rare event that there is one or more open minor non-compliances at the conclusion of the assessment stage, this must be clearly described in the template, together with appropriate follow-up actions to close them, and expected completion timelines to be followed by the manufacturer under the supervision of the notified body.

The sections covered in Annex I of this template are generally applicable depending on the type of assessment. The sections covered in Annex II may be applicable, depending upon the device under evaluation. **All applicable sections should be completed, relevant conclusions reached and corresponding boxes ticked for the report to be complete**. The CEAR should be signed-off by the relevant personnel in accordance with the quality management system of the notified body. When making available the CEAR to third parties, the notified body should treat the personal data within

[8] MDCG 2019-13
[9] Article 61(10)
[10] Based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer.
[11] MDR, Annex VII Section 4.6
[12] MDR, Annex IX Section 4.8
[13] MDR, Annex VII Section 4.6
[14] MDR, Article 45(3)
[15] MDR, Annex IX Section 5.1(c)
[16] MDR, Annex IX Section 5.1(b)

it as per its procedures for the management of personal data, in compliance with Regulation (EU) 2016/679 General Data Protection Regulation.

Template CEAR

<table>
<tr><th colspan="4">Section A: Administrative particulars (notified body, manufacturer, product and clinical evaluation report reference)</th></tr>
<tr>
<td>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:</td>
<td>Manufacturer(s) name and SRN:

Authorised representative (if applicable) name and SRN:</td>
<td>Notified body:

Notified body number:

E-mail contact of NB:

Telephone contact of NB:</td>
<td rowspan="2">Parts of this template which have been applied

General considerations[17]
☐ Section A: Administrative particulars
☐ Section B: Reviewers involved
☐ Section C: Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, common specifications and harmonised standards applied, equivalence and state of the art
☐ Section D: Clinical literature review
☐ Section E: Clinical investigations and related documentation
☐ Section F: PMS and PMCF
☐ Section G: IFU, SSCP, labelling and other information supplied with the device
☐ Section H: Summary of all available data and conclusions
☐ Overall Conclusions

Specific Considerations</td>
</tr>
<tr>
<td>Type of assessment:
☐ Initial conformity assessment
☐ Assessment of changes[18] and update of the clinical evaluation[19]
☐ Re-certification assessment
☐ Assessment of technical documentation for class IIa / IIb devices on a sampling basis</td>
<td>Intended purpose:</td>
<td>Check of clinical evaluation report authors
☐ CER dated and signed
☐ CVs provided for CER author(s)

Comments:
Confirm CVs are up to date

Confirm CER authors have full range of required expertise represented (e.g. research methods, information</td>
</tr>
</table>

[17] These must be completed in all cases
[18] MDR, Annex IX Section 4.10
[19] For example in accordance with Annex VII, Section 4(10)

According to Annex / section: *Insert the Annex and section*		*management, regulatory requirements, device technology, diagnosis and management of conditions to be treated)* CVs are considered acceptable: ☐	☐ Section I: Clinical evaluation consultation procedure for certain class III and class IIb devices (Article 54) ☐ Section J: Where demonstration of conformity based on clinical data is not deemed appropriate (Article 61(10)) ☐ Section K: The voluntary clinical consultation on the clinical development strategy (Article 61(2))

Technical file identification number and technical documentation assessment report (TDAR) reference if available or any other references that allow the correlation between TDAR and CEAR:

Documents assessed:

For example, clinical evaluation report, clinical investigation plan, clinical investigation report, ethics committee approval, Competent Authority approval, post market surveillance data, publications.

Include the title, version number/reference and date of the documents.

When the CER has been updated verify that this update corresponds to the most recently updated PMS/PMCF reports and any conditions set on the first certification, if applicable.

Note that references to the technical documentation should be made in order to ensure document control.

Section B: Reviewers involved in the notified body assessment of the clinical evaluation
Provide the name or the employee code of the personnel with relevant clinical expertise (as per 3.2.4 of annex VII):
Relevant clinical expertise:
Have additional reviewers been involved?

