**Annex 5 Clinical evaluation checklist**

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| Manufacturer name and address: | Manufacturer: \*\*\*  Address: \*\*\* |
| Product | Device name: \*\*\* |
| Assessor/expert: | ***【补充临床专家的签字】*** |
| Date: | ***【补充临床专家的签字日期】*** |

The following content is follows the “A10. Proposed checklist for the release of the clinical evaluation report” of MEDDEV 2.7.1 rev.4:

The following aspects should be checked for the release of a clinical evaluation report:

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| **Clinical evaluation checklist for Notified Bodies** | | | |
| **Ref** | **Requirement** | **Fulfilled** | **Comment** |
| **1** | **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?** | Yes √  No □  N/A. □ | The report can be read and understood by a third party. Sufficient details see Clinical Evaluation Report . |
| **2** | **If clinical data have been generated and are held by the manufacturer, are all**  **data mentioned and adequately summarized in the report?** | Yes √  No □  N/A. □ | Yes. The clinical data generated and held by manufacturer are mentioned and adequately summarized in section 4.3 and 4.5 of clinical evaluation report  . |
| **3** | **If equivalence is claimed** |  |  |
| 3.1 | is demonstration of equivalence included in the report? | Yes √  No □  N/A. □ | Yes. The demonstration of equivalence is in section 4.2 of clinical evaluation report. |
| 3.2 | does the report disclose all the differences between the device under evaluation and  the equivalent device? | Yes √  No □  N/A. □ | Yes. The information is in section 4.2 of clinical evaluation report. |
| 3.3 | does it explain why the differences are not expected to affect the clinical performance and clinical safety of the device? | Yes √  No □  N/A. □ | Yes. The information is in section 4.2 of clinical evaluation report.. |
| **4** | **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?** | Yes √  No □  N/A. □ | Yes. The information is in section 4.3 of of clinical evaluation report. |
| **5** | **In respect to current knowledge/ the state of the art** |  |  |
| 5.1 | has the report been updated? | Yes √  No □  N/A. □ | Yes. The information is in first page of CER |
| 5.2 | is current knowledge/ the state of the art summarized in the report and is it adequately substantiated by literature? | Yes √  No □  N/A. □ | Yes. Current knowledge/the state of the art summarized in the report in section 3 of clinical evaluation report.. It is adequately substantiated by literature in section 3 of clinical evaluation report.. |
| 5.3 | does the content of the report fully correspond to current knowledge/ the state of the art? | Yes √  No □  N/A. □ | Yes. The information can refer to Clinical Evaluation Report |
| 5.4 | 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? | Yes √  No □  N/A. □ | Yes. The information can refer to section 4.6.2 and section 4.6.4 of of clinical evaluation report. |
| **6** | **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** |  |  |
| 6.1 | all the devices? | Yes √  No □  N/A. □ | Yes. The information can refer to Section 2 of clinical evaluation report.. |
| 6.2 | all its sizes, models and settings? (including the smallest/ largest size, highest/ lowest dose, etc.) | Yes √  No □  N/A. □ | Yes. The information can refer to Section 2 of clinical evaluation report.. |
| 6.3 | every medical indication? (as described in the IFU/ not excluded with  contraindications in the IFU) | Yes √  No □  N/A. □ | Yes. The information can refer to Section 2 of clinical evaluation report.. |
| 6.4 | the entire target population? (from pre term infants to old age, for males and females, etc., if not restricted in the IFU) | Yes √  No  □  N/A. □ | Yes. The information can refer to Section 2 of clinical evaluation report.. |
| 6.5 | 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) | Yes √  No  □  N/A. □ | Yes. The information can refer to Section 2. |
| 6.6 | all intended users? (including lay persons, if not excluded in the IFU, and any  unusual user group) | Yes √  No  □  N/A. □ | Yes. The information can refer to Section 2 of clinical evaluation report.. |
| 6.7 | the whole duration of product use, including the maximal number of repeated  exposure? (as allowed by the IFU) | Yes √  No □  N/A. □ | Yes. The information can refer to Section 2 of clinical evaluation report.. |
| 6.8 | if there are any discrepancies as to the above, are they identified in the  report’s conclusions? | Yes √  No □  N/A. □ | Yes. The information can refer to Section 5 of clinical evaluation report.. |
| **7** | **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?** | Yes √  No □  N/A. □ | The information can refer to Section 5 of clinical evaluation report. |
| **8** | **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?** | Yes √  No □  N/A. □ | The information can refer to Section 5 of clinical evaluation report. |
| **9** | **Do the report’s conclusions identify all residual risks and uncertainties or unanswered questions that should be addressed with PMS/ PMCF studies?** | Yes √  No □  N/A. □ | The information can refer to Section 5 of clinical evaluation report.. |
| **10** | **Is the report dated?** | Yes √  No □  N/A. □ | Yes. The information can refer to cover page. |
| **11** | **Is the qualification of the evaluators included in the report and correct?** | Yes √  No □  N/A. □ | Yes. The information can refer to Section 8 of clinical evaluation report.. |
| **12** | **Does the manufacturer hold a CV and declaration of interests of each of the**  **evaluators and are these up-to-date?** | Yes √  No □  N/A. □ | Yes. The information can refer to Annex 1 CV of evaluators and Annex 6 Declaration of Interests. |

