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Abbreviations

CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
CEAR	Clinical Evaluation Assessment Report
CECP	Clinical Evaluation Consultation Procedure, sometimes also called Scrutiny Procedure
CS	Common Specification
GSPR	General Safety and Performance Requirements
MDCG	Medical Device Coordination Group [MDR Article 102]
MDR	Regulation (EU) 2017/745 on medical devices (Medical Device Regulation)
MEDDEV 2.7/1	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
PMS	Post Market Surveillance
PMCF	Post Market Clinical Follow-up
PSUR	Periodic safety update report
SSCP	Summary of safety and clinical performance
SOTA	State of the art in science and technology/ established medical knowledge
WET	Well-Established Technology

Examples are presented at some places throughout the document. They do not claim to be complete! The information is displayed in boxes like this one.

A Objective of the document

In this document the regulatory required content of the clinical evaluation is presented in form of a structure for the CEP (Clinical Evaluation Plan) and CER (Clinical Evaluation Report). Besides the regulatory requirements the document also includes interpretations by mdc.
If this structure is considered for the CEP and CER the documentation's assessment can be carried out faster and more purposively without spending time for searching and identifying content. Furthermore, it is the objective to present the assessment criteria transparently so that a complete CEP and CER can be submitted.

B Regulations and guidelines

Regulation (EU) 2017/745 on medical devices (MDR)
MDCG 2020-1 (Software)
MDCG 2020-5 (similarity, equivalence)
MDCG 2020-6 (Legacy devices)
MDCG 2020-7 (PMCF plan)
MDCG 2020-8 (PMCF report)
MDCG 2020-13 (Report template evaluation report CEAR)
MDCG2023-7 (Exemptions from the requirement to perform clinical investigations)
MEDDEV 2.7/1 Rev. 4 (2016) (sections named in MDCG 2020-6 Annex I)

The MDR is in force since May 2017, with various transitional periods. It applies to the entire EU area.
The Medical Device Coordination Group (MDCG) was created by MDR Article 102. The guidelines it publishes are not formally binding, but generally represent the recognised "state of the art" in the respective field. It is expected that these guidelines will be taken into account.
The MEDDEV guidelines have a similar status as MDCG guidelines, but were drawn up for Directive 93/42/EEC (MDD) and are partially referenced by MDCG guidelines. They should be taken into account where they have not been superseded by more recent guidelines. The continued validity of certain chapters of MEDDEV 2.7/1 Rev. 4 of 2016 is explicitly stated in MDCG 2020-6 (Annex I).

The regulations and guidelines listed here represent the most important principles for the clinical evaluation of medical devices at the present time (April 2024). There are further MEDDEV and MDCG documents that must be considered in individual cases. Further MDCG documents are continuously being created and existing ones revised.

If individual requirements are not implemented/considered, this must be appropriately justified. Activities carried out must be presented.

Guidelines from other organisations (e.g. IMDRF - International Medical Device Regulators Forum) are not binding and merely represent a supplement to the currently recognised "state of the art" within the framework of the MDR.

C General information

The Clinical Evaluation Report, like all technical documentation, should be "presented in a clear, organised, readily searchable and unambiguous manner" [MDR Annex II and Annex III].
This is supported by a suitable file format (e.g. PDF) with a table of contents and bookmarks.
The Clinical Evaluation Report should be readable as a stand-alone document. It must therefore contain all important points; however, it is possible to refer to suitable documents in the technical documentation and only provide a summary in the CER.
The clinical evaluation report should be written in one language throughout the document (German or English).
The total path length (folder name and file name together) of the submitted documents must not exceed 150 characters.