☐Yes

☐No

Provide a justification:

Additional reviewers assigned to review the clinical evaluation

Number of additional reviewers Names of additional reviewers: *Separate the internal and external clinical reviewers.* *You may use employee codes*	Specific aspects assessed (by each additional reviewer): *For example, rationale for the design and chosen statistical methodology of clinical investigation etc.*	Competence area / codes: *List of relevant MDR codes or area this person is authorised to, according to the Authorisation Matrix, as of Annex VII, 3.3.2)* Relevant expertise:

Section C: Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, common specifications and harmonised standards applied, equivalence and state of the art

Device description

Describe the device and comment on the intended purpose, including:

- *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.*

Classification

List the applicable classification rule(s) and indents.

Device configurations/variants included in this application:

Include the manufacturers description of the sizes, differences in design features, different configurations etc.

Include an image of the device where possible.

If applicable, include the manufacturers description of the device history and/or changes in the device since its last assessment.

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

Accessories or compatible devices:

Describe any accessories or compatible devices if any or state, "none").

Include 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, identify this here.

If it is necessary to understand the usage of the device, include images or other relevant information such as diagrams.

Previous generations of the device and similar devices (if applicable):

Verify that the manufacturer has provided:

- *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.*

Non-compliances identified and resolved for this section may be briefly described in this box

Device details, intended purpose and classification are:

Compliant with the applicable requirements of the MDR: ☐

Include any relevant comments

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐

Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.

Clinical evaluation plan

Briefly summarise the manufacturer's clinical evaluation plan and confirm that it meets the requirements of Annex XIV Part A Section 1a, highlighting the areas which require particular attention for this assessment:

- 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 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; and
- 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.

A detailed description of the clinical development plan is not required for the purpose of this template unless there are specific concerns.

Add the manufacturer's reference and version and date of the clinical evaluation plan.

Clinical performance

Summarise the 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.

Describe the clinical benefits.

Safety

Does the clinical evaluation adequately addresses 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 provided for in Annex I?

Summarise the clinical data regarding safety, and also describe residual risks and any undesirable side- effects.

Does the clinical evaluation specify 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 undesirable side-effects?

If relevant, briefly summarise any significant complaint, trends or vigilance issues associated with earlier device iterations, which may be equivalent or similar devices, and explain whether or not they have any impact on the clinical evaluation assessment.

Non-compliances identified and resolved for this section may be briefly described in this box

The clinical evaluation plan is: Compliant with the applicable requirements of the MDR: ☐ *Include any relevant comments* Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐ *Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.*
Common specifications, harmonised standards or other solutions applied
Are there common specifications relevant to the device under evaluation? *Have they been complied with?* *If not:*[20] • *Explain any deviations and how these might affect the validity of the clinical evaluation and its conclusions, and any equivalence claims.* • *Confirm that the manufacturer has adopted solutions that ensure a level of safety and performance that is at least equivalent thereto in accordance with Article 9(3).* Are there harmonised standards relevant to the clinical evaluation of the device under evaluation? *Have they been applied?* *If partially applied add the manufacturers justification and confirm that the manufacturer has adopted solutions that ensure a level of safety and performance required by the Regulation (EU) 2017/745.* *If there are deviations explain any deviations and how these might affect the validity of the clinical evaluation and its conclusions, and any equivalence claims.* *Is the most up-to-date revision being used by the manufacturer? (state which revision was used)* Are there other solutions that have been applied? *Describe any standards, guidance or other solutions that have been applied, and the manufacturers justification*
Non-compliances identified and resolved for this section may be briefly described in this box

[20] Excluding devices listed in Annex XVI which must comply with the relevant common specifications in accordance with Article 9(4).

The application of CS, harmonised standards or other solutions is:

Compliant with the applicable requirements of the MDR: ☐

Include any relevant comments

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐

Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.

The demonstration of equivalence

Is the clinical evaluation 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?
State Yes / No
Device(s) to which equivalence has been claimed:

Is the clinical evaluation based upon reports published in peer reviewed scientific literature on a device for which equivalence to the device in question can be demonstrated?
State Yes / No
If yes, specify the source(s) of the data, if it is the device in question, or an equivalent device, or both.

Device(s) to which equivalence has been claimed:

Device which is most relevant:

Assessment of equivalence

1. Equivalence rationales:

Indicate which devices are/are not equivalent, and confirm 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.

