How to avoid pitfalls with your Usability report? A Notified Body perspective.

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Disclaimer for this presentation

This presentation is based on the information available as of today and prepared to my best knowledge as subject matter expert.

This presentation is not intended to provide any consultancy but only an overview of the notified body perspective about the assessment of usability technical documentation for medical devices.

Agenda

01	**Usability – Regulatory Background and State of the Art Standards**
02	**TÜV SÜD TDAR – Usability Section**
03	**Usability Technical Documentation – Common Pitfalls**
04	**Q&A**

Usability – Regulatory Background and State of the Art Standards

- EU Medical Device Regulation 2017/745 (abbreviated as MDR in the next slides)
- IEC 62366-1:2015 + Cor1:2016 + Amd1:2020 - Medical devices – Part 1: Application of usability engineering to medical devices
- IEC/TR 62366-2:2016, Medical devices – Part 2: Guidance on the application of usability engineering to medical device
- ISO 11607-1:2019 + Amd 1:2023 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

Usability – MDR Regulatory Background

Annex I GSPRs – Explicit references to usability evaluation

✓Estimate and evaluate the risks associated with an incorrect use reasonably predictable (GSPR 3)

✓Eliminate or reduce the risks linked to the use errors (considering the ergonomic characteristics of the device, the characteristics of the use environment and those of the intended users) (GSPR 5a).

Note: GSPR stands for General Safety and Performance Requirement.

Usability – MDR Regulatory Background

Annex I GSPRs – Explicit references to usability evaluation

- ✓Specific risks derived from the combination with other medical devices (GSPR 14.1)
- ✓Specific risks resulting from not appropriate ergonomic characteristics (GSPR 14.2)
- ✓Medical devices shall be designed considering ergonomic principles (GSPR 14.6)
- ✓Information showed on the display of a medical device shall be comprehensible (GSPR 21.3)

Usability – MDR Regulatory Background

Annex I GSPRs – Explicit references to usability evaluation

✓Protection against the risks presented by medical devices intended to be used by lay users (GSPR 22)

✓Labels and instructions for use shall be suitable for the user comprehension (GSPR 23.1a)

Usability – MDR Regulatory Background

Annex II Technical Documentation – Explicit references to usability evaluation

- ✓ Intended users definition
- ✓ Description of the medical devices with which the device under development can/shall be combined/connected
- ✓ Test activities and results

Differently from MDD, MDR includes specific references to usability aspects to be considered in the technical documentation for medical devices.

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TÜV SÜD Technical Documentation Assessment Report – Usability Section

5.1 Analysis of risks due to use error (usability)

Reference documents regarding use error risks (Document ID no or section of TD): Click or tap here to enter text.

The following key assumptions made as the basis for acceptance/verification have been challenged to show compliance with the manufacturer´s specification and General Safety and Performance Requirements including evaluation of requirements based on the state of the art. The manufacturer provided sufficient and acceptable rationales: *Click or tap here to enter text.***Conclusion as applicable for this assessment module**

GSPR 4: Risk control measures adopted by manufacturers for the design and manufacture of the device shall conform to safety principles, taking account of the generally acknowledged state of the art.	**Please select**
GSPR 5(a): In eliminating or reducing risks related to use error, the manufacturer shall reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and;	**Please select**
GSPR 5(b): In eliminating or reducing risks related to use error, the manufacturer shall give consideration to the technical knowledge, experience, education, training and use environment, where applicable	**Please select**
GSPR 5(b): In eliminating or reducing risks related to use error, the manufacturer shall give consideration to the medical and physical conditions of intended users (design for lay, professional, disabled or other users)..	**Please select**
For the devices without an intended medical purpose (Annex XVI), the manufacturer shall give consideration to the degree to which users and consumers commonly understand the risks linked to the use of the device in order to effectively reduce risks.	**Please select**
GSPR 21.3: The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and as appropriate, the patient.	**Please select**

General approach of the assessor to usability aspects of MDR technical documentation:

- ✓ **Focus on the evidence of compliance to usability-related GSPRs and to state of the art represented by the requirements of IEC 62366-1 standard**
- ✓ **Assessment of the provided documentation related to usability, referenced and/or collected inside the usability engineering file.**

TÜV SÜD Technical Documentation Assessment Report – Usability Section

GSPR 22.1: Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment;	**Please select**
GSPR 22.2: Devices for use by lay persons shall be designed and manufactured in such a way as to:	
• ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,	**Please select**
• reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and	**Please select**
• reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results;	**Please select**
GSPR 22.3: Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:	
• can verify that, at the time of use, the device will perform as intended by the manufacturer, and	**Please select**
• if applicable, is warned if the device has failed to provide a valid result	**Please select**

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

The assessor pays special attention to:

- ✓ **The acceptability of the applied approach for usability evaluation (e.g. full usability process or annex C)**
- ✓ **The coherence between product risk analysis and usability risk analysis**
- ✓ **The efficacy verification of the risk control measures related to the risks linked to use errors**
- ✓ **The acceptability of the defined intended users and use environment**
- ✓ **The acceptability of formative and summative evaluation strategy.**

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Usability Technical Documentation – Common Pitfalls

Requirements:

IEC 62366-1 clause 4.1.1 – Usability Engineering Process
[…] The PROCESS shall address USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENTATION, including, but not limited to:
– * transport;
– * storage;
– installation;
– operation;
– maintenance and repair; and
– disposal.