D Structure - clinical evaluation plan

D.1 From MDR Annex XIV (1a)

- Specification of the General Safety and Performance Requirements to be supported by relevant clinical data;
- Specification of intended purpose, indications, contraindications, target groups;
- Detailed description of the intended clinical benefit for patients with relevant specific parameters for the clinical outcome;

Clinical benefit	Parameters
Example 1 Bone plates for fracture treatment	
Fracture healing	Fracture healing rate
Restoring the functionality of the limb	Functional scores (DASH, HHS, ...), ROM
Pain relief/reduction	VAS
...	...
Example 2 Intraocular lenses	
Correction of defective vision	Visual acuity
...	...

- Specification of methods for examination of qualitative and quantitative aspects of clinical safety. The methods refer to the determination of residual risks and side effects;

Examples of methods for identifying and assessing clinical risks:
- Research in literature and competent authority's databases and/or registers in the context of the clinical evaluation, PMS/PMCF
- Generation of clinical data on the own device as part of the PMCF
- Feedback from customers
- Risk management

- List of parameters for determining the acceptability of the risk-benefit ratio. Parameters must be specified and are based on the established state of medical knowledge for the indications and intended purpose of the device. The list of parameters for the clinical benefit must be included in this list; exceptions are possible with justification.
  Verification and quantification are carried out when determining the SOTA.

Benefit and risk	Parameters
Example 1 Bone plates for fracture treatment	
Benefit (performance)	Fracture healing rate
	Functional scores (DASH, HHS, ...), ROM
	VAS
Safety (risks, side effects)	Complication rates (device- and procedure-related)
Example 2 Intraocular lenses	
Benefit (performance)	Deviation from planned refraction < 0.5D
Safety (risks, side effects)	Complication rates (device- and procedure-related)

- Indication of how questions regarding the risk-benefit ratio for certain components are to be clarified. Examples include the use of pharmaceutical substances, non-viable animal or human tissue;
- Clinical development plan:
  Collecting data on the own device through exploratory studies (such as first-in-man studies, feasibility studies, pilot studies), confirmatory studies and post-market clinical follow-up including the indication of milestones and describing possible acceptance criteria.

pre-CE certification	explorative studies confirmatory studies
post-CE certification	post-market clinical follow-up

Post-market clinical follow-up includes not only PMCF studies but also other PMCF activities. The clinical development plan corresponds to the PMCF plan in this aspect.

D.2 From MEDDEV 2.7/1 Rev. 4

Under the MDR still valid sections from MEDDEV 2.7/1 Rev. 4 are listed in MDCG 2020-6, Appendix I.

D.2.1 Literature

[MEDDEV 2.7/1 Rev. 4, A5.3, Chap. 9.2, 9.3]

Planning:
- Selection of databases with a brief explanation.
- Selection of search terms, filters (especially the search period) with a brief explanation.
- Definition of criteria for narrowing down the hits before full text evaluation (output: potentially relevant literature)
- Definition of criteria for narrowing down the hits in full-text analysis, if applicable (output: relevant literature)
  - Relevance of content (indications, device, target group, type of treatment, ...) and allocation of data (pivotal data, supporting data, contribution to SOTA)

- Methodological relevance (quality of the data/study) and weighting of the data

Examples of literature databases: PubMed, Cochrane, Google Scholar, AWMF guidelines.

Other databases can be consulted. Clinicaltrials.gov and other study databases can be used to identify further data/publications, but also other suitable search terms.

The references of articles found can be checked as part of a manual search. Publications from the in-house literature collection can be added to the result without a specific search.

Any validated methods used for research and documentation should be mentioned, e.g.

- 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).

D.2.2 Notifications to competent authorities

[MEDDEV 2.7/1 Rev. 4, A4]

Planning:

- Selection of databases (specify, not just name the authority) with a brief explanation.
- Selection of search terms, filter if necessary (especially the search period) with a brief explanation.
- Criteria for narrowing down the hits, if applicable

Specifying the database, e.g. MAUDE or TPLC for the FDA.