The following content is follows the “A9. Clinical evaluation report - proposed table of contents, examples of contents” of MEDDEV 2.7.1 rev.4:

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| **Table of contents** | **Example of contents** | **The relate section of the clinical evaluation report** |
| 1.Summary | Executive summary, summary for external purposes.  This section should summarize the determination of the benefit/risk profile in the intended target groups and medical indications, and the demonstration of acceptability of that profile based on the state of the art in the medical fields concerned. | see section 1 of clinical evaluation report. |
| 2.Scope of the clinical evaluation | See Section 7 and Appendix A3.  Identification of devices covered by this clinical evaluation report, products, models, sizes, software versions, accessories, their proprietary names, code names assigned during device development. Name and address of the manufacturer.  Whether this clinical evaluation is submitted to the AIMDD as amended by directive 2007/47/EC, or to the MDD as amended by directive 2007/47/EC.  Concise physical and chemical description, including materials. Whether the device incorporated medicinal substances (already on the market or new), tissues, or blood products. Mechanical and physicochemical characteristics; others (such as sterile vs. non- sterile, radioactivity etc.); picture or drawing of the device.  Technologies used, whether the device is based on a new technology, a new clinical application of an existing technology, or the result of incremental change of an existing technology. Description of innovative aspects of modified, identification of new products, models, sizes, software, accessories, new intended purposes, new claims, new events related to the device with an  Other aspects. | see section 2 of clinical evaluation report. |
| 3.Clinical background, current knowledge, state of the art | See Sections 8-10 and Appendices A4-A5.  Identification of medical fields concerned/relevant medical conditions.  Brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/ the state of the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. Appraisal criteria used.  Applicable standards and guidance documents.  Description, natural course and consequences of the medical conditions concerned. Whether there are different clinical forms, stages and severities of the conditions. Frequency in the general population, by age group, gender, ethnicity, familiar predispositions, genetic aspects.  Description of available therapeutic/ management/ diagnostic options, historical context and developments, summary of advantages and disadvantages of the different options, benefit/ risk profiles and limitations in relation to the different clinical forms, stages, and severities of the medical conditions and in relation to different target populations. Description of the benefits and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects and other risks (including the nature, severity, probability and duration of acceptable harm).  Hazards due to substances and technologies that could be relevant to the device under evaluation. The mechanisms of harm, clinical aspects of minimisation and management of side effects and other risks.  Types of users. Diverging opinions of professionals as to the use of the different medical options. Unmet medical needs. | see section 3 of clinical evaluation report. |
| 4 Device under evaluation  4.1 Type of evaluation | Whether the clinical evaluation is based on :  - scientific literature currently available, and/or  - clinical investigations made or  - whether demonstration of conformity with essential requirements based on clinical data is not deemed appropriate.  If clinical data is not deemed appropriate, include considerations according to Section 10.3. See Appendix A1. | see section 4.1 of clinical evaluation report. |
| 4.2. Demonstration of equivalence (only when equivalence is claimed) | Identification of the equivalent device and its manufacturer. Exact name, models, sizes, software versions, accessories, etc. Name of the manufacturer. Relationship to the device under evaluation (predecessor/ successor, others). Regulatory status. If the device is not CE-marked, justification for the use of the data.  Comparison of clinical, biological and technical characteristics (see Appendix A1 for details). Justification of equivalence, description of relevant clinical, biological and technical characteristics that affect clinical properties of the device, differences between the intended purpose of the device under evaluation and the equivalent device (indications, contraindications, precautions, target patient groups, target users, mode of application, duration of use/ number of re-applications, others), type of device-body interaction. Choice, justification and validity of parameters and models for non-clinical determination of characteristics.  Identification of pre-clinical studies carried out and literature used concise summaries of studies and literature (methods, results, conclusions of the authors), evaluation of the methodological quality of the study or document, the scientific validity of the information.  Comparative tabulations for the device under evaluation versus the equivalent device showing parameters relevant to the evaluation of the three characteristics. Comparative drawings or pictures of the device and the equivalent device showing the elements in contact with the body.  Identification of differences, evaluation if differences are expected or not to influence the clinical performance and clinical safety of the device, reasons for assumptions made.  Conclusions concerning equivalence. Whether the comparison carried out covers all products/ models/ sizes/ settings/ accessories and the entire intended purpose of the device under evaluation, or only certain products/ models/ sizes/ settings/ accessories, or selected aspects of the intended purpose, which ones.  Conclusions whether equivalence is demonstrated or not; if it is demonstrated, confirmation that the differences are not expected to affect the clinical performance and clinical safety of the device under evaluation; description of any limitations and gaps | see section 4.2 of clinical evaluation report. |
| 4.3 Clinical data generated and held by the manufacturer | See Section 8.1.Identification of clinical data generated and held by the manufacturer. | See section 4.3 of clinical evaluation report. |
