

# Questionnaire "Cybersecurity for Medical Devices - Audit"

(Version 2, 25.02.2025)

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## Preliminary remarks

- 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 and interested parties.
- This document is covering cybersecurity in regular scheduled MDR / IVDR audits.
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- This document, together with the questionnaire „Cybersecurity for Medical Devices – Technical Documentation“, replaces the questionnaire "IT security for Medical Devices" (Version 5, 09.06.2022).
- Questions regarding the security risks of artificial intelligence can be found in latest version of IG-NB's "Questionnaire Artificial Intelligence (AI) in Medical Devices" (<https://www.ig-nb.de/veroeffentlichungen>).
- Not all requirements of MDR, IVDR and MDCG 2019-16 are covered in this document. Compliance to IEC 81001-5-1 is not expected prior end of its transition period. Compliance to IEC 81001-5-1 prior its transition period is however recommended.
- In the following tables IEC 81001-5-1 is mentioned only for complementary purposes. Questions for manufacturers are solely based on the current requirements (MDR, IVDR, MDCG 2019-16)
- Since cybersecurity evolves on a regulatory and technological level, this document is intended to reflect the current state of the art at the time of creation only.

- There are few cybersecurity experts today and it is likely that the situation will continue to be a similar in the foreseeable future. Therefore, it is one goal of this paper to help making conformity assessment(s) of cybersecurity aspects as efficient as possible without compromising quality.
- The terminology used in this document is derived from the terms and definitions within the referenced sources. E.g. cybersecurity as defined in ISO 81001-1:2021-12, cl. 3.30.
- Included in this document are references to paragraphs from the standards IEC 62034 and IEC 81001-5-1. These standards have different scopes (medical device software (IEC 62304) and healthcare software (IEC 81001-5-1)) and use different terms for similar subjects and processes. Specific terms and their use in the context of the respective standard are defined in clause 3 "Terms and Definitions" of the respective standard.
- 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)
- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (2017/746/EU) (IVDR)
- [MDCG 2019-16](#) - Guidance on Cybersecurity for medical devices, Rev. 1, 2020-07
- ISO 13485:2016-03 Medical devices - Quality management systems - Requirements for regulatory purposes
- IEC 62304:2005-05 Medical device software - Software life cycle processes
- IEC 81001-5-1:2021-12 Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle

## 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

- 1.1. second question deleted
- 1.3. note 3 reworded
- 2.3. new questions, note 1 reworded
- 3.1. note to first question reworded
- 3.2. note 1 and 3 reworded

## 1 General

|    | Source                     | Requirements  | Questions / Comments  |
|----|----------------------------|---|---|
| 1. | ISO 13485<br>cl. 5.5.1     | <ul style="list-style-type: none"> <li>– definition, documentation and communication of responsibilities and authorities by top management</li> <li>– documentation of interrelations</li> <li>– ensure independence and authority</li> </ul>   | Has the auditee defined responsibilities and authorities for cybersecurity?   |
|    | IEC 81001-5-1<br>cl. 4.1.2 | <ul style="list-style-type: none"> <li>– designate and document organizational roles</li> <li>– designate and document personnel responsible for activities and processes</li> </ul>  |   |
| 2. | ISO 13485<br>cl. 6.2       | <ul style="list-style-type: none"> <li>– only competent personnel should be performing work affecting quality</li> <li>– basis: appropriate education, training, skills, experience</li> </ul>  | Has the personnel carrying out cybersecurity tasks appropriate education and/or work experience and/or training?  |
|    | IEC 81001-5-1<br>cl. 4.1.4 | <ul style="list-style-type: none"> <li>– established activities for identifying and providing security training and assessment programs</li> <li>– personnel should be assigned to the organizational roles and duties demonstrated security expertise</li> <li>– role descriptions, training profiles, training records</li> </ul> |   |
| 3. | ISO 13485<br>cl. 7.4.1     | <ul style="list-style-type: none"> <li>– establish criteria for evaluation and selection of suppliers</li> <li>– basis: specific criteria (supplier - ability to provide product that meets requirements and performance of the supplier, effect of purchased product on quality, proportionate to the risk)</li> </ul>             | <p>Are the suppliers (penetration testing laboratories, 3<sup>rd</sup> party component suppliers) appropriately qualified?</p> <p>Note 1: Penetration testing laboratories should be accredited where available.</p> <p>Note 2: Supplier evaluation of 3<sup>rd</sup> party components is not necessary when the quality of the code can fully be verified.</p> |