If equivalence has been claimed to more than one device, each demonstration of equivalence can only be based on a single device. Each equivalent device must meet all three equivalence criteria (clinical, technical, biological).

2. Are the devices equivalent in accordance with Section 3 of Annex XIV including technical, biological and clinical characteristics?

State Yes / No
Identify any differences in these parameters, and verify why these are not expected to adversely affect the safety and performance of the medical device under evaluation.

Non-compliances identified and resolved for this section may be briefly described in this box
The demonstration of equivalence is: Compliant with the applicable requirements of the MDR: ☐ *Include any relevant comments* Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐ *Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.*
Access to data
Comment on the manufacturer's access to data, relating to devices with which they are claiming equivalence in order to justify their claims of equivalence. *For implantable and Class III devices, if equivalence is claimed with a device marketed by another manufacturer, confirm 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.* *Has the original clinical evaluation been performed in compliance with the requirements of Regulation 2017/745, and has the manufacturer of the second device provided clear evidence thereof?* *State Yes / No* *Confirm 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.* Any other limitations with respect to equivalent devices: *Comment on any other limitations with respect to the equivalent devices or manufacturer's equivalence claims, and the extent to which these limitations impact the manufacturer's clinical evaluation and conclusions.*
Non-compliances identified and resolved for this section may be briefly described in this box
Manufacturer demonstration of equivalence and access to data is: Compliant with the applicable requirements of the MDR: ☐ *Include any relevant comments*

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐ *Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.*
State of the art
Benchmark devices, state of the art and other available treatment options: *Describe the alternative available treatment options identified by the manufacturer which could offer comparable safety and performance for the same treatment indications / patient populations, etc.* *Briefly describe how benchmarks for safety and performance have been identified by the manufacturer 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 should be provided.* *Confirm that the manufacturer's description of the state of the art is based upon an appropriate literature search (see section D)?* *For devices previously marketed, is the description of the state of the art still accurate? Can the device still be considered to be state of the art?* Safety, performance and benefit-risk claims - requirements in terms of the state of the art: *What performance and safety endpoints has the manufacturer identified?* *In light of the outcomes achievable with benchmark products and other treatment options, are these endpoints appropriate and clinically relevant? Have surrogate endpoints been adequately justified?* *Has the manufacturer adequately described 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 intended purpose or purposes of the device?*
Non-compliances identified and resolved for this section may be briefly described in this box
Manufacturer demonstration of state of the art is: Compliant with the applicable requirements of the MDR: ☐ *Include any relevant comments*

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐ *Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.*
Novelty
Include the manufacturer's explanation of any novel features of the device and/or the related clinical procedures and their purpose. What is the possible clinical or health impact in terms of benefit/risk?
Is novelty adequately addressed? ☐

Section D: Clinical literature review
With respect to the **search criteria** of the literature review, does it: ☐ Address all device sizes, variants, model and accessories? ☐ Address the same clinical condition? *Further information regarding literature search methods is available in MEDDEV 2.7/1 revision 4, section A5.* *Searches for the device in question, equivalent devices and other devices (for example to support a description of the state of the art) should be described separately.* With respect to the **selection criteria** of the literature review, does it relate to both below: ☐ The device under evaluation or to a device demonstrated to be equivalent? ☐ The state of the art or alternative available treatment option? The clinical evaluation should clearly describe the selection criteria with respect to the regulatory purpose to which it will apply. The CER should clearly differentiate between the two types of data referenced above. If the data does not relate to either of the above, provide a rationale with respect to its inclusion.
Literature search protocol[21]
Provide a brief summary of the literature search strategy applied, commenting on:

[21] For general guidance on a literature search, see MEDDEV 2.7/1 revision 4, A5. Literature search and literature review protocol, key elements.

- *The adequacy of search terms: for example, it should be sufficiently broad to establish benchmarks, determine the general state of the art, determine potential risk, adverse events, undesirable side-effects, etc.*

  Note that a search which is restricted to the manufacturer's own product or the name of their chosen equivalent could miss important information and therefore is not acceptable.
- *Databases used (to minimize bias multiple databases should be used).*
- *Acceptability of inclusion and exclusion criteria.*
- *Both favourable and unfavourable data included.*
- *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 from the manufacturer's literature search protocol.*
- *Overall conclusions regarding the adequacy of search methods, likelihood of having retrieved all relevant data, and methods used to avoid bias.*

Comment if systematic search and review methods such as the following have been used:

- *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).*
- *Other (specify or describe).*

Literature search documentation:

☐ Literature search protocol provided

☐ Literature search reports provided

☐ Full list of retrieved articles provided

☐ Full list of excluded articles provided, with reasons for exclusion

☐ Full text copies of relevant documents available

Comments:

Provide rationale if any of the above has not been provided.