D.2.3 PMCF data

[MDR Art. 2(48); MEDDEV 2.7/1 Rev. 4, Chap. 8.1]

Planning:

- Inclusion of ongoing and completed PMCF studies
- Inclusion of other actively collected clinical data (e.g. user surveys)

D.2.4 PMS data (on the device under evaluation)

[MDR Art. 2(48); MEDDEV 2.7/1 Rev. 4, Chap. 8.1].

Planning:

- Inclusion of the complaint rate and complaint evaluation
- Inclusion of other clinical data (e.g. feedback from users)

D.2.5 Register data

[MEDDEV 2.7/1 Rev. 4, A4]

Planning:

- Selection of registers with brief explanation
- Analysis of the data

D.2.6 Risk management

Planning:

- Inclusion of risk management: Risks that are mentioned in the risk management and whose assessment is to be supported by clinical data

E Structure - Clinical Evaluation Report

E.1 Device description

[MEDDEV 2.7/1 Rev. 4 A3 and MDCG 2020-13]

Disclosure/description of the following aspects:

- Name of the device incl. trade name(s)
- Description of the device including all device variants (with illustrations), accessories, combination with other devices
- Novelty of the device
- Functionality/application principle
- Clinical benefit
- Intended purpose
- Indications, contraindications
- Patient population (e.g. adults, children)
- Users (healthcare professionals, laypersons)
- Classification, with indication of the rule
- Regulatory status (date of first CE certification (MDD and/or MDR)), if needed separately for different device components should there be differences here
- The time of first placing on the market, if needed separately for different device components, should there be differences here
- Markets (countries) in which the device is sold (EU and non-EU)
- Device modifications (device history)
- Previous generations of the device.
  "Previous generations" refers to devices that are rather different from the current device and are tending in the direction of another device. The term overlaps with the aforementioned "device modifications" and it is up to the manufacturer to decide how to categorise a change.
- Similar devices on the international market (including the distribution period and sales figures or a justification why this information is not disclosed)

E.2 Methodology of the clinical evaluation

Specification and justification of the level of clinical evidence necessary to demonstrate compliance with the GSPR. The level of the clinical evidence must be appropriate to the characteristics of the device and its intended purpose. [MDR Art. 61 (1)]

Additionally:

- Listing of the data/data sources used and their respective purpose (presentation of safety, performance, SOTA) for the clinical evaluation and justification why this is sufficient, including, if applicable

  Statement that the device under evaluation belongs to the WET
  - According to MDR Art. 52 (2 and 4).
  - According to the criteria set out in MDCG 2020-6 with a demonstration of the criteria's fulfilment later on.
    - Only applicable when the device under evaluation is not listed in MDR Art. 52(4).
    - The criteria in MDCG 2020-6 refer to the generic product group not to a specific product.
  - Indication why WET is claimed.
    - To generally show, that the generic product group of the device under evaluation has already proven itself on the market.

  - In order to be able to demonstrate the safety and performance of products under evaluation with low risk on the basis of data on similar products, according to MDCG 2020-6 Chap. 6.2.2 and 6.5e.

- Implants and device of class III:
  Justification if no clinical investigation is conducted prior to CE marking under MDR, see exemptions MDR Art. 61 (4) - (6). The exemption applied must be named and the evidence for its applicability must be provided.
- Proof of compliance with the GSPR without clinical data
  - Reasons for the applicability of MDR Art. 61 (10). This means why clinical data is not appropriate to demonstrate safety and performance.

E.3 Qualification of the author

- According to MEDDEV 2.7/1 Rev. 4, Chap. 6.4
- Current and meaningful professional CV focussing on aspects relevant to the clinical evaluation
- Specialist requirements must be fulfilled by the team, not by each individual author/examiner
- Signed declaration of interest must be provided by all authors and reviewers

E.4 Consideration of equivalence (when choosing equivalent device)

When considering equivalent devices, a distinction is made between different constellations.