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|  |  |  | Note 3: Auditing penetration testing laboratories does not seem to be necessary. Other means for rating performance and ability of penetration-testing suppliers (e.g. penetration test report reviews, questionnaires) seem more plausible. |
|--|--|--|--|

## 2 Research and Development

|    | Source  | Requirements  | Questions / Comments   |
|----|---|---|--|
| 1. | MDR<br>Annex I (17.2)<br><br>IVDR<br>Annex I (16.2) | 'For devices that incorporate software or for software that are devices in themselves, the software shall be <b>developed</b> and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, <b>including information security</b> , verification and validation.  | Note 1: Cybersecurity risk assessment should be conducted prior to the finalization of specifications / cybersecurity risk management shall be conducted at the design input phase. (applicable for R&D projects that started after the release of MDCG 2019-16 in November 2019).                         |
|    | MDCG 2019-16 chapter 3                              | 'Safety, <b>security</b> and effectiveness are critical aspects in the design of security mechanisms for in vitro diagnostic medical devices and medical devices. Therefore, there is a <b>clear requirement</b> that these aspects need to be considered by the manufacturers <b>from an early stage of development</b> and manufacturing process and throughout the entire life cycle.' | Note 2: For legacy devices, the approach as defined in 81001-5-1 appendix F may be used.<br><br>Note 3: It is not acceptable to add cybersecurity countermeasures (e.g. encryption) at the end of a development cycle project since this concept is following the outdated "penetrate and patch" approach. |

|    | Source                   | Requirements  | Questions / Comments  |
|----|--------------------------|---|---|
|    | MDCG 2019-16 chapter 3.2 | ‘The security risk management process has the same elements as safety risk management process, all documented in a <b>security risk management plan</b> . The process elements are <b>security risk analysis, security risk evaluation, security risk control, evaluation of residual security risk and reporting</b> . When a security risk or control measure could have a <b>possible impact on safety</b> and effectiveness, then it <b>should be included in the safety risk assessment</b> . Similarly, any safety risk control or consideration that might have an impact on security should be included in the security risk analysis.’ | Is a dedicated and plausible security risk assessment available for all MDR / IVDR certified devices?   |
| 2. | MDCG 2019-16 chapter 3.4 | ‘ <b>Threat Modelling techniques are a systematic approach</b> for analyzing the security of an item in a structural way such that vulnerabilities can be identified, enumerated, and prioritized, all from a hypothetical attacker’s point of view. Risks related to data and systems security are specifically mentioned within the scope of the risk management process, <b>to avoid any misunderstanding that a separate process would be needed to manage security risks</b> related to medical devices. Specific methods (and requirements) are however used for security risks.’   | <p>Note 1: Threat modelling (e.g. <a href="#">STRIDE</a>) should be used in security risk assessment.</p> <p>Note 2: Security risk assessment is assessed in depth during the Technical Documentation Assessment (TDA). During audit, it should be focused on identifying if non-sampled devices also have security risk management including threat modelling.</p> |
|    | IEC 81001-5-1 cl. 4.2    | <ul style="list-style-type: none"> <li>– establish process for managing risks associated with security</li> <li>– use threat modelling for identifying vulnerabilities</li> <li>– estimate, evaluate and control associated threats</li> <li>– monitor effectiveness of (security) risk control measures</li> <li>– intended use and use environment</li> </ul>   |   |

|    | Source                      | Requirements  | Questions / Comments  |
|----|-----------------------------|---|---|
| 3. | MDCG 2019-16<br>chapter 3.7 | 'The primary means of security verification and validation is testing. Methods can include security feature testing, fuzz testing, vulnerability scanning and <b>penetration testing.</b> '                   | Do all MDR / IVDR devices of the auditee have a up to date security test?<br><br>Have criteria been defined under which a security test has to be repeated?   |
|    | IEC 81001-5-1<br>cl. 5.7.4  | <ul style="list-style-type: none"> <li>– establish activities to identify and characterize weaknesses</li> <li>– Establish tests that focus on discovering and exploiting security vulnerabilities</li> </ul> | <p>Note 1: Vulnerability scanning and penetration testing shall be done for all medical devices, unless duly justified.</p> <p>Note 2: Security test reports (including penetration test reports) are assessed in depth during Technical Documentation Assessment (TDA). During audit, it should be focused on identifying if non-sampled devices also have penetration test reports.</p> |

