

Summative Usability Evaluation according to IVDR – Your Checklist

Are you unsure about one of the sub-items? Take a look at [our article](#) about the checklist. There we have explained each point to you in detail. You are also welcome to contact us at any time via [our contact form](#) our contact form. We look forward to your feedback.

01. Are you properly prepared?

- Are you planning the right process?
 - User Interface of Unknown Provenance for existing products
 - the complete Usability Engineering process according to IEC 62366-1 for new IVDs

- Have you found the right partner for the execution?

- Have you defined all important factors around your IVD?
 - The Use Specification
 - The right user groups
 - All characteristics of the user interface related to its safety
 - The list of all potential usage errors
 - A use related risk analysis has been performed

- Are there specific MDCG guidance documents for your IVD?

- Do you need to samples from real people for your Summative Evaluation, or can a simulated use take place?

If sampling real users:

 - You have sought approval from the federal agency?
 - You have sought approval from an ethics committee?
 - You have requested patient insurance for each participating user?

02. Is your product ready for the Summative Evaluation?

- Is your product available in a pilot series or as a Product Equivalent Device?
- Are your IFUs and instructions available in final form?

03. Your product is prepared for the requirements of Summative Evaluation?

- Have you demonstrated that the user interface of your IVD is safe to use?
- Are the performance requirements set by the IVDR met?
- You have demonstrated that your IFUs and instructions accompanying the product are easy to understand?
- You have demonstrated safe and error-free use across all phases of use?
- You have minimized all use-related risks of your IVD?
 - The risks due to ergonomic features
 - The risks due to the consideration of the capabilities of the intended users

04. You have recruited the right users and enough of them

- The recruited users match your Intended User Group?
- The recruited users are a representative sample of the respective group?
- You have considered to recruit more users than needed?

05. You have prepared the Usability-labs properly?

- Is the right equipment available and prepared?
- Are the right premises available for the tests? Do the premises allow you to create a realistic use environment for the tests?
- You have checked the completeness of the equipment for recording and streaming?
- Sie haben die Vollständigkeit des Equipments für die Aufzeichnungen und den Stream geprüft?
- You have chosen the right location for the right authority?

06. If necessary: Have you properly trained your users?

- You have trained according to your IFUs and trainings?
- You have thought of a realistic time interval between training and use?

07. Do you have the appropriate personnel to perform the Summative Usability Evaluation?

- The people conducting the evaluation are not involved in the development of your product?
- You have sufficient usability researchers for your study?
- You have designated a „person responsible for regulatory compliance“?

08. The execution of the Summative Evaluation is in accordance with the IVDR??

- You have created realistic conditions of use?
- You avoid user questions during the implementation?
- The safety-critical use errors (Hazard Related Use Scenarios) are tested?
- For self-use IVDs: you have demonstrated that users can interpret all the results of your IVD without error?
- You consider that Knowledge Tasks have to be queried as well?
- You think about the post-hoc interviews, i.e. the follow-up surveys after use?

09. You have done the follow-up and data evaluation?

- You have collected the data of your Summative Usability Evaluation and would like to analyze it?
- You have done a Root Cause Analysis?
- You have created a Summative Report?
- You have checked your evaluation for completeness?
- You have demonstrated the safe use of your IVD?

We wish you a successful planning, implementation and follow-up of your Summative Usability Evaluation according to IVDR! We are happy to help you with the following steps:

- The Usability Engineering process according to IEC 62366-1 and the formative evaluations of your IVD.
- Summative Usability Evaluation incl. recruitment and training of users and descriptive evaluation.
- With the preparation of your documentation for the Notified Body.