Nota bene: • *A literature search and other retrieval of data should be carried out based on a search protocol. The search protocol should document the planning of the search before execution.* • *Once the searches have been executed, the adequacy of the searches should be verified and a literature search report should be compiled to present details of the execution, any deviations from the literature search protocol, and the results of the search.* • *It is important that the 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.* • *Abstracts lack sufficient detail to allow issues to be evaluated thoroughly and independently, but may be sufficient to allow a first evaluation of the relevance of a paper. Copies of the full text papers and documents should be obtained for the appraisal stage.* • *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.*
Non-compliances identified and resolved for this section may be briefly described in this box
Literature search protocol and outputs are: Compliant with the applicable requirements of the MDR: ☐ *Include any relevant comments* Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐ *Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.*
Data appraisal:
Provide a brief summary of the manufacturer's data appraisal methods (i.e. how they determine 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. Retrieved studies and data sets should be weighted on the basis of scientific quality and relevance to the scope and objectives of the clinical evaluation for the subject devices). *Justify the acceptability of the appraisal in terms of:* • *Methodological quality and scientific validity of articles retrieved and evaluated appropriately.* • *Relevance of the information to the clinical evaluation determined and documented.* • *Contribution of each data set to the clinical evaluation weighted according to systematic criteria.*

Non-compliances identified and resolved for this section may be briefly described in this box
Data appraisal is: Compliant with the applicable requirements of the MDR: ☐ *Include any relevant comments* Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐ *Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.*

Section E: Clinical investigations and related documentation
Has the manufacturer conducted clinical investigation(s)? *State Yes / No* Has the manufacturer conducted pre-market or post-market clinical investigations? *Provide detail* If the manufacturer has not conducted clinical investigation: *What is the rationale?* *Why is this acceptable / unacceptable?* Has the manufacturer provided a copy of all clinical investigation reports? *State Yes / No* Were all clinical investigations publicly registered? *State Yes / No* Have been verified that clinical investigations conducted with respect to Regulation (EU) 745/2017 publicly registered on EUDAMED? *State Yes / No* *Provide the EUDAMED single registration number where available.* Did the clinical investigations result in a publication in a scientific journal? *State Yes / No*

If yes, does the clinical investigation report reflect 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? If there are any differences describe these and summarise the rationale provided by the manufacturer.

Has the manufacturer provided all Competent/Regulatory Authority correspondence (from all countries, including outside of EU)
State Yes / No

Are the conclusions drawn by the manufacturer, based upon the results of the clinical investigation, valid in the light of the approved clinical investigation plan?
Provide detail

If clinical investigations not performed under Regulation (EU) 745/2017 were not publicly registered or published:

- *Confirm that a rationale was provided.*
- *Confirm that the SSCP and where relevant the IFU (for example with respect to the description of clinical benefits) adequately provide information for the intended user and if relevant, the patient.*

Clinical Investigation Plan (CIP) reference

CIP complies with MDR, Annex XV, and EN ISO 14155 Annex A
State Yes / No

CIP scope and study design

Adequacy of CIP scope and study design for demonstration of safety, performance and benefit risk of subject devices:

- Study design.
- Devices identified.
- Patient population.
- Patient numbers.
- Objectives and endpoints.
- Length of follow up and intervals.
- Study locations.
- Overall conclusions.

Non-compliances identified and resolved for this section may be briefly described in this box

Manufacturer clinical investigations and related documentation are:

Compliant with the applicable requirements of the MDR: ☐

Include any relevant comments

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐

Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.

Section F: PMS, PMCF and the plan for updates

Documents reviewed, where relevant:

☐ PMS Plan
☐ PMS Report (where relevant)
☐ PMCF Plan
☐ PMCF Report (where relevant)
☐ PSUR (if available)

Include references to the above documents.