- Device is of class III or implantable and is not yet CE certified (MDD or MDR) and does not belong to the group listed under MDR Art. 61 (6b)[1]:
  - Adequate scientific justification of the similarity of the (potential) equivalent device to the device under evaluation, including assessment of any differences in clinical relevance (impact on performance and safety) [MDR Annex XIV (3), MDCG 2020-5].
  - Proof of a contract with the other manufacturer for access to the technical documentation of the equivalent device if it is placed on the market by another manufacturer [MDR Art. 61 (5)].
  - Proof that the clinical evaluation of the similar device complies with the MDR [MDR Art. 61 (5)].
- All other devices:
  - Adequate scientific justification of the similarity of the (potential) similar device to the device under evaluation, including assessment of any differences with clinical relevance (impact on performance and safety) [MDR Annex XIV (3), MDCG 2020-5].
  - Proof of sufficient access to the device data to be able to prove the equivalence [MDR Annex XIV (3)].

    Examples of sources of device data to prove the equivalence are the instructions for use and data sheets, the manufacturer's website, scientific publications and, if applicable, own laboratory tests of the device.

E.5 Identification of clinical data and data on SOTA

The term "clinical data" refers to the definition according to MDR Art. 2 (48).
When documenting searches in databases, the following must be stated for each search run for the purpose of reproducibility (in the case of several search runs, it is possible to summarise same information):

- Database used incl. internet address (for safety databases, do not just name the authority)
- Time of the search

[1] Sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors

- Searched period
- Search terms
- Filter for narrowing down (in addition to the time period)
- Number of hits

E.5.1 Clinical trials (prior to CE certification)

[MDR Article 62 ff, MDCG 2020-13]

Concerns clinical trials conducted prior to CE marking (according to MDD or MDR) for the intended purpose.

E.5.1.1 Regulatory aspects

- Vote of the ethics committee
- Official authorisation
- Proof of entry in a study register and register number

E.5.1.2 Synopsis clinical investigation plan

- Investigation plan (latest approved version), changes to the investigation plan
- Study objective
- Study design
- Patient population (indications)
- Target parameters: Performance and safety endpoints
- Devices used
- Number of cases (calculation of number of cases if necessary)
- Inclusion/exclusion criteria (summary)
- Follow-up examinations/follow-up (summary)
- Statistical analysis plan
- Investigation centres (for larger numbers only countries/regions)
- Timetable (from study initiation to final visit)

E.5.1.3 Quality assurance

- Conducting the clinical trial in accordance with EN ISO 14155 and GCP
- Study monitoring (monitoring plan)
- Conduction of quality assurance audits

E.5.1.4 Study report

- Study report according to EN ISO 14155 Annex D, or interim report
- if available, scientific publications

E.5.2 Literature

[MDR, Annex XIV (1b, c); MEDDEV 2.7/1 Rev. 4, Chap. 8.2, 9.1, 9.3, A5]

- Documentation of the search runs so that they are reproducible, see above
- If published systematic search methods such as PICO are used these have to be stated.
- List of hits from the search runs combined with the result of applying the criteria for narrowing down, if necessary stating reasons for exclusion per article

No. of the search run - No. of the hit	Publication	Inclusion/ exclusion	Reason
1-1	Citation of publication 1 according to scientific standards	Inclusion	n.a.

No. of the search run - No. of the hit	Publication	Inclusion/ exclusion	Reason
1-2	Citation of publication 2 according to scientific standards	Exclusion	other device used
2-1	...		

- List of relevant hits with evaluation of the criteria for methodological and content relevance per article
- Differentiation between literature on safety and performance (device under evaluation /equivalent device) and on SOTA (similar/other devices)
- Enclosure of the full texts of the relevant hits
- Optional: additional visualisation of the determination of relevant hits using a flow chart such as PRISMA 2009

E.5.3 Notifications to authorities

[MDR, Annex XIV (1b, c); MEDDEV 2.7/1 Rev. 4, Chap. 8.2, 9.1, 9.3]

- Documentation of the search runs so that they are reproducible, see above
- Summary and evaluation of the relevance of the hits, if necessary with additional reference for details to PSUR/…

No. of the hit	Manufacturer, device/ device group	Message	Reference no.	Inclusion/ exclusion	Reason
1	Manufacturer A, device 1	Device incorrectly labelled	12345	Exclusion	Labelling is not relevant for assessing the fundamental safety of a device
2	Manufacturer B, device 2	Implant breakage	23456	Inclusion	n.a.
3	...				