### 3 Post Market Activities

|    | Source                   | Requirements  | Questions / Comments  |
|----|--------------------------|---|---|
| 1. | MDCG 2019-16 chapter 3.8 | <p>'During the support lifetime of the device, the manufacturer should put in place a process to gather post-market information with respect to the security of the device (see also Chapter 6). This process should take into account:</p> <ol style="list-style-type: none"> <li>1. Security incidents directly related to medical device software</li> <li>2. Security Vulnerabilities that are related to the medical device hardware/software and the 3rd party hardware/software used with the medical device</li> <li>3. Changes in the threat landscape, including interoperability aspects'</li> </ol> | <p>Does the post-market surveillance system gather and evaluate:</p> <ul style="list-style-type: none"> <li>• security incidents directly related to the medical devices of the manufacturer?<br/>Note: These may be reported via complaint and feedback processes.</li> <li>• the cybersecurity threat landscape?</li> </ul> <p>Note 1: The auditee should be capable of using appropriate measures if a significant increase is detected / the auditee should have appropriate threat intelligence at his/her disposal.</p> <p>Note 2: Security vulnerabilities directly related to the medical devices of the manufacturer are discussed in the following.</p> |
|    | IEC 81001-5-1 cl. 6.2.1  | – establish activities to collect and review relevant sources of information about vulnerabilities  |   |
| 2. | IEC 81001-5-1 cl. 9.2    | <ul style="list-style-type: none"> <li>– establish activities that enable reporting of information regarding vulnerabilities (from an internal/external entity or via a complaint-handling system)</li> <li>– reception activity: receive and track closure reports on security related issues</li> <li>– including (minimum) sources as security verification/validation tester, suppliers of third-party components, product developers and testers, ...</li> </ul>   | <p>Does the auditee have an appropriate Vulnerability Disclosure Program in place?</p> <p>Note 1: The Vulnerability Disclosure Program shall make it possible for security researches etc. to submit vulnerabilities to the manufacturer securely. Information about possible vulnerabilities shall be assessed / triaged and mitigated appropriately with an appropriate timeline by the manufacturer. Bug bounties may be provided to the security researchers.</p>   |

|    | Source                   | Requirements   | Questions / Comments  |
|----|--------------------------|--|---|
|    |                          |  | <p>Note 2: The Vulnerability Disclosure Program can be governed by the feedback process.</p> <p>Note 3: Security event logs shall be obtained and analysed timely and appropriately.</p>  |
| 3. | IEC 62304<br>cl. 5.1.1   | <ul style="list-style-type: none"> <li>– establish software development plan/plans that address software configuration and change management</li> <li>– including SOUP configuration items</li> </ul>  | <p>Do all medical devices have a list of software of unknown provenance (SOUP) components?</p> <p>Note: The list of SOUP-components can be part of SBOM / can be the SBOM (Software Bill of Materials).</p>   |
|    | IEC 62304<br>cl .8.1.2   | – document for each SOUP configuration item used (including standard libraries): title, manufacturer, unique SOUP designator   |   |
| 4. | MDCG 2019-16 chapter 3.8 | <p>The manufacturer should <b>evaluate</b> the information thus gathered, evaluate the associated security and safety risk and take <b>appropriate measures</b> that control the risk associated with such security incidents or vulnerabilities. Measures may include:</p> <ul style="list-style-type: none"> <li>• Information to operators of medical devices on the identified risk and possible mitigations in the operating environment.</li> <li>• Quick fixes, e.g. network <b>configuration changes</b>.</li> <li>• Medical device software updates.</li> <li>• 3rd party software <b>updates</b> or <b>patches</b>.</li> </ul> | <p>Does the auditee conduct proper security patch management?</p> <p>Note 1: Scanning / Checking SOUP components for vulnerabilities shall be conducted in intervals commensurate with the risk to patient safety and or data. Checks / Scans should be documented.</p> <p>Note 2: Any necessary corrective action (patching, firewall configuration updates, etc.) should be commensurate with the</p> |

