

# Questionnaire “Interoperability of Medical Devices”

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## Preliminary remarks

- The aim of this document is to support the application of the ISO/IEEE 11073 family of standards for interoperable medical devices (Service-oriented Device Connectivity / SDC).
- This document was compiled by the German Notified Bodies Alliance (Interessengemeinschaft der Benannten Stellen für Medizinprodukte in Deutschland - IG-NB) and is intended to serve as orientation for Notified Bodies, manufacturers, Health Delivery Organisations (HDOs) and other interested parties.
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- The document makes no claim to completeness or mandatory application.

## References

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (2017/745/EU) (MDR)
- EN ISO 13485:2016-08 + AC:2018 + A11:2021 Medical devices - Quality management systems - Requirements for regulatory purposes

- EN 62304:2006 + Cor:2008 + A1:2015 Medical device software - Software life-cycle processes
- EN ISO 14971:2019 + A11:2021 Medical devices - Application of risk management to medical devices
- ISO TR 80001-2-6:2014: Application of risk management for IT-networks incorporating medical devices -- Part 2-6: Application guidance -- Guidance for responsibility agreements
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV (Consolidated Version) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 62366-1:2021-08 - Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020); German version  
EN 62366-1:2015 + AC:2015 + A1:2020

## Terms and Definitions

- In this document, the term medical device is frequently used. Whenever the term medical device is mentioned, both types are meant, medical devices and in vitro diagnostic medical devices.

## Changes to last version

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## 1 Design and development planning

	Source	Requirements	Questions / Comments
1.	ISO 13485, 7.3.2	<ul style="list-style-type: none"> <li>- organization shall plan and control the design and development of product</li> <li>- design and development planning documents shall be maintained and updated as the design and development progresses</li> </ul>	
		<ul style="list-style-type: none"> <li>- document the review(s) needed at each design and development stage</li> </ul>	Are the reviews covered at each stage also interoperability issues?
		<ul style="list-style-type: none"> <li>- document the verification, validation, and design transfer activities that are appropriate at each design and development stage</li> </ul>	Are there dedicated provisions for interoperability verification to give objective evidence, that the interface works according to the specification (see MDR Annex 14.5 and 17.1)?

## 2 Design and development input

	Source	Requirements	Questions / Comments
1.	ISO 13485, 7.3.3	- functional, performance, usability and safety requirements, according to the intended use	<p>Have all stakeholders been identified? e.g.:</p> <ul style="list-style-type: none"> <li>➤ Risk Manager for Medical IT-Networks</li> <li>➤ Medical Network Administrator</li> </ul> <p>Have personae being characterized for those rolls?</p> <p>Have those being used for carrying out usability tests on accompanying documents covering installation and integration of the product?</p> <p>Has the Manufacturer established the mandatory use of an NTP time server for time synchronization within the responsibility agreement?</p>
		- applicable output(s) of risk management	Have the above rolls been involved in risk management activities related to interoperability?
		- other requirements essential for design and development of the product and processes	Are contractual agreements with HDO's and Service Providers / Consumers of interoperable Products in place as specified in ISO TR 80001-2-6?
2.	MDR 2017/745 Annex 1, Chapter II, Cl. 14.5	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	
3.	MDR 2017/745 Annex 1, Chapter II, Cl. 17.2	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of	<ul style="list-style-type: none"> <li>➤ Development life cycle - EN ISO 62304-1</li> <li>➤ Risk Management - EN ISO 14971</li> <li>➤ Information Security - IG-NB Questionnaires "Cybersecurity for Medical Devices – Audit" and "Cybersecurity for Medical</li> </ul>

	Source	Requirements	Questions / Comments
		development life cycle, risk management, including information security, verification and validation.	Devices – Technical Documentation” ( <a href="https://www.ig-nb.de/veroeffentlichungen">https://www.ig-nb.de/veroeffentlichungen</a> ) ➤ Verification - Type / Lab / Simulator Testing ➤ Validation - Usability / Installation in HDO with functional (not in the sense of 60601-1, 14)
4.	MDR 2017/745 Annex 1, Chapter II, Cl. 17.4	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.	Have minimum requirements concerning hardware been specified?  Have minimum requirements concerning IT networks characteristics been specified?  Have IT security measures, including protection against unauthorized access been specified? (see IG-NB Questionnaires “Cybersecurity for Medical Devices – Audit” and “Cybersecurity for Medical Devices – Technical Documentation” ( <a href="https://www.ig-nb.de/veroeffentlichungen">https://www.ig-nb.de/veroeffentlichungen</a> ))

