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Expectation on performance-based CER

Medical device: Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate

(MDD Ax X 1.1d/AIMDD Ax VII 1.5/ MDR Art. 61 paragraph 10)

- A clinical evaluation needs to be performed and documented according to the MDD/AIMDD or future MDR taking into account relevant guidance documents (state of the art).
- Within the scope it should be stated that the clinical evaluation is based on the results of nonclinical testing methods alone.
- The Clinical Evaluation Report (CER) needs to include an adequate justification[1] why a demonstration of conformity with essential requirements[2] based on nonclinical testing methods alone, **including performance evaluation, bench testing and preclinical evaluation,** is considered to be adequate.
  - This justification needs to be based on risk-management output and under consideration of the specifics of the device/body interaction, the clinical performance intended and the claims[3] of the manufacturer.
  - Applicable performance standards and common specifications need to be identified and compliance demonstrated.[4]
- The CER needs to include all performance and safety claims (e.g. from instructions for use (IFU), promotional material, websites) with a clear link to the supporting evidence. Without clinical data or data with a scientifically valid justification on transferability, no clinical claims can be made.
- The MDD/AIMDD or future MDR requirements taking into account relevant guidance documents shall be followed in **all** aspects **except** for those referring to clinical data.

Aspects to be covered in the CER include, but are not limited to:

- Systematic literature search and review
- State-of-the-art review
- Summary, critical appraisal and analysis of non-clinical data including **usability testing**
- Conclusion whether the data are adequate and sufficient to demonstrate safety and performance when used as intended
- Adequate and proportionate Post-Marketing Surveillance (PMS)/Post-Market Clinical Follow-up (PMCF) activities including proactive-systematic measures to confirm performance and safety

Your contact partner at TÜV SÜD Product Service can provide further information.

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[1] MDR: Due substantiation.
[2] MDR: General safety and performance requirements.
[3] Any clinical claim would require clinical data.
[4] If applicable performance standards require clinical testing; this exemption acc. to MDD Ax X 1.1d/AIMDD Ax VII 1.5/ MDR Art. 61 paragraph 10 is not applicable.

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