|    | Source                  | Requirements   | Questions / Comments   |
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|    |                         | The measures should be implemented at the operator site in a <b>time appropriate</b> to the security and safety risk determined by the manufacturer and operator.'   | risk and implemented in a timely manner. Rationales for not conducting actions should be appropriate.  |
|    | IEC 81001-5-1 cl. 9.3   | <ul style="list-style-type: none"> <li>- establish activities that enable investigation of vulnerabilities in a timely manner to determine applicability</li> <li>- verifiability, related threats</li> </ul>  |  |
|    | IEC 81001-5-1 cl. 9.4   | <ul style="list-style-type: none"> <li>- establish activities for analysing vulnerabilities</li> <li>- identifying root cause of the issue</li> <li>- identifying impact on safety and effectiveness</li> </ul>  |  |
|    | IEC 81001-5-1 cl. 9.5   | <ul style="list-style-type: none"> <li>- establish activities to address security-related issues</li> </ul>  |  |
| 5. | IEC 81001-5-1 cl. 4.1.8 | <ul style="list-style-type: none"> <li>– establish activities for conducting periodic reviews of the software problem resolution process</li> <li>– periodic reviews of activities</li> <li>– examine (minimum) security-related issues managed through process (since last periodic review)</li> <li>– determine if management process was complete, efficient, led to resolution of security-related issues</li> <li>– periodic reviews at least annually or as part of monitoring, measurement, analysis</li> </ul> | <p>Does the auditee conduct at minimum an annual review of the security patch management process?</p> <p>Note 1: In case periodic review shows lack of performance of the software problem resolution process working appropriately, corrective measures need to be implemented.</p> <p>Note 2: An efficient measure to verify effectiveness of security patches implemented can be penetration testing.</p> |

#### 4 Vigilance Reporting

|    | Source  | Requirements   | Questions / Comments   |
|----|---|--|--|
| 1. | MDCG 2019-16<br>chapter 5.2                         | <ul style="list-style-type: none"> <li>• The reporting tools made available to the Manufacturer enable the <b>use of IMDRF codes</b> to index.</li> <li>• IMDRF Annex A codes on cybersecurity-related device problems:               <ul style="list-style-type: none"> <li>○ Level 2: A1105 — Computer System Security Problem.</li> <li>○ Level 3: A110501 — Application Security Problem.</li> <li>○ Level 3: A110502 — Unauthorised Access to Computer System.</li> </ul> </li> </ul>   | Do all <a href="#">Manufacturer Incident Report (MIR)</a> forms have an IMDRF code?                              |
|    | IEC 81001-5-1<br>cl. 4.1.7                          | – establish activities for informing regulatory authorities and users about vulnerabilities in a timely manner   |  |
| 2. | MDR<br>Article 88 (1)<br><br>IVDR<br>Article 83 (1) | ‘Manufacturers shall report, by means of the electronic system referred to in Article 92, any <b>statistically significant increase</b> in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.’ | Is the auditee able to report trends in cybersecurity-related incidents once the electronic system is available? |

|  | <b>Source</b>               | <b>Requirements</b>   | <b>Questions / Comments</b> |
|--|-----------------------------|---|-----------------------------|
|  | MDCG 2019-16<br>chapter 5.8 | <ul style="list-style-type: none"> <li>• ‘Incidents that have <b>cybersecurity related incident root causes</b> are <b>subject to Trend Reporting</b> under the Medical Devices Regulations.’</li> <li>• ‘Using IMDRF codes to index the cybersecurity medical root causes related to non-serious incidents is desirable and may be implemented into the Trend Report’:               <ul style="list-style-type: none"> <li>○ C1007 — Software Security Vulnerability</li> </ul> </li> </ul> |                             |