Summarized Checklist for IVDR Technical Documentations

This list is based on Regulation (EU) 2017/746 (IVDR) Annex II and Annex III. It helps to identify if all requirements are fulfilled and if you have all relevant documents included in your Technical Documentation.

| **Pos.** | **Requirement** | **Applicable** | **Fulfilled** | **Source** | **Comment or Justification** |
| --- | --- | --- | --- | --- | --- |
| **1** | **Device description and specification, including variants and accessories**  Regulation (EU) 2017/746 (IVDR), Annex II Section 1 | | | | |
| 1.1 | Device description and specification |  |  |  |  |
| 1.1.1 | Product or trade name and manufacturer |  |  |  |  |
| 1.1.2 | Basic unique device identifier |  |  |  |  |
| 1.1.3 | Intended purpose and intended user |  |  |  | If you need help with the intended purpose of your device, you may use our intended purpose generator AstraPurpose for free: https://astracon.eu/tools/intended-purpose/ |
| 1.1.4 | General device description |  |  |  |  |
| 1.1.5 | Qualification and classification |  |  |  | If you need help with the classification of your device, you may use our classification tool AstraClass for free: https://astracon.eu/tools/classification/ |
| 1.1.6 | Declaration of Conformity |  |  |  |  |
| 1.1.7 | Composition of the device |  |  |  |  |
| 1.1.8 | Sampling and preparation |  |  |  |  |
| 1.1.9 | Accessories and device combinations |  |  |  |  |
| 1.1.10 | Configurations and variants of the device |  |  |  |  |
| 1.2 | Reference to previous and similar Generations of the Device |  |  |  |  |
| 1.3 | Summary of safety and performance (SSP)  (Only for class C and D devices) (Regulation (EU) 2017/746 (IVDR), Article 29) |  |  |  |  |
| **2.** | **Information supplied by the manufacturer**  **(Regulation (EU) 2017/746 (IVDR), Annex II Section 2)** | | | | |
|  | **A complete set of labels and IFU** |  |  |  |  |
| **3.** | **Design and manufacturing information**  **(Regulation (EU) 2017/746 (IVDR), Annex II Section 3)** | | | | |
| 3.1 | Design Information |  |  |  |  |
| 3.2 | Manufacturing Information |  |  |  |  |
| **4.** | **General Safety and Performance Requirements**  **(Regulation (EU) 2017/746 (IVDR), Annex II Section 4)** | | | | |
| 4.1 | GSPR Checklist |  |  |  |  |
| 4.2 | List of applicable standards |  |  |  |  |
| **5.** | **Benefit-Risk Analysis and Risk Management**  **(Regulation (EU) 2017/746 (IVDR), Annex II Section 5)** | | | | |
| 5.1 | Benefit-Risk Analysis and Risk Management |  |  |  |  |
| 5.2 | Specific Usability Risks (only for Self-Testing / Near-Patient Testing) |  |  |  |  |
| **6.** | **Product Verification and Validation** | | | | |
| 6.1 | Analytical Performance |  |  |  |  |
| 6.1.1 | Specimen Type / Handling |  |  |  |  |
| 6.1.2 | Analytical Performance |  |  |  |  |
| 6.1.3 | Analytical Performance Report |  |  |  |  |
| 6.2 | Clinical Performance |  |  |  |  |
| 6.2.1 | Clinical Performance |  |  |  |  |
| 6.2.2 | Performance of self-testing devices / Near-patient testing devices |  |  |  |  |
| 6.3 | Scientific Validity |  |  |  |  |
| 6.4 | Performance Evaluation Report |  |  |  |  |
| 6.5 | Stability  (Regulation (EU) 2017/746 (IVDR), Annex II Section 6.3) |  |  |  |  |
| 6.5.1 | Claimed shelf-life |  |  |  |  |
| 6.5.2 | In-use stability |  |  |  |  |
| 6.5.3 | Shipping stability |  |  |  |  |
| 6.6 | Software Verification and Validation / Functional Safety / Cybersecurity  (Regulation (EU) 2017/746 (IVDR), Annex II Section 6.4) |  |  |  |  |
| 6.7 | Chemical, Physical and Biological Properties  (Regulation (EU) 2017/746 (IVDR), Annex II Section 6.5) |  |  |  |  |
| 6.7.1 | Nanoparticle Technology |  |  |  |  |
| 6.7.2 | Hazardous Substances |  |  |  |  |
| 6.7.3 | Biological Evaluation |  |  |  |  |
| 6.7.4 | Substances of Animal / Human / Microbiological Origin |  |  |  |  |
| 6.7.5 | Sterile Devices or Devices with Defined Microbiological Condition |  |  |  |  |
| 6.7.6 | Constructional Safety |  |  |  |  |
| 6.7.6.1 | Mechanical Safety |  |  |  |  |
| 6.7.6.2 | Electrical safety / electromagnetic compatibility |  |  |  |  |
| 6.7.6.3 | Ionising and non-ionising radiation |  |  |  |  |
| 6.7.6.4 | Environmental protection and safe disposal |  |  |  |  |
| 6.7.6.5 | Packaging |  |  |  |  |
| 6.7.6.6 | Devices with connection to other device(s) |  |  |  |  |
| 6.7.7 | Devices with a Measuring Function |  |  |  |  |
| **7.** | **Post-Market Surveillance**  **(Regulation (EU) 2017/746 (IVDR), Annex III)** | | | | |
| 7.1 | Post-market surveillance plan |  |  |  |  |
| 7.2 | Post-Market Surveillance Report (only class A and B devices) |  |  |  |  |
| 7.2 | Periodic Safety Update Report (PSUR) (only class C and D devices) |  |  |  |  |
| 7.3 | Post Market Performance Follow-Up (PMPF) |  |  |  |  |
| 7.3.1 | PMPF Plan |  |  |  |  |
| 7.3.2 | PMPF Evaluation Report |  |  |  |  |
| **8.** | **Proposed Perimeters for Products Verification Program (only class D devices)** | | | | |