### 3 Design and development verification

	Source	Requirements	Questions / Comments
1.	ISO 13485, 7.3.6	<ul style="list-style-type: none"> <li>- design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements</li> </ul>	
		<ul style="list-style-type: none"> <li>- document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size</li> </ul>	Are solid activities in place for interoperability verification?
		<ul style="list-style-type: none"> <li>- verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced (if the intended use requires that the medical device be connected to, or have an interface with, other medical device(s))</li> </ul>	<p>Are for a given SDC system realization documented test results available?</p> <p>Standalone Device Tests - functionality in non-network mode</p> <p>SDC Integration Tests - peer/simulated communication partners</p> <p>Are those complemented by reference system tests including SDC devices from other manufacturers under worst case conditions?</p> <p>Has the manufacturer specified the extent the HDO has to perform system integration verification and confirmation?</p> <p>Has the HDO performed an integration analysis acc. to ISO 80001 standard series?</p> <p>Have further validation activities been carried out?</p>

	Source	Requirements	Questions / Comments
		<ul style="list-style-type: none"> <li>- records of the results and conclusions of the verification and necessary actions shall be maintained</li> </ul>	<p>Have corresponding trainings been performed?</p>

#### 4 Design and development validation

	<b>Source</b>	<b>Requirements</b>	<b>Questions / Comments</b>
1.	ISO 13485, 7.3.7	<ul style="list-style-type: none"> <li>- design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use</li> </ul>	
		<ul style="list-style-type: none"> <li>- document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size</li> </ul>	

## 5 Installation activities

	Source	Requirements	Questions / Comments
1.	ISO 13485, 7.3.7	<ul style="list-style-type: none"> <li>- document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate</li> </ul>	<p>Does manufacturers accompanying product documentation include the following aspects so that the HDO is able to collect all requirements from different products to be connected within its IT network, assessed along with the effects on the network caused by each product and considered associated impact:</p> <ul style="list-style-type: none"> <li>- required user trainings,</li> <li>- safety measures related to infrastructure and configuration of devices,</li> <li>- instructions for operation, service and maintenance,</li> </ul> <p>Use specifications - Has the manufacturer provided documentation for:</p> <ul style="list-style-type: none"> <li>- safe use like required installation tests,</li> <li>- characteristics and configuration of the IT-network,</li> <li>- information on how the product affects the net-work?</li> </ul> <p>Are critical parameters such as maximum bandwidth consumption, latency times, etc. of the product specified?</p> <p>Remark: Guidance on the integration at HDO-level can be found in ISO 80001 – Application of risk management for IT-networks incorporating medical devices.</p>
		<ul style="list-style-type: none"> <li>- if agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements</li> </ul>	<p>Is installation by 3rd party authorised in general?</p> <p>Are validated documents available, which lists the installation steps?</p>

	Source	Requirements	Questions / Comments
		for medical device installation and verification of installation.	<p>Has the Manufacturer provided a checklist for minimum validation activities to be performed before sign-off?</p> <p>Has the Manufacturer specified and laid down in the responsibility agreement that HDO performed and documented results of the installation tests as specified:</p> <ul style="list-style-type: none"> <li>- after integrating new products into the network,</li> <li>- after major changes of the IT network?</li> </ul>
		<ul style="list-style-type: none"> <li>- maintain records of medical device installation and verification of installation performed by the organization or its supplier</li> </ul>	<p>Has the manufacturer specified activities, performed by the HDO to ensure proper functioning of his device in the IT-network?</p> <p>Are contractual agreements to report results of integration to the manufacturer in force?</p> <p>Has the manufacturer specified and laid down in the responsibility agreement that HDO has to establish a whitelist for SDC products and services?</p>

## 6 Planning of product realization

	Source	Requirements	Questions / Comments
1.	ISO 13485, 7.1	- document one or more processes for risk management in product realization	Does risk management considers disclosure of private information?  Does risk management address Impairment of hospital workflows?  Does risk management address Impairment of device functions (same or another device)?
		- records of risk management activities shall be maintained	
		- required verification, validation, monitoring, measurement, inspection and test, handling, storage,	

## 7 Control of production and service provision

	Source	Requirements	Questions / Comments
1.	ISO 13485, 7.5.1	- production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification	Has the manufacturer stated necessary logging requirements at all?  Has the manufacturer specified mandatory information to reconstruct devices connectivity status at any given time by responsibility agreement?
		- documentation of procedures and methods for the control of production	Has the manufacturer specified logging when SDC provider refuses to execute certain system functions, due to consumer use restrictions?
		- qualification of infrastructure	Is an agreed log formatting structure established to assure compatibility amongst different vendors?
		- implementation of monitoring and measurement of process parameters and product characteristics	Is there a guidance available, how to protect the logs against tampering?
		- availability and use of monitoring and measuring equipment	Is there a guidance available, how HDO can access logs for error analysis?