Johner Institut

Checklist: MDR Usability Requirements

1 Aims and target group of this checklist

This checklist should help medical device manufacturers to

1. Quickly check how well they meet the MDR's requirements regarding usability
2. Introduce the measures necessary to ensure patient safety and avoid problems during audits and authorizations.

Manufacturers who still place their devices on the market under EU directive certificates (MDD, IVDD, AIMD) should also use these checklists because the MDR requirements reflect the state of the art, which is already required by the EU directives.

2 Checklist

2.1 Intended purpose

Requirement	**Implementation**
The intended purpose or/and use specification defines the characteristics of the **users**, e.g., based on age, sex, education, experience with the device (class), physical and mental impairments	☐ Complies ☐ Does not comply Measure / comment
The intended purpose or/and use specification describes the characteristics of the **use environment**: - Physical attributes (e.g., brightness, noise, distance between the user and the device) - Tools and materials (e.g., use of gloves) - Social context (e.g., stress, shift operation, frequent interruptions)	☐ Complies ☐ Does not comply Measure / comment
For devices to be used by lay persons, the intended purpose specifies the range or variations that exist in terms of the users and use environment.	☐ Complies ☐ Does not comply Measure / comment
The intended purpose describes the other devices that the medical can be connected to or combined with.	☐ Complies ☐ Does not comply Measure / comment

2.2 Use scenarios

The manufacturer has created a list of all "**use scenarios**" for the device.	☐ Complies ☐ Does not comply Measure / comment
The "use scenarios" include connections to and combinations with other medical devices and their disconnection (if applicable)	☐ Complies ☐ Does not comply Measure / comment
The manufacturer has evaluated each "use scenario" to determine whether it is relevant to safety.	☐ Complies ☐ Does not comply Measure / comment
During this evaluation, the manufacturer looked at the consequences of users not knowing something as well as those of the users not understanding something.	☐ Complies ☐ Does not comply Measure / comment

2.3 Risk management

The risk management file contains all safety-related "use scenarios"	☐ Complies ☐ Does not comply Measure / comment
The risk management file describe at least one measure for each safety-related "use scenario".	☐ Complies ☐ Does not comply Measure / comment
If these measures do not contain any inherently safe measures or any protection measures, the manufacturer must explain why it thinks that training and accompanying materials are the only possible measures.	☐ Complies ☐ Does not comply Measure / comment
For each measure, there is a reference to proof of effectiveness. Proof usually takes the form of formative and summative evaluations and/or the analysis of post-market data.	☐ Complies ☐ Does not comply Measure / comment

2.4 Formative evaluations

The manufacturer has carried out and documented one or more formative evaluations of the device's usability.	☐ Complies ☐ Does not comply Measure / comment

2.5 Summative evaluations

The manufacturer has carried out and documented a summative evaluation or a validation of the device's usability.	☐ Complies ☐ Does not comply Measure / comment
This summative evaluation or evaluation of the usability was performed with at least five representative individuals for each role. This applies in particular for lay persons.	☐ Complies ☐ Does not comply Measure / comment
This summative evaluation or validation of the usability includes all safety-related "use scenarios". This can also relate to the connection with other devices.	☐ Complies ☐ Does not comply Measure / comment

2.6 Post-market surveillance

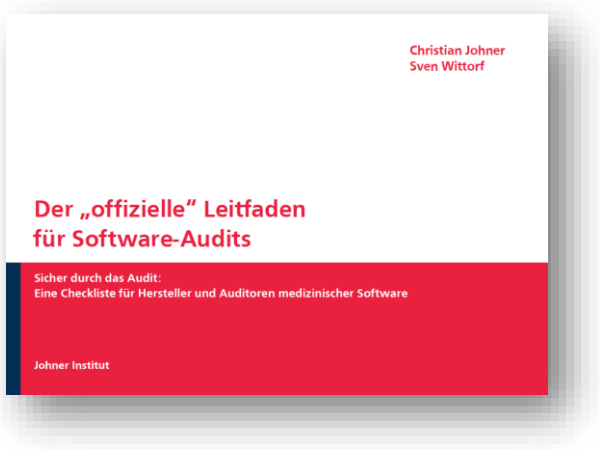
There is a process description for the post-market surveillance.	☐ Complies ☐ Does not comply Measure / comment
This process description describes which data is collected and how this data is evaluated.	☐ Complies ☐ Does not comply Measure / comment
The process description provides for the involvement of usability experts and risk managers.	☐ Complies ☐ Does not comply Measure / comment

2.7 Other

The specification of the user interface refers to or uses design guidelines, as specified by ISO 9241.	☐ Complies ☐ Does not comply Measure / comment
The manufacturer has also demonstrated, in particular for devices used by lay persons, the usability of the instructions for use through questionnaires, tests or summative evaluations.	☐ Complies ☐ Does not comply Measure / comment

2.8 Other aspects

The audit guide is over 100 pages long and contains detailed checklists. This allows manufacturers to quickly check the conformity of devices and processes with the MDR requirements, as well as the requirements of numerous standards, such as IEC 62366-1, IEC 62304, ISO 14971 and ISO 13485.



You can find more on the audit guidelines on the website https://www.johner-institut.de/produkte/buecher/auditleitfaden/.

3 Support from the Johner Institute

3.1 Identifying gaps and establishing measures

The Johner Institute's usability experts will help you to quickly identify deviations and to establish the perfect measures for closing these gaps.

Tasks that the Johner Institute can support you in are:

- Review of existing usability files for conformity with IEC 62366-1
- Review of the risk management file
- Analysis of process descriptions, e.g., for post-market surveillance
- Review of the instructions for use to check they are understandable and comply with the relevant laws and standards

3.2 Implementing measures as quickly and as easily as possible

The Johner Institute's experts focus on avoiding any type of unnecessary work and instead work on a risk-based basis. They work with you towards the aim of ensuring safety for patients and confidence for your company during when it comes to authorization audits.

Tasks that the Johner Institute can support you in are:

- Revising and honing the **use specification** (to avoid unnecessary usability tests)
- Describing any missing **use scenarios** and assess their relevance for safety
- Suggesting **improvements to the user interface**
- Amending (or creating) **instructions for use** to ensure they conform to the MDR
- Performing **formative and summative evaluations**
- Defining your **post-market process** and supporting you with the analysis of your data

4 Contact

Do you want support? Do you have any questions about the switch to the MDR? The Johner Institute's team is looking forward to hearing from you!

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