Johner Institut
Member of GBAGROUP

Checklist: MDR Usability Requirements

1 Objectives and Target Audience of this Checklist

This checklist helps medical device manufacturers

1. quickly assess how well they meet the MDR's requirements for usability and
2. identify necessary measures to ensure patient safety and avoid issues during audits and approvals.

Manufacturers who are still placing their products on the market under EU Directives (MDD, IVDD, AIMD) should also use these checklist. This is because the MDR requirements reflect the state of the art already mandated by the EU Directives.

2 Checklist

2.1 Intended Use

REQUIREMENT	IMPLEMENTATION
The intended use and/or use specification characterizes the users based on, for example, age, gender, education, experience with the product (or product class), and physical and mental limitations.	☐ Met ☐ Not met Action / Comment:
The intended use and/or the use specification characterizes the use environment: • physical attributes (e.g., brightness, noise, distance between the user and the product) • tools and materials (e.g., use of gloves), and • social context (e.g., stress, shift work, frequent interruptions)	☐ Met ☐ Not met Action / Comment:
For lay users, the intended use specifies the range or variations that exist among users and in the use environments.	☐ Met ☐ Not met Action / Comment:
The intended use describes which other products the medical device may be connected to or combined with.	☐ Met ☐ Not met Action / Comment:

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2.2 Use Scenarios

REQUIREMENT	IMPLEMENTATION
The manufacturer has compiled a list of all **"use scenarios"** for the product.	☐ Met ☐ Not met Action / Comment:
The "Use Scenarios" include connecting, combining, and disconnecting with and from other products (where applicable)	☐ Met ☐ Not met Action / Comment:
The manufacturer has evaluated each "use scenario" to determine whether it is hazard-related.	☐ Met ☐ Not met Action / Comment:
In this assessment, the manufacturer examined both the consequences that arise when users fail to recognize something and the consequences that arise when they fail to understand something.	☐ Met ☐ Not met Action / Comment:

2.3 Risk Management

REQUIREMENT	IMPLEMENTATION
The risk management file contains all hazard-related "use scenarios."	☐ Met ☐ Not met Action / Comment:
For each hazard-related "use scenario," the risk management file describes at least one measure.	☐ Met ☐ Not met Action / Comment:
If these measures do not include inherently safe measures or protective measures, the manufacturer must explain why it believes that training and accompanying materials are the only possible measures.	☐ Met ☐ Not met Action / Comment:
For each measure, there is a reference to evidence of its effectiveness. The evidence typically consists of formative and summative evaluations and/or the analysis of post-market data.	☐ Met ☐ Not met Action / Comment:

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2.4 Formative and Summative Evaluations

REQUIREMENT	IMPLEMENTATION
The manufacturer has conducted and documented one or more formative evaluations of the product's usability for this product.	☐ Met ☐ Not met Action / Comment:
The manufacturer has conducted and documented a summative evaluation or a usability validation for the product.	☐ Met ☐ Not met Action / Comment:
This summative evaluation – or usability validation – was conducted with at least ten representative participants from each role. This applies in particular to lay users.	☐ Met ☐ Not met Action / Comment:
This summative evaluation or validation of usability includes all hazard-related "use scenarios." This may also involve connection to other products.	☐ Met ☐ Not met Action / Comment:

2.5 Post-Market Surveillance

REQUIREMENT	IMPLEMENTATION
There is a procedure for post-market surveillance.	☐ Met ☐ Not met Action / Comment:
This procedure describes what data is collected and how that data is evaluated.	☐ Met ☐ Not met Action / Comment:
The procedure calls for the involvement of usability experts and risk managers.	☐ Met ☐ Not met Action / Comment:

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2.6 Miscellaneous

REQUIREMENT	IMPLEMENTATION
The user interface specification refers to or uses design guidelines as specified in ISO 9241.	☐ Met ☐ Not met Action / Comment:
The manufacturer has also demonstrated – particularly with regard to lay users – that the instructions for use are suitable for their intended purpose through interviews, tests, or summative evaluations.	☐ Met ☐ Not met Action / Comment:

2.7 Other Aspects

The AUDIT GUIDE is over 100 pages long and contains detailed checklists. This allows manufacturers to quickly verify the compliance of products and processes with the requirements of the MDR, as well as with many standards such as IEC 62366-1, IEC 62304, ISO 14971, and ISO 13485.



You can find more information about the audit guidelines on this website

Go to the Shop

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3 Support from the Johner Institute

3.1 Identify Gaps, Define Actions

The usability experts at the Johner Institute help you quickly identify non-conformities and determine the right measures to close these gaps.

The Johner Institute can assist you with the following tasks:

- Reviewing existing usability engineering files for compliance with IEC 62366-1
- Reviewing the risk management file
- Analyzing process descriptions, e.g., for post-market surveillance
- Reviewing instructions for use for clarity and compliance with laws and standards

3.2 Implement measures quickly and with as little effort as possible

The experts at the Johner Institute focus on avoiding any form of unnecessary work and instead adopt a risk-based approach. Together with you, they pursue the goal of ensuring patient safety and guaranteeing your company's success in audits.

The Johner Institute can assist you with the following tasks:

- Revise and refine the **use specification** (to avoid unnecessary usability tests)
- Describing missing **use scenarios** and assessing their relevance to safety
- Proposing **improvements to the user interface**
- Supplementing (or creating) **instructions for use** to achieve MDR compliance
- Conducting **formative and summative evaluations**
- Defining your **post-market process** and assisting with data analysis

4 Contact

Would you like some assistance? Do you have questions about the transition to the MDR? The team at the Johner Institute looks forward to hearing from you!

Phone	+49 (7531) 94500 20
E-Mail	info@johner-institut.de
Web	www.johner-institut.de/en/contact
Articles	blog.johner-institute.com
Locations	Reichenaustraße 39a, 78467 Konstanz Niddastraße 91, 60329 Frankfurt am Main Tafelstattstraße 13a, 6415 Arth (Switzerland) 8403 Colesville Road (Suite 1100), Silver Spring, MD 20910 (USA) Level 5, 9 Haymarket Square, Edinburgh, EH3 8RY (Scotland)

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