

Clinical Data Requirements for EC Certificate Extension

The Med-Info “New Forms and requirements for the extension of EC certificates according to AIMDD, MDD, IVD” (March 2005) issued by TÜV SÜD Product Service GmbH has specified the process for the extension of certificates. The requirements for clinical data to be submitted for this purpose are detailed below:

Clinical data for EC certificate extension shall include:

1. a recent **update of the “state of the art” review:**
 - 1.1. a documented systematic literature review according to the requirements as outlined in MEDDEV 2.7.1, including a protocol for identification, selection, collation and review of relevant publications comprising search terms, data bases, criteria for inclusion/exclusion of particular references.
 - 1.2. a detailed **discussion about limitations and benefits of:**
 - 1.2.1. all current therapeutic alternatives as well as
 - 1.2.2. competitor products used for the treatment the assessed device is indicated for
 - 1.3. a discussion whether, and if yes, why the assessed device can further on be regarded to be in compliance with the “state of the art”
2. a **post-market experience:**
 - 2.1. marketing period
 - 2.2. number of devices sold
 - 2.3. number and type of complaints
 - 2.4. number and type of incidents
 - 2.5. corrective actions (yes; no; if yes, which?)
 - 2.6. post-market clinical follow-up studies
 - 2.7. registries
 - 2.8. long-term follow-up of pre-marketing clinical studiesIf any item is not applicable, this shall be stated.
3. a current version of the **instructions for use**, including indications/contraindications, risks/side effects
4. a current version of the **risk analysis**, taking into account any issues related to clinical safety and side effects detected after market release

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