Customer Clinical Evaluation Report (CER)
Validation checklist of clinical evidence

Product Service

Customer name:

Name of MD/system:

Device category (e.g. cardiovascular, orthopedic):

Title of CER:

Date/revision of CER:

Are these aspects addressed?	Yes	No
1. Please check whether the submission along with the CER is complete. Are at least the following documents available? • Product description • Clinical evaluation report • Literature search protocol and report for the state of the art • Literature search protocol and report for the device under assessment • CVs of author and reviewer • Risk management file (plan, analysis, report) • Instructions for use • Product brochure/website/promotional material • Scientific literature	☐	☐
If no, please comment:		
2. Please check whether the CER and associated documents are written in English or German.	☐	☐
If no, please comment:		
3. Please check whether the CER is up to date. The date of approval of the CER shall not be older than six months when submitted to TÜV SÜD and shall be signed and dated by the author and the reviewer (or any responsible evaluator).	☐	☐
If no, please comment:		

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Are these aspects addressed?	Yes	No
4. Please check whether the CER includes the scope according to the current applicable revision of MEDDEV 2.7.1.	☐	☐
If no, please comment:		
5. In case clinical investigations or PMCF studies have been conducted with medical devices under assessment, please check if the relevant documentation such as signed and dated clinical investigation/study plan, signed and dated clinical investigation/study report, letter of no objection of relevant competent authorities, and ethics committee votes are included in the submission.	☐	☐
If no, please comment:		
6. Please check whether the CER includes literature search documentation related to the state of the art (indication-related) and to the device under assessment and/or comparable devices (as described in MEDDEV 2.7.1).	☐	☐
If no, please comment:		

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Are these aspects addressed?	Yes	No
7. Please check the date of the scientific literature search whether if it is not older than 6 to 12 months.	☐	☐
If no, please comment:		
8. Please check whether the full-text publications of scientific literature referenced in the CER are submitted either as electronic or hard copies.	☐	☐
If no, please comment:		
9. In case of an equivalence route, please check whether the CER includes a chapter demonstrating the equivalence between 'similar device' and 'device under assessment' from clinical, technical, and biological points of view.	☐	☐
If no, please comment:		

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Are these aspects addressed?	Yes	No
10. If the device is already in the market in the EU or elsewhere, please check whether the post market data include market period, number of sold devices, number and kind (short description) of complaints, number and kind (short description) of incidents reportable to competent authorities, number and kind (short description) of CAPAs, number and kind (short description) of FSCAs and recalls. The PMS data shall be up to date.	☐	☐
If no, please comment:		
11. Please check whether the post market data are broken down to the different sizes/models and system components.	☐	☐
If no, please comment:		
12. Please check whether it is clearly discernible that the risk management team involved appropriate clinical expertise.	☐	☐
If no, please comment:		

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Are these aspects addressed?	Yes	No
13. Please check whether the most recent version of the instruction for use (IFU) is available in the submitted package.	☐	☐
If no, please comment:		
14. Please check whether the IFU includes a product description, intended use, indications, contraindications as well as risks/side effects, and whether it is consistent with the information in the CER.	☐	☐
If no, please comment:		
15. Please check whether promotional material such as product brochures and/ or product information on the company website exists and that all claims are included and substantiated within the CER.	☐	☐
If no, please comment:		