I3CGLOBAL

EU MDR CER

Clinical Evaluation Report Sample Contents

Given below are the **Clinical Evaluation Report Sample Contents.** This is only considered an easy reference sample. We are read template (https://www.i3cglobal.com/clinical-evaluation-plan-report-template/) for online purchase.

Clinical Evaluation Report for Medical Device

- A Clinical Evaluation Report (CER) for Medical Device (https://www.i3cglobal.com/medical-device-consultants/) is a docum contains the conclusions of the clinical evaluation performed on the medical device based on all relevant clinical data avai
- The CER and the clinical data are used together to prove the conformity of the medical device to the general safety and performance requirements.
- The CER includes the details of the clinical background, current knowledge, and state of the art which can be used to evalu safety and performance of the device for corresponding to its intended purpose.
- If a well-established CE marked (https://www.i3cglobal.com/medical-device-ce-marking/) device which is similar to the de under evaluation, then the reports of that device can be used to prove the safety and performance of the device under evalu claiming equivalency, provided a contract is in place between the two manufacturers.
- Details of the post-market activities conducted are also provided in the CER, which is used to answer any unanswered ques residual risks that are not covered by the available clinical data.
- Also, the results of the various tests conducted are listed to prove the safety and performance of the device.

- During the analysis of the appraised data, the requirements on safety, performance, acceptability of benefit/ risk profile, ar effects are assessed to establish conformity to GSPR.
- The conclusion of CER (https://en.wikipedia.org/wiki/Clinical_trial) includes the acceptability of the risk-benefit profile acc to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives.
- It also includes the adequacy of the information materials supplied, whether the intended purpose and risk reduction mea are adequate and any discrepancies.
- Summary of the suitability of the device, including its IFU, for the intended users and usability aspects, any discrepancies included along with the adequacy of claims and its discrepancies.
- If there is consistency between the clinical data, the information materials, the risk management documentation for the de under evaluation; discrepancies should be summarized.
- The CER is used to ultimately evaluate and prove the device is safe for use on humans and that it performs as expected wh according to the manufacturer's instructions.
- Also, the CER shows that the presence of the device on the market is justified because of side-effects and risks, if any, are outweighed by the benefits of the device.

> CER REPORT (https://www.i3cglobal.com/clinical-evaluation-report-cer/)

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