The demonstration of equivalence and the link to post-market clinical follow-up

Describe how the manufacturer will 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 post market clinical follow-up?

Is there a post-market clinical follow-up planned?

State Yes / No

Is this an implantable or class III device for which clinical investigations have not been performed in accordance with Article 61(4)?

State Yes / No

For these devices the PMCF plan should include post market clinical studies to demonstrate the safety and performance of the device.

Comments on appropriateness of PMS/PMCF Plan:

If no PMCF is planned, has the manufacturer provided an acceptable justification for not conducting a PMCF?

State Yes / No

Clinical evaluation updates:

Identify when updates to the clinical evaluation report shall be assessed during the surveillance and post certification monitoring activities and which frequency should be considered.

Provide further detail taking into account the manufacturer's PMCF plan and the post-market surveillance plan.

Non-compliances identified and resolved for this section may be briefly described in this box

The PMS, PMCF and the plan for updates are:

Compliant with the applicable requirements of the MDR: ☐

Include any relevant comments

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐

Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.

Section G: IFU, SSCP, labelling and other information supplied with the device

Information materials supplied by the manufacturer and the instructions for use:

Describe what has been reviewed – IFU, promotional materials (if available), SSCP, labelling etc. In case several documents have been assessed, identify answers to the questions below for each of the documents.[22]

Intended purpose:

Does the clinical evidence support this?

Intended patient population:

Who is the intended patient population?

Does the clinical evidence support this?

Are all the appropriate/relevant restrictions, warnings or contraindications in place?

[22] Note that the SSCP requires a separate validation report.

Intended users:
Is the device to be used by healthcare professionals or lay users? Does the IFU provide all the appropriate/relevant information for the intended user?
Has the manufacturer taken into account 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).
Is any training for users required as a risk control measure? If not, is this justified with respect to the risk management file and the clinical evaluation?

Limitations:
Has the manufacturer adequately/clearly described any limitations for the device use?
Does the device require any specific limitations?

Contraindications:
Have contraindications been adequately/clearly described?
Are any further contraindications necessary?

Warnings and precautions:
Have 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 been adequately descried?

Does the information supplied by the manufacturer adequately/clearly provide the safety and performance information relevant to the user, or any other person, as appropriate/relevant?
Is the estimation of associated risks and residual risk adequate? Is this estimation quantitative (i.e. a percentage rate or rate with a confidence interval) or qualitative? Is the description appropriate for patients and users?
Is the information provided to the end user written in a clear and understandable way (instructions of use, indications, and warnings)?

Is the IFU and other information materials supplied by the manufacturer aligned with the other parts of the technical documentation?

Consider:

- *the clinical evaluation (the device description used for the clinical evaluation, other contents of the clinical evaluation report).*
- *the available clinical data (such as the public registration and results of clinical investigations, publications, PMCF studies, etc.).*
- *PMS report or PSUR.*
- *the risk management file.*

Non-compliances identified and resolved for this section may be briefly described in this box

IFU, promotional materials, labelling are:

Compliant with the applicable requirements of the MDR: ☐

Include any relevant comments

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐

Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.

Section H: Summary of all available data and conclusions

Has the manufacturer conducted clinical investigation(s) for the device under evaluation?

State Yes / No

Has the manufacturer demonstrated equivalence with respect to section 3 of Annex XIV of the MDR?

State Yes / No

If the manufacturer conducted CIs, does clinical data from clinical investigations of the device under evaluation adequately demonstrate compliance with the relevant general safety and performance requirements?

State Yes / No

Has the reliability of the source of clinical investigation data been assured through monitoring activities and verification of the application of appropriate clinical research standards?

State Yes / No

If the manufacturer demonstrated equivalence with respect to section 3 of Annex XIV of the MDR does the data from an equivalent device demonstrate compliance with Annex I?*State Yes / No*

Provide a summary of safety data (with reference to the relevant section of the CER).

Provide a summary of performance data (with reference to the relevant section of the CER)

Does the clinical data provide sufficient clinical evidence to:[23]

- *Demonstrate compliance with the relevant general safety and performance requirements? State Yes / No, and provide additional information if relevant*
- Support the intended purpose, the claims and the information in the IFU and SSCP? *State Yes / No, and provide additional information if relevant*

What are the remaining unanswered questions regarding the device under evaluation?