E.5.4 PMCF data

[MDR, Annex XIV (1b, c); MEDDEV 2.7/1 Rev. 4, Chap. 8.1]

- Ongoing PMCF study: presentation of the current status with regard to the timetable, if applicable, mentioning and enclosing the study plan and interim report
- Completed PMCF study: mentioning and enclosing the final report
- Documentation of other identified sources of clinical data (e.g. user surveys)
- Additionally reference to PMCF reports

E.5.5 PMS data (on the device under evaluation)

[MDR, Annex XIV (1b, c); MEDDEV 2.7/1 Rev. 4, Chap. 8.1].

- Documentation of the references (PSUR/...)

E.5.6 Register data

[MDR, Annex XIV (1b, c); MEDDEV 2.7/1 Rev. 4, Chapters 8.2, 9.1, 9.3]

- Documentation of the identified and selected registers
- Enclosure of documents used (e.g. annual reports, special analyses)

E.6 Results from the data analysis

E.6.1 SOTA - Data on similar devices and alternatives

[MDR, Art. 61 (3c), Annex XIV (1a), indent 6, MEDDEV 2.7/1 Rev.4 Chapter 8.2].

E.6.1.1 Data from literature

- Presentation of the currently established therapies for the claimed indications.
- Structured (tabular) presentation of the results for the individual clinical outcome parameters for performance and safety ("indicative list of parameters"according to the clinical evaluation plan) for comparable/similar devices (benchmark) representing the SOTA.

  Benchmarks are usually based on composite/collected data from multiple products that show acceptable performance (e.g. systematic reviews or registry evaluations). If individual products are selected as benchmarks, this must be justified.
- Specification of the acceptance values and their calculation.
- No comparison with the device under evaluation at this point.

Ex.1 Bone plate for fracture treatment

Parameters	Device	determined value	# Patients with FU*	FU*	Study design/ LoE*	Refer-ence	Acceptance value
Fracture healing rate	similar device 1	94 %	21			Pub. 1	≥ 97 %
Fracture healing rate	similar device 1	98 %	45			Pub. 2	
Fracture healing rate	similar device 2	100 %	13			Pub. 3	
Parameters	Device	determined complication rate	# Patients with FU*	FU*	Study design/ LoE*	Refer-ence	Acceptance value
Complication 1	similar device 1	4 %	21			Pub. 1	≤ 3,5 %
Complication 1	similar device 2	3 %	45			Pub. 2	
Complication 2	similar device 2	2,5 %	21			Pub. 1	≤ 2,5 %

* Information required for certain device groups (e.g. endoprostheses).

Ex.2 Intraocular lens

Parameters	Device	determined value	# Patients with FU*	FU*	Study design/ LoE*	Refer-ence	Acceptance value
Visual acuity: Deviation from planned refraction < 0.5D	similar device 1	79 %	142			Pub. 1	≥ 50 %
	similar device 1	57 %	97			Pub. 2	
	similar device 2	50 %	n.a.		Guideline	Pub. 3	
Parameters	Device	determined complication rate	# Patients with FU*	FU*	Study design/ LoE*	Refer-ence	Acceptance value
Complication 1	similar device 1	2,5 %	97			Pub. 1	≤ 2,5 %

Ex.2 Intraocular lens

Parameters	Device	determined value	# Patients with FU*	FU*	Study design/ LoE*	Refer-ence	Acceptance value
Complication 1	similar device 2	2,1 %	56			Pub. 2	
Complication 2	similar device 2	1,2 %	42			Pub. 1	≤ 1,2 %

* Information required for certain device groups (e.g. endoprostheses).

