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IVDR QM System Requirements

TÜV SÜD Product Service GmbH

Introduction

Regulation (EU) 2017/746 of the European Parliament and of the Council (IVDR) requires all manufacturers of In Vitro Diagnostic Devices to comply with all applicable requirements – including, among others, an effective QMS.

This is specified in Article 10(8). Every manufacturer must determine what needs to be implemented for compliance with the IVDR or which existing part of the QMS is already compliant.

EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes serves as a basis for an IVDR compliant QMS, however, not all specific aspects of the IVDR are covered therein. There might be gaps or specifics to consider.

Sections 1 to 4 below are directly derived from Annex IX, Chapter I, Quality Management System. Sections 5 to 12 are requirements that can be found in various Articles throughout the IVDR. The list does not show how the specific requirements can be fulfilled, and does not claim to be exhaustive; however, it can serve as a summary of key issues.

There are fillable sections that will help you as a manufacturer and the audit team to prepare for the audit and see at a glance where the requirements are fulfilled / described.

Please submit the completed document ahead of the audit to your personal Client Handler.

1. Quality Objectives

Please state which procedure in your QMS defines how Quality Objectives are determined, where they are recorded, and where their evaluation is described.

2. Organisation of the Business

2.1. Organisational Structures

Please state where in your QMS the organisational structures, including the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority is defined.

2.2. Monitoring of Processes and Product

Please state where in your QMS the methods of monitoring whether the operation of the quality management system is efficient and -in particular- the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform, are described.

2.3. Outsourced Processes

If the design, manufacture, and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party: Please state where in your QMS the methods of monitoring the efficient operation of the quality management system and -in particular- the type and extent of control applied to the other party, is described.

2.4. Authorised Representative

If you do not have a registered place of business in a Member State: Please state where there is a mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate. If the agreement is not final yet, please provide a draft.

3. Design and Development

Sections 3.1 to 3.8 below ask not only for the output of the processes, i.e. the records, but also for the procedures that are in place to describe, monitor, verify, validate and control them. Please state the respective procedures in the sections below, not the records.

3.1 Regulatory Compliance

Please state where in your QMS the following is described:

- strategy for regulatory compliance
- processes for identification of relevant legal requirements
- classification
- handling of equivalence
- choice of, and compliance with, conformity assessment procedures

3.1.1. Product Scope Change / Expansion

The scope of IVD devices covered under the regulation will be significantly expanded to include high-risk devices manufactured for use within a single healthcare institution, as well as diagnostic (including internet-based) services, genetic testing and other tests that provide information about a patient's predisposition for a specific disease or for susceptibility for a medical treatment, and others, see Article 2 of the IVDR. Please make sure that the respective procedure covers these new requirements / definitions, and that all your devices' qualifications are revaluated. Please state where in your QMS this evaluation is described.

3.2 General Safety and Performance Requirements

Please state where in your QMS the identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS into account and, where opted for, harmonised standards are described.

3.3 Risk Management

Please state where in your QMS risk management as referred to in Section 3 of Annex I is described.

3.4. Performance Evaluation and Clinical Evidence

Article 56 and Annex XIII of the IVDR provides specific requirements for performance evaluation and clinical evidence, such as a sound procedure for the demonstration of scientific validity, analytical performance and clinical performance. Please state where in your QMS this methodology is described.

3.5. Design and Construction, including appropriate Pre-clinical Evaluation

Please state where in your QMS the solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I, are described.

3.6. Information to be supplied with the Device

Please state where in your QMS the solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I, are described.

3.7 Identification Procedures

Please state where in your QMS the device identification procedures are drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture.

3.8 Design or Quality Management System Changes

Please state where in your QMS the management of design or quality management system changes, is described.

4. Quality Control Procedures

Please state where in your QMS the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly with regard to sterilisation, are described.

Also state the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

5. Person responsible for regulatory compliance

Article 15 of the IVDR requires that at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of in vitro diagnostic medical devices. Please state where in your QMS the person responsible for regulatory compliance is designated and where her/his authorities and responsibilities are defined, also when outsourced.

6. Unique Device Identification system

Articles 24 and 25 describe requirements for a Unique Device Identification system ('UDI system'). Please state where your QMS assures that there is an adequate process for complying with these requirements.

7. Registration and Single Registration Number

Article 28 requires the manufacturer to submit specific data to EUDAMED and to obtain a single registration number. Please state where your QMS assures that there is an adequate process.

8. Performance Evaluation and Clinical Evidence

Article 56 of the IVDR provides specific requirements for performance evaluation and clinical evidence, such as a sound procedure for the demonstration of scientific validity, analytical performance and clinical performance. Please state where in your QMS this methodology is described.

9. Post-market Surveillance

Articles 78 – 81 require a systematic approach to post-market surveillance that is proportionate to the risk class and appropriate for the type of device, including a post-market surveillance plan, post-market surveillance report, update of the summary of safety and performance, and periodic safety update report (where appropriate). Please state where your QMS assures that there is an adequate process.

10. Reporting of Serious Incidents and Field Safety Corrective Actions

Article 82 requires a systematic reporting of serious incidents and field safety corrective actions. Please state where your QMS assures that there is an adequate process.

11. Trend Reporting of Incidents

Article 83 requires a trend reporting of incidents. Please state where your QMS assures that there is an adequate process.

12. Analysis of Serious Incidents and Field Safety Corrective Actions and Trend Reporting

Article 84 requires a systematic analysis of serious incidents and field safety corrective actions. Please state where your QMS assures that there is an adequate process.

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