Describe these with respect to the plan for PMS / PMCF

Overall Conclusions:

Benefit-risk conclusions:

Summarise the clinical benefits. Describe them briefly in relation to the meaningful and measurable patient relevant clinical outcomes, including outcome(s) related to diagnosis. Describe their positive impact on patient management or public health.

Summarise the risks with clinical relevance (e.g uncertainties or limitations of clinical data, undesirable side-effects, potential for misuse, etc) and provide a short description (e.g. incidence, severity, duration, vulnerable patient subgroups, dose-response relationship where relevant, etc).

Discuss 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.

Have all the risks that could have a significant impact on the benefit-risk analysis' been identified in the clinical evaluation?
Is there alignment between the risk management and clinical evaluation?

State Yes / No
Describe how the clinical benefits outweigh the risks also considering the current state of the art.

Have all deficiencies/non-compliances been raised and satisfactorily addressed in the course of this clinical evaluation assessment?

[23] For legacy products, see MDCG 2020-6

State Yes / No

Is it possible to follow the changes that have been made to address them?

Overall conclusion on the assessment of the manufacturer's clinical evaluation including a clinical judgement of the opinion provided by any external expert.

Make a clear recommendation to the notified body's decision maker in regards to the conclusions of this assessment for the purpose of granting certification, stating in addition:

- *whether the post-market surveillance plan, including the PMCF plan, is adequate.*
- *specific milestones to be set for further review of the up to date clinical evaluation by the notified body.*
- *considerations to define the period of certification.*
- *additional conditions on the certification to be considered.*

Sufficient information are provided to demonstrate acceptability of benefit-risk conclusions and confirm that the relevant MDR requirements are met : ☐

Specific Considerations

Section I: Clinical evaluation consultation procedure for certain class III and class IIb devices (Article 54)

Is the procedure required by Article 54(1) to be applied?
State Yes / No
Provide further information where necessary with respect to this justification

If this procedure is not to be applied, with respect to Article 54(2) what is the reason?[24]
(a) renewal of a certificate issued under the MDR; ☐
(b) the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, and 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; ☐

Provide a summary of the modification(s) that have been made to the device?

[24] See MDCG 2019-3, Interpretation of Article 54(2)b

Provide a summary of the manufacturer's rationale demonstrating that the benefit-risk ratio of the device is not adversely affected.
Has the clinical data been provided to support the conclusions of the manufacturer regarding the benefit-risk of the modified device with respect to the previous version?

For legacy devices, verify:

- *that the modifications do not adversely affect the benefit-risk ratio.*
- *that the device in question had a valid certificate under the Directives.*
- *in case the certificate has been withdrawn, suspended[25] or expired, if there is an impact on compliance with the general safety and performance requirements, and*
- *that there is no pending assessment of changes for the device or outstanding non-compliance.*
- *the description of modifications provided and assess if these modifications are limited only to those needed in order to comply with the new legal requirements introduced by the MDR.*

Note: limitations of the intended purpose of the device should not trigger the consultation procedure in accordance to Art. 54.

(c) the principles of the clinical evaluation of the device type or category have been addressed in a CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device. ☐

Relevant scientific panel and associated competence area(s)

Indicate your opinion on the relevant scientific and associated competence area(s) for the device under assessment:

	Medical area(s)		Associated competence-related areas
☐	**Orthopaedics, traumatology, rehabilitation, rheumatology**	☐	Joint replacements (hip, knee, shoulder)
		☐	Spinal devices
		☐	Non-articulating devices, rehabilitation
		☐	*Other*
☐	**Circulatory system: cardiovascular / lymphatic system**	☐	Prosthetic heart valves and devices for heart valve repair
		☐	Cardiovascular stents (metallic and bioresorbable) and vascular prostheses
		☐	Active implantable cardiac devices and electrophysiological devices
		☐	Structural interventions and new devices (e.g. LAA/PFO occluders, heart failure devices)

[25] The devices for which the certificates were withdrawn or suspended due to lack of compliance with essential requirements will require a clinical evaluation consultation procedure as this adversely affects the benefit-risk ratio of the device.