If there are large differences in the number of patients or the values, the values must be weighted with regard to the number of patients.

If there are several parameters and complications, it may be useful to summarise the acceptance values separately.

E.6.1.2 Data from competent authority databases

- Identification of previously unknown/rare side effects
- Identification of design-specific problems of a device group
- Structured (tabular) presentation of the results for each authority database

E.6.1.3 Data from registers

- Structured (tabular) presentation of the results for the clinical outcome parameters

E.6.1.4 Summary

- Summary of all results
- Determination of acceptance values/ranges for the device under evaluation (see clinical evaluation plan, indent 6)

E.6.2 Safety and performance

[MDR, Art. 61 (3a, b); MDR Annex XIV, (1e) and (1a indents 4-5)]

Contains data on the device under evaluation and/or equivalent devices, not on similar devices.
Exemption: When the exemption according to MDCG 2020-6 is claimed (see E.2 of this document) data of similar devices can be presented here.

E.6.2.1 Data from clinical trials

- Summary of the performance data obtained in the clinical investigation
- Summary of adverse events, side effects
- Conclusion regarding fulfilment of the General Safety and Performance Requirements

E.6.2.2 Data from literature

- Structured (tabular) presentation of the results for the individual parameters for the clinical outcome (see clinical evaluation plan) including the indication of values for methodological study parameters (e.g. number of patients, FU, ...) for the purpose of weighting the results
- Separate presentation for different variants and/or different indications
- If there are large differences in the number of patients and/or the values determined, the values must be weighted with regard to the number of patients, see Example 2.
- The study design must be taken into account when discussing the data.
- If preoperative values are available, these must be stated.

Ex.1 Bone plate for fracture treatment

Parameters	Device*	determined value	# Patients with FU	FU	Study design/ LoE	Refer-ence
Fracture healing rate	own device	98 %	15	10 months	prospective	Pub. 1
Fracture healing rate	own device	97 %	57	7 months	retrospective	Pub. 2
Fracture healing rate	equivalent device	96 %	32	12 months	RCT	Pub. 3
Mean value		97 %				
Acceptance value from SOTA		≥ 97 %				
Parameters	Device*	determined complication rate	# Patients with FU	FU	Study design/ LoE	Refer-ence
Complication 1	own device	2 %	15	10 months	prospective	Pub. 1
Complication 1	equivalent device	3 %	32	12 months	RCT	Pub. 3
Mean value		2,5 %				
Acceptance value from SOTA		≤ 3,5 %				
Complication 2	equivalent device	2,1 %	32	12 months	RCT	Pub. 3
Mean value		2,1 %				
Acceptance value from SOTA		≤ 2,5 %				

* State device name

Ex.2 Intraocular lens (also example for weighted data)

Parameters	Device*	determined value	# Patients with FU	FU	Study design/ LoE	Refer-ence
Deviation from planned refraction < 0.5D	own device	85%	42	1 - 6 months	retrospective	Pub. 1
	own device	65%	34	1 month	prospective	Pub. 2
	equivalent device	87%	93	3 months	retrospective	Pub. 3
Weighted average		82%				
Acceptance value from SOTA		≥ 50%				
Parameters	Device*	determined complication rate	# Patients with FU	FU	Study design LoE	Referenc e
Complication 1	own device	2 %	42	1 month	retrospective	Pub. 1
Mean value		2 %				
Acceptance value from SOTA		≤ 2,5 %				
Complication 2	equivalent device	1 %	93	3 months	retrospective	Pub. 3
Complication 2	equivalent device	1,7 %	44	3 months	retrospective	Pub. 4
Weighted average		1,2 %				
Acceptance value from SOTA		≤ 1,2 %				

