

Checklist: Clinical Evaluation Report

1. Summary

Herein, we verify the completeness and consistency of the release of the Clinical Evaluation Report with the requirements stated in Appendix A10 of the MEDDEV 2.7/1 revision 4 Guideline.

This checklist is actually copy-pasted from the Appendix A10 of the MEDDEV 2.7/1 revision 4 Guideline.

This template is the bare minimum to ensure that your Clinical Evaluation Report is compliant with the requirements for the initial CE-marking and follows the key points the notified bodies in the EU will assess your Clinical Evaluation Report for. Feel free to add further rows and / or adapt the current ones in the checklist if they make sense for your SaMD. Make sure to fill it out before you continue working on other technical documentation of your SaMD especially post-market surveillance and risk assessment-related activities.

2. Relevant Other Documentation

- Clinical Evaluation Report (Doc-ID)

3. Checklist Overview

The following documents are up to date:

The table below shows examples only. Add - or reference - a list of all your required TechDoc records.

| Item | Yes | No | Comment |
|-------------------------------------|-----|----|---------|
| SOP Clinical Evaluation (Doc-ID) | | | |
| Clinical Evaluation Plan (Doc-ID) | | | |
| Clinical Evaluation Report (Doc-ID) | | | |
| Declaration of Conformity | | | |

The following activities have been performed:

Checklist Items

Can the report be read and understood by a third party, does it provide sufficient detail for understanding the data that are available, all assumptions made and all conclusions reached?

If clinical data have been generated and are held by the manufacturer, are all data mentioned and adequately summarised in the report?

If equivalence is claimed,

- is demonstration of equivalence included in the report?
- does the report disclose all the differences between the device under evaluation and the equivalent device?
- does it explain why the differences are not expected to affect the clinical performance and clinical safety of the device?

If the product is already in the market in Europe or elsewhere, has the latest PMS/ PMCF data been taken into consideration and has it been summarised and referenced in the report?

In respect to current knowledge/ the state of the art,

- has the report been updated?
- is current knowledge/ the state of the art summarised in the report and is it adequately substantiated by literature?
- does the content of the report fully correspond to current knowledge/ the state of the art?
- does the report explain why the benefit/risk profile and the undesirable side-effects are acceptable in relation to current knowledge/ the state of the art?

If the report covers several models/ sizes/ settings and/or different clinical situations, is there sufficient clinical evidence and are the report's conclusions correct for

- all the devices?
- all its sizes, models and settings? (including the smallest/ largest size, highest/ lowest dose, etc.)
- every medical indication? (as described in the IFU/ not excluded with contraindications in the IFU)
- the entire target population? (from pre term infants to old age, for males and females, etc., if not restricted in the IFU)

Checklist Items

- every form, stage and severity of the medical condition, as applicable? (including the most severe/ most benign forms, acute/ chronic stage, if not excluded in the IFU)
 - all intended users? (including lay persons, if not excluded in the IFU, and any unusual user group)
 - the whole duration of product use, including the maximal number of repeated exposure? (as allowed by the IFU)
 - if there are any discrepancies as to the above, are they identified in the report's conclusions?
- Is conformity to each of the relevant Essential Requirements (AIMDD ER1,2,5 / MDD ER1,3,6) clearly stated and are all discrepancies identified in the report's conclusions?
- Do the information materials supplied by the manufacturer correspond with the contents of the report and are all discrepancies identified in the report's conclusions?
- Do the report's conclusions identify all residual risks and uncertainties or unanswered questions that should be addressed with PMS/ PMCF studies?
- Is the report dated?
- Is the qualification of the evaluators included in the report and correct?
- Does the manufacturer hold a CV and declaration of interests of each of the evaluators and are these up-to-date?

4. Comments

<Insert comments if applicable>

5. Result

- ☐ Checklist passed
- ☐ Checklist not passed
- ☐ Checklist passed with the following obligations: <Insert if applicable>

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