		☐	Cardiac surgery including extracorporeal membrane oxygenation, cardiopulmonary bypass devices, artificial hearts (and left ventricular assist devices)
		☐	*Other*
☐	**Respiratory, anaesthesiology, intensive care**	☐	Respiratory and anaesthetic devices
☐	**Neurology**	☐	Central and peripheral nervous system devices
		☐	Implants for hearing and vision (sensory recovery)
		☐	Neurosurgical devices
		☐	*Other*
☐	**Endocrinology and diabetes**	☐	Endocrinology and diabetes (e.g. insulin delivery systems and closed-loop systems, continuous glucose monitoring) Implantable systems
☐	**General and plastic surgery, dentistry**	☐	Surgical implants and general surgery
		☐	Plastic surgery and wound care
		☐	Maxillofacial surgery
		☐	Dentistry (devices for dentistry (oral surgery, implantology, dental materials incl.))
		☐	*Other*
☐	**Obstetrics & gynaecology including reproductive medicine**	☐	Devices for obstetrics and gynaecology
☐	**Gastroenterology & hepatology**	☐	Devices for gastroenterology and hepatology
☐	**Nephrology & urology**	☐	Devices for nephrology and urology
☐	**Ophthalmology**	☐	Devices for ophthalmology

Provide further information necessary with respect to this justification

Conclusion for certain class III and IIb devices to be considered by the expert panel

Novel aspects
See section C, subsection 'Novelty'

Benefit-risk determination
See section H and the Overall Conclusion sections

Consistency of clinical evidence with intended purpose and PMCF
Provide an assessment of the consistency of the clinical evidence with:
(a) the intended purpose, including medical indication(s),
(b) the post-market clinical follow-up (PMCF) plan.

Section J: Where demonstration of conformity based on clinical data is not deemed appropriate (Article 61(10))

Has the manufacturer claimed that the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate in accordance with Article 61(10)?
State Yes / No
Nota bene*: A clinical evaluation is still required and the above information and evidence-based justification shall be presented in the clinical evaluation report.*

Has the manufacturer provided a justification for reliance upon Article 61(10)?
State Yes / No

If **yes**, describe the evidence which the manufacturer is relying on, with respect to:
- Performance evaluation
- Bench testing
- Pre-clinical evaluation

Consider:
- Has any available clinical data for the device or an equivalent device been searched for and/or identified by the manufacturer?

If yes –was the identified clinical data integrated in the clinical evaluation.
This should include an evaluation of clinical data identified from the literature, and an appraisal of their relevance to the device under evaluation.

- Is clinical data available for similar devices, does this provide information with relevant to the safety and performance of the device under evaluation?

Has the manufacturer conducted an appropriate search of scientific literature?
If clinical data for similar devices is available – this should be included in the CER and evaluated and may be of particular relevance to post-market surveillance / PMCF planning.

- The results of the manufacturer's risk management

Are the results of the manufacturer's risk management supportive of the use of non-clinical testing methods?

- Consideration of the specifics of the interaction between the device and the human body

Is the device under assessment part of a system or stand-alone?
Is there sufficient information regarding this interaction available from sources other than clinical data?

- The clinical performance intended

What is the intended performance? Is it reasonable to rely upon non-clinical data for the proposed intended performance?

- The claims of the manufacturer

The manufacturer should not make any claims which are not supported by clinical data.

Overall conclusion

Non-compliances identified and resolved for this section may be briefly described in this box

The justification of the manufacturer for reliance upon Article 61(10) is:

Compliant with the applicable requirements of the MDR: ☐

Include any relevant comments

Compliant with the applicable requirements of the MDR with the exception of the minor non-compliance below: ☐

Add a clear description of any remaining minor non-compliance together with required follow-up actions to close them and timelines for their completion to be followed by the manufacturer.

Section K: The voluntary clinical consultation on the clinical development strategy (Article 61(2))
Expert Panel consultation reference: Expert Panel recommendations: *Have the views of the expert panel been given due consideration by the manufacturer?* *Has this been included in the clinical evaluation report?* *Is there any divergence between the manufacturers clinical development strategy and the views of the expert panel? If yes – what is the justification for this? Is this acceptable? Explain why.*