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AWMF Ad Hoc Commission “In Vitro Diagnostic Medical Devices”

**IVDR checklist for commissioning in-vitro diagnostic medical devices that fall under the categories reagent, reagent product, calibrator, control material, kit, and which are manufactured and used exclusively within a health institution**

Name of the device: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Category pursuant to Art. 2 (2) of the IDVR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The primary purpose of this checklist is to verify whether clearly required documents or items are available for a device manufactured in a health institution. Items from Annex I (IVDR) are specifically listed without claiming to be complete. The checklist can be used as *part* of the IVDR compliance check.

| **#** | **Requirement** | **Reference** | **Fulfilled?** | **Objective evidence / viewed document** |
| --- | --- | --- | --- | --- |
| 1 | Manufacture and use within a suitable **QM system** | Art. 5 (5) b) and c) |  | e.g., accreditation certificate or QM handbook showing conformity with Rili-BÄK |
| 2 | **Documentation** about the device is available and contains the following: |  |  |  |
| 3 | - the purpose of the device | Art. 5 (2) |  |  |
| 4 | - justification that the target patient group’s specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market | Art. 5 (5) d) |  |  |
| 5 | - information about the use of the device, including a justification for its manufacture, modification and use, as well as the date it was commissioned | Art. 5 (5) e) |  |  |
| 6 | A **declaration about the device** is publicly accessible.  This includes: | Art. 5, 5 f) |  |  |
| 7 | - Name and address of the health institution | Art. 5, 5 f) |  |  |
| 8 | - details necessary to identify the device | Art. 5, 5 f) |  |  |
| 9 | - declaration that the device meets the general safety and performance requirements (outlined in Annex I) and, where applicable, information on which requirements are not fully met. | Art. 5, 5 f) |  |  |
| 10 | Documentation of a **risk management system** for manufacturing | Annex I, Chapter 1., 3. |  |  |
| 11 | A **risk management plan** is available for the device | Annex I, Chapter 1., 3. A) |  |  |
| 12 | Where applicable, documentation is available showing that the device achieves the analytical performance as stated by the manufacturer  in particular, the analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interferences and cross-reactions | Annex I, Chapter II, 9.1 a) |  |  |
| 13 | Where applicable, documentation is available showing that the device achieves the clinical performance as stated by the manufacturer  In particular, the diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations. | Annex I, Chapter II, 9.1 b) |  |  |
| 14 | The metrological traceability of calibrators and control materials is assured | Annex I, Chapter II, 9.3 b) |  |  |
| 15 | The device has a **label** that is regulation compliant | Annex I, Chapter III, 20.1 und 2 |  |  |
| 16 | A **safety data sheet** and hazard labels are available, where necessary | Annex I, Chapter III, 20.1 |  |  |
| 17 | The device is labelled as an IVD | Annex I, Chapter III, 20.2 e) |  |  |
| 18 | The lot/serial/batch number is indicated on the device | Annex I, Chapter III, 20.2 f) |  |  |
| 19 | Date of manufacture and/or expiry date are indicated on the device | Annex I, Chapter III, 20.2 h) and i) |  |  |
| 20 | Quantity of content and storage conditions are indicated on the device | Annex I, Chapter III, 20.2 j) and k) |  |  |
| 21 | For kits, the required labels are indicated on each component | Annex I, Chapter III, 20.2 s) |  |  |
| 22 | **Instructions for use** in accordance with Annex I are available | Annex I, Chapter III, 20.4.1 a)-z) |  |  |
| 23 | Documentation is available to enable an understanding of the manufacturing site, the **manufacturing process**, the design and performance data of the devices, including their intended purpose and conformity with Annex I. | Art. 5 (5) g) and the Act on Adapting the Medical Device Law to the Regulation (EU) … 2017/746, Article 3, point 62 |  |  |
| 24 | A process is in place to review the experience gained from the clinical use of the product and to take any necessary corrective action | Art. 5 (5) i) |  |  |
| 25 | A risk classification has been carried out for the device in accordance with Annex VIII | 5(5) g)] |  |  |
| 26 | A performance evaluation report has been drawn up  Evidence of scientific validity, analytical performance, clinical performance are assessed (= clinical evidence required to demonstrate compliance with the essential safety and performance requirements). Assessment of the acceptability of the risk-benefit ratio. | Art. 5 (3) and Article 56 |  |  |
| 27 | A performance evaluation plan has been drawn up to continuously evaluate the device’s performance | Art. 56 (2) |  |  |

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