**Review of a Clinical Evaluation Report (CER)**

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## 1 General information

| **Device name** |  |
| --- | --- |
| **Company** |  |
| **Author of the reviewed CER** |  |
| **Version of the reviewed CER** |  |
| **Document name** |  |
| **Reviewer of the CER** |  |
| **Review date** |  |

## 2 Reference documents

| **Document** | **Document name** | **Date of release** |
| --- | --- | --- |
| **Intended Purpose** |  |  |
| **CEP** |  |  |
| **Literature Search Protocol** |  |  |
| **…** |  |  |
| **….** |  |  |

## 3 Checklists for the review of a Clinical Evaluation Report

**Checklist according to MEDDEV 2.7/1 Rev. 4 A10**

| **No.** | **Requirement** | **Yes** | **No**  | **N/A** | **Comment** |
| --- | --- | --- | --- | --- | --- |
| 1 | Can a third party read and understand the report, and does it provide sufficient detail to understand the data available, any assumptions made, and any conclusions drawn? |[ ] [ ] [ ]   |
| 2 | If clinical data has been generated and is in the manufacturer's possession, is all data mentioned and appropriately summarized in the report? |[ ] [ ] [ ]   |
| 3 | If equivalence is the aim, |[ ] [ ] [ ]   |
|  | is proof of equivalence included in the report? |[ ] [ ] [ ]   |
|  | does the report contain all the differences between the device being assessed and the equivalent device? |[ ] [ ] [ ]   |
|  | does it explain why the differences are not expected to affect the clinical performance and clinical safety of the device? |[ ] [ ] [ ]   |
| 4 | If the device is already on the market in Europe or elsewhere, has the latest PMS/PMCF data been considered, and is it summarized and referenced in the report? |[ ] [ ] [ ]   |
| 5 | In relation to the current state of knowledge/state of the art, |  |  |  |  |
|  | has the report been updated? |[ ] [ ] [ ]   |
|  | is the current state of knowledge/state of the art summarized in the report, and is it sufficiently substantiated by the literature? |[ ] [ ] [ ]   |
|  | does the content of the report fully reflect the current state of knowledge/state of the art? |[ ] [ ] [ ]   |
|  | does the report explain why the benefit-risk profile and the undesirable side effects are acceptable in relation to the current state of knowledge/state of the art? |[ ] [ ] [ ]   |
| 6 | If the report covers multiple models/sizes/settings and/or different clinical situations, is there sufficient clinical evidence, and are the conclusions of the report correct for |[ ] [ ] [ ]   |
|  | all devices? |[ ] [ ] [ ]   |
|  | all their sizes, models and settings? (including smallest/largest size, highest/lowest dose, etc.) |[ ] [ ] [ ]   |
|  | any medical indication? (as described in the IFU/not excluded in case of contraindications in the IFU) |[ ] [ ] [ ]   |
|  | the entire target population? (from premature infants to old age, for men and women, etc., if not restricted in the IFU) |[ ] [ ] [ ]   |
|  | each form, stage and severity of the disease, if 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 total duration of product use, including the maximum number of repeated exposures? (as permitted by the IFU) |[ ] [ ] [ ]   |
|  | If there are any discrepancies in this regard, are these listed in the report's conclusions? |[ ] [ ] [ ]   |
| 7 | Is conformity with each relevant general safety and performance requirements (MDDD ER1, 3, 6/MDR GSPR 1, 8) clearly presented, and are all discrepancies listed in the report's conclusions? |[ ] [ ] [ ]   |
| 8 | Are the information materials provided by the manufacturer consistent with the report's content, and have all discrepancies identified in the report's conclusions been taken into account? |[ ] [ ] [ ]   |
| 9 | Do the report's conclusions identify any residual risks, uncertainties, or unanswered questions that should be addressed with PMS/PMCF studies? |[ ] [ ] [ ]   |
| 10 | Is the report dated? |[ ] [ ] [ ]   |
| 11 | Are the qualifications of the evaluators included in the report, and are they correct? |[ ] [ ] [ ]   |
| 12 | Does the manufacturer have a resume and statement of interest from each evaluator, and are they current? |[ ] [ ] [ ]   |

## 4 Conclusion