Common Pitfall:

Usability evaluation considered only the user interactions related to the operation phase and not the entire life cycle of the device.

Usability Technical Documentation – Common Pitfalls

Requirements:

IEC 62366-1 clause 4.1.3 – Information for SAFETY as it relates to USABILITY
When, in accordance with the priorities of 4.1.2, information for SAFETY is used as a RISK CONTROL measure, the MANUFACTURER shall subject this information to the USABILITY ENGINEERING PROCESS to determine that the information
– is perceivable by,
– is understandable to, and
– supports CORRECT USE of the MEDICAL DEVICE by USERS of the intended USER PROFILES in the context of the intended USE ENVIRONMENT.

Common Pitfall:

Usability reports do not contain clear evidence of the efficacy verification of the labelling risk mitigations linked to use errors (information for safety).

Usability Technical Documentation – Common Pitfalls

Requirements:

IEC 62366-1 clause 4.2 – Usability Engineering File
The results of the USABILITY ENGINEERING PROCESS shall be stored in the USABILITY ENGINEERING FILE.

IEC 62366-1 (all clauses): Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

Common Pitfall:

Only usability engineering reports (e.g. summative test report) are included in the provided technical documentation.

Usability Technical Documentation – Common Pitfalls

Requirements:

IEC 62366-1 clause 5.6 - Establish USER INTERFACE SPECIFICATION
[…]
The USER INTERFACE SPECIFICATION shall include:
[…]
– an indication as to whether MEDICAL DEVICE-specific training is required.

IEC 62366-1 clause 5.7.1 - General
b) if USABILITY TESTS are employed,
[…]
– specify whether MEDICAL DEVICE-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test.

IEC 62366-1 clause 5.8 - Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION
If training on the specific MEDICAL DEVICE is required for the safe use of the MEDICAL DEVICE by the intended USER, the MANUFACTURER shall design and implement a training capability for the EXPECTED SERVICE LIFE of the MEDICAL DEVICE by doing at least one of the following:
– provide the materials necessary for training;
– ensure that the materials necessary for training are available;
– make the training available; or
– make training available to the RESPONSIBLE ORGANIZATION that enables it to train its USERS.

Common Pitfalls:

- ✓ **Usability evaluation does not appropriately consider the training needs of the users.**
- ✓ **Usability reports do not contain clear evidence of the efficacy verification of the training materials provided to the users and considered as risk mitigations linked to use errors (information for safety).**
- ✓ **Usability test activities does not properly consider the learning decay related to the provided training,**

Usability Technical Documentation – Common Pitfalls

Requirements:

IEC 62366-1 clause 3.15
UOUP - USER INTERFACE OF UNKNOWN PROVENANCE
USER INTERFACE or part of a USER INTERFACE of a MEDICAL DEVICE previously developed for which adequate RECORDS of the USABILITY ENGINEERING PROCESS of this standard are not available.

IEC 62366-1 Annex C.2 - USABILITY ENGINEERING PROCESS for USER INTERFACE OF UNKNOWN PROVENANCE
C.2.1 * USE SPECIFICATION
C.2.2 * Review of POST-PRODUCTION information
C.2.3 HAZARDS and HAZARDOUS SITUATIONS related to USABILITY
C.2.4 RISK CONTROL
C.2.5 RESIDUAL RISK evaluation

Common Pitfalls:

- ✓ No clear usability evaluation approach described in the technical documentation (e.g. full usability process or annex C).
- ✓ No clear identification and justification of the user interface elements for which annex C approach is applicable.
- ✓ No usability engineering file provided in case of application of annex C.
- ✓ No appropriate justification for the time period considered for the evaluation of the PMS data about usability.
- ✓ No clear comparison between usability PMS data and the existing use risk analysis.

Usability Technical Documentation – Common Pitfalls

Requirements:

ISO 11607-1 section 7 - Usability evaluation for aseptic presentation

Clause 7.1 - A documented usability evaluation shall be conducted to demonstrate that the sterile contents can be aseptically removed from the sterile barrier system for presentation.

Clause 7.2 - The usability evaluation for aseptic presentation shall include an assessment of
a) the ability to identify where to begin opening,
b) the ability to recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents, and
c) the ability to subsequently present the contents aseptically.

Common Pitfalls:

- ✓ The usability evaluation does not consider the packaging system as part of the user interface of the device.
- ✓ The use risk analysis does not include considerations about aseptic presentation.
- ✓ No clear justification for declaring aseptic presentation as not applicable.
- ✓ The formative/summative evaluation does not properly include tasks related to the aseptic presentation.
- ✓ The formative/summative evaluation does not properly consider conditions of use, including utilizing personal protective equipment as applicable (e.g. gloves and gowns).

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Thank you!

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