| 4.4. Clinical data from  Literature | See Section 8.2 and Appendices A4-A5.  Brief summary and justification of the literature search strategy applied for retrieval of clinical data, including objectives, sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. | See section 4.4 of clinical evaluation report. |
| 4.5. Summary and appraisal of clinical data | See Section 9 and Appendix A6  - Feasibility Studies  - Pivotal clinical investigations  - PMCF Studies PMCF  - Other use data  Summaries of clinical data generated and held by the manufacturer and of scientific literature found to be pertinent.  Including brief summary of the studies or references (methods,results, conclusion of the authors), evaluation of their methodological quality, scientific validity of contents, relevance tothe clinical evaluation, weighting attributed to the data, contents used (performance data, safety data, both) reasons for rejecting a study or document, reasons for rejecting some of its contents. | See section 4.5 of clinical evaluation report. |
| 4.6. Analysis of the clinical data  4.6.1. Requirement on safety (MDD ER1  / AIMDD ER1) | See Section 10 and Appendix A7.1.  Summary of conformity assessment with requirement on safety(MDD ER1 / AIMDD ER1).  Analysis whether there are special design features that pose special safety concerns (e.g. presence of medicinal, human or animal components) that where identified in the device risk management documentation and that required evaluation from a clinical perspective, and whether these have been adequately addressed.  Whether the risks identified in the risk management documentation and literature have been adequately addressed.  Whether all the hazards and other clinically relevant information (e.g. clinical precautions for reduction of risks, clinical management of risks) have been identified appropriately.  Whether the safety characteristics and intended purpose of the device requires training of the end-user or other precautions, if users foreseen are adequate, if training requirements and other precautions are described in the IFU.  Whether there is full consistency between current knowledge/ the state of the art, the available clinical data, the information materials supplied by the manufacturer, and the risk management documentation for the device. | See section 4.6.1 of clinical evaluation report. |
| 4.6.2. Requirement  on acceptable benefit/risk profile  (MDD ER1 / AIMDD ER1) | See Section 10 and Appendix A7.2  Summary of conformity assessment with requirement on acceptable benefit/risk profile (MDD ER1 / AIMDD ER1).  Summary of the total experience with the device, including estimated numbers and characteristics of patients exposed to the device in clinical investigations, PMCF, from other user experience, and in the market; duration of follow-up. Nature, extent/severity, probability/frequency, duration of benefits to the patients and of undesirable side-effects and other risks. For each aspect of the intended purpose, whether the benefit/risk profile including its uncertainties or unanswered questions is compatible with a high level of protection of health and safety, corresponding justifications. | See section 4.6.2 of clinical evaluation report. |
| 4.6.3. Requirement on Performance (MDD ER3 / AIMDD ER2) | See Section 10 and Appendix A7.3.  Summary of conformity assessment with requirement on performance (MDD ER3 / AIMDD ER2). Description of clinical performance. For each intended performance, extent to which evaluation of benefits is possible based on available data, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions. whether available data allows adequate evaluation of performance, limitations of the data, gaps, uncertainties or unanswered questions. Whether there is sufficient clinical evidence for every intended performance. | See section 4.6.3 of clinical evaluation report. |
| 4.6.4. Requirement on acceptability of side-effects (MDD ER6 / AIMDD ER5) | See Section 10 and Appendix A7.4  Summary of conformity assessment with requirement on acceptability of undesirable side-effects (MDD ER6 / AIMDD ER5). Whether the data available is of sufficient amount and quality for the detection of undesirable side-effects and their frequency, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions. Whether the undesirable side-effects are acceptable and corresponding justifications. | See section 4.6.4 of clinical evaluation report. |
| 5. Conclusions | See Section 11.  Clear statement concerning compliance to Essential requirements.  Acceptability of the benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives.  Adequacy of the information materials supplied by the manufacturer, whether the intended purpose and risk reduction measures are adequate; discrepancies.  Suitability of the device, including its IFU, for the intended users and usability aspects; discrepancies.  Adequacy of claims foreseen by the manufacturer; discrepancies. If there is consistency between the clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under evaluation; discrepancies.  Whether there is consistency between these documents and the current knowledge/ the state of the art; discrepancies. Description of residual risks and uncertainties or unanswered questions, whether these are acceptable for CE-marking, how these should be followed during PMS (uncertainties regarding medium- and long term performance, safety under wide-spread use, residual risks such as undesirable side-effects and complications occurring at rates below detection possibilities of currently available clinical data, others). Whether these are already being addressed in ongoing PMS activities, e.g. in currently ongoing PMCF studies. Whether new or additional PMS activities, including PMCF studies, should be foreseen. | See section 5 of clinical evaluation report. |
| 6. Date of the next clinical evaluation | See Section 6.2.3.  Suggested date, justification of the date. | See section 6 of clinical evaluation report. |
| 7.Dates and signatures | See Section 11.  Date of the clinical evaluation report.  Statement that the evaluators agree with the contents of the report. Dates, names and signatures of the evaluators.  Final release by the manufacturer. Date, name and signature. | See section 7 of clinical evaluation report. |
| 8. Qualification of the responsible evaluators | See Section 6.4. | See section 8 of clinical evaluation report. |
| 9. Reference | See Section 11. | See section 9 of clinical evaluation report. |