* State device name

E.6.2.3 Data from competent authority databases

- Structured (tabular) presentation of clinically relevant reports per authority database, grouped by type of adverse event if necessary
  Reports of labelling errors, for example, are not clinically relevant.
- Separate presentation for different variants and/or different indications
- Evaluation of the reports with regard to applicability and impact on the device under evaluation

Authorities database 1					
Manufacturer, device/ device group	Message	Reference no.	Relevant for clinical evaluation	Reason	Measures
Manufacturer C, device 1	Implant breakage after pseudarthrosis (plus any other relevant information)	34567	no	known, evaluated in RM	none
Manufacturer D, device 2	Ulcer on the implant (with relevant details)	45678	Yes	not known	Observation whether it occurs more often.

E.6.2.4 Data from PMCF

- Description of the study (key data) and other sources of clinical data (e.g. user surveys)
- Structured (tabular) presentation of the results
- Separate presentation for different variants and/or different indications

Device*				
Parameters	determined value	# Patients with FU	FU	Acceptance value from SOTA
End point A	98 %	83	6 months	≥ 97%
End point B				

Device*				
Parameters	determined complication rate	# Patients with FU	FU	Acceptance value from SOTA
Complication 1				
Complication 2				

* If several devices are analysed in one study, state device names.

E.6.2.5 Data from PMS

- Structured (tabular) presentation of the results
- Separate presentation for different variants and/or different indications

E.6.2.6 Data from registers

- Structured (tabular) presentation of the results for the clinical outcome parameters
- Separate presentation for different variants and/or different indications

General note:
In addition or in some cases as an alternative to the separate presentation of data from the individual sources, a summarised presentation (combination of data) is also possible.

E.6.3 Discussion

[MDR, Art. 61 (3), Annex XIV, Part A, (1e)]

- Discussion/evaluation of the results from all sources with each other
- Classification of the results on safety and performance in the SOTA in relation to the acceptance values/ranges for the device under evaluation, if necessary with a structured (tabular) presentation
- Listing of identified side effects and complications
- Evaluation of clinical risks from risk management
- Integration of new risks into risk management
- Identification of gaps/limitations in the clinical evidence (e.g. in certain indications) that need to be considered in the PMCF
- Conclusion from all data regarding fulfilment of the General Safety and Performance Requirements

E.7 Assessment procedure for certain class III and class IIb devices (CECP)

According to Article 54, a consultation procedure must be conducted for certain devices.[2]
The procedure is described in MDR Annex IX (5.1).

The conditions for excluding a consultation procedure in accordance with MDR Art. 54 (2b) are explained in MDCG 2019-3:
Art. 54 (2b) also applies to devices that have already been placed on the EU market under Directive 93/42/EEC with the same intended purpose and identical design. Changes to the device are limited to those that serve to comply with the new requirements of Regulation (EU) 2017/745 and do not affect the benefit-risk ratio.
The following evidence must be submitted:

- a declaration that the device in question has been placed on the market for the same intended purpose under Directive 93/42/EEC;
- a description of the changes made to the device to fulfil the new requirements of Regulation (EU) 2017/745;
- a summary demonstrating that the changes made to the device do not adversely affect the risk-benefit ratio;
- a copy of the most recently issued certificate(s) together with the certificate history

F Plan for "Post Market Clinical Follow up" (PMCF)

A reasoned statement on the necessity and scope of PMCF activities is required in the CER. [MEDDEV 2.7/1 Rev. 4 Chap. 10]
According to Annex XIV Part B, a PMCF plan must always be drawn up or a justification must be provided why a post-market clinical follow-up is not applicable (in exceptional cases) (MDR Annex III (1.b), last indent). D groups for which no PMCF plan is applicable: e.g. for devices that are not directly patient-related, such as devices for cleaning and sterilising instruments.

A template for the PMCF plan can be found in MDCG 2020-7, where examples of PMCF activities are also given. PMCF activities are not limited to PMCF studies.

[2] Class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12)