Fact Sheet

Summary of Technical Documentation (STED)

Critical content for compliance with the In Vitro Diagnostics Regulation (IVDR)

What is STED format?

A Summary of Technical Documentation (STED) file is a detailed description of your IVD Devices' intended purpose, demonstration of its performance and compliance with Harmonized standards. Compiling your STED is an important part of the EU CE-Mark process and is required to comply with the In Vitro Diagnostic Medical Devices Regulation [EU] 2017/746.

Manufacturers of all Classes of IVD medical devices (Class A, Class B, Class C, and Class D) are expected to demonstrate conformity of the IVD medical device to the General Safety and Performance Requirements of Medical Devices (GSPR) through the preparation and holding of technical documentation. The STED shows how each IVD medical device was developed, designed, verified and validated, and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity.

STED includes detailed information about the design, function, composition, use, claims, and clinical studies and performance evaluation of your IVD medical device. One STED may be sufficient for multiple catalogue products if their intended purpose claim, fundamental technology and Risk class are the same.

Claims made by a manufacturer regarding the performance of a IVD must be supported by objective, scientific data presented in a structured and logical manner.

Unless you manufacture a sterile Class A device that is for sterile purpose, your STED may not be reviewed by a Notified Body (NB) before applying the CE-Mark, however a STED still needs to be prepared and updated periodically and to demonstrate the compliance with the regulation.

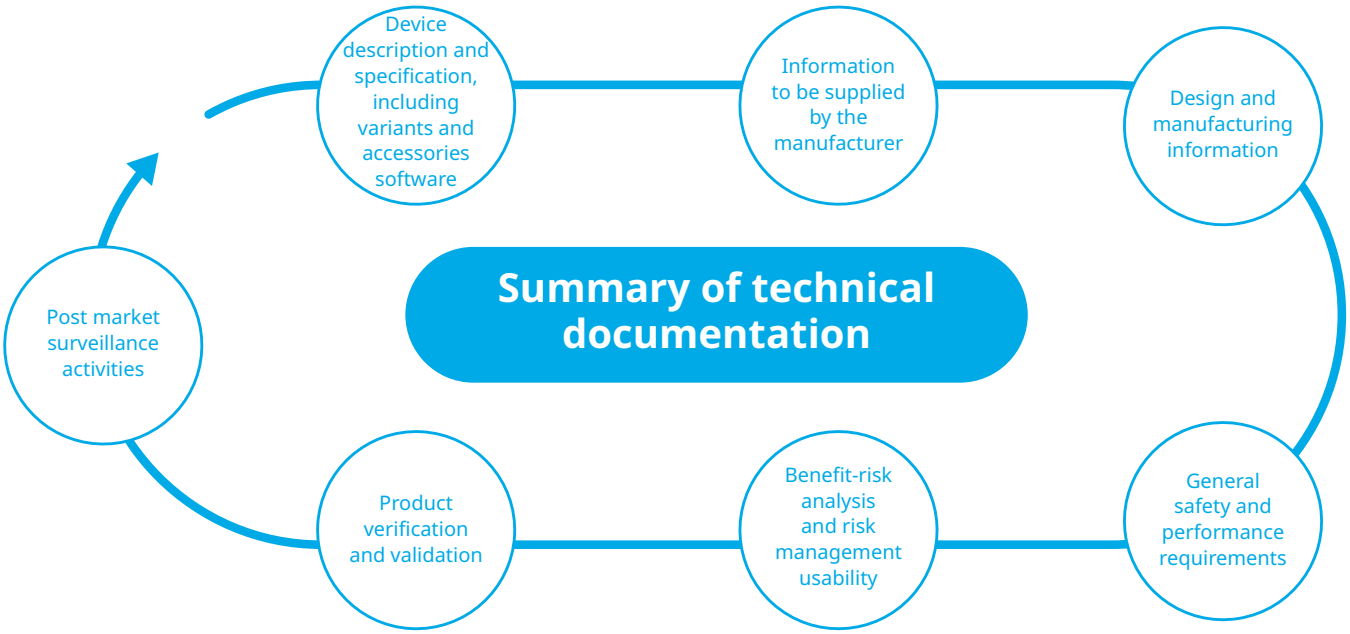
The higher the risk classification of a IVD, the more information (and documentation) is to be expected.

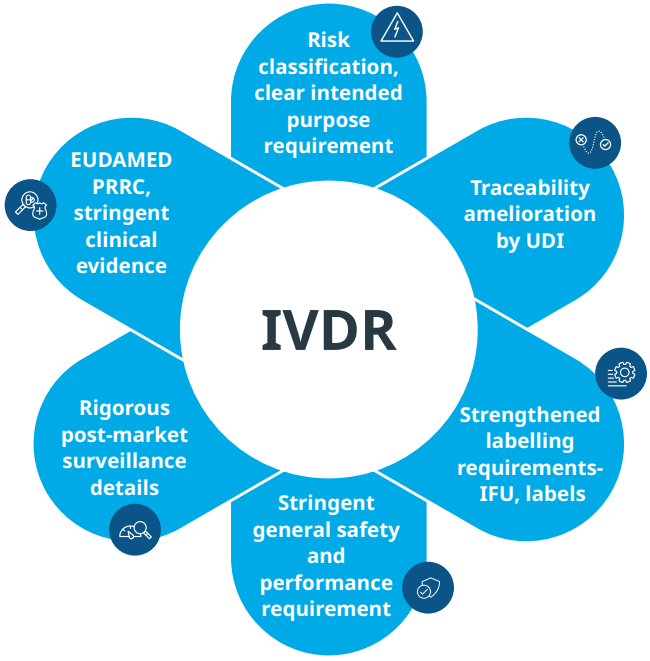
Why STED format and which regulators use STED?

- The STED format was created by the Global Harmonization Task Force (GHTF), the precursor to the current International Medical Device Regulators Forum (IMDRF), in an effort to globally standardize medical device regulatory submissions across markets, assisting both manufacturers and regulatory agencies.
- STED is recognized by US, European, Canadian, Australian and Japanese regulators, as well as in other markets.

Preparation of STED

As a manufacturer, STED documents should be prepared for your IVD device as per Annex II of regulation EU 2017/746, and includes Annex I General Safety and Performance Requirement details and Annex III Technical documentation on Post Market Surveillance (PMS). It should be noted that there are many changes and additional details required by the IVDR with respect to predecessor In Vitro Diagnostic Directive (IVDD) technical file.





How can IQVIA help you?

IQVIA MedTech's dedicated regulatory team will help you in determining your devices' classification and grouping of products as per the IVDR. We provide strategic guidance and implementation for Directive to Regulation remediation activities. Dedicated regulatory writers can also support STED remediation, Performance Evaluation Plan (PEP), Report (PER) and its components writing services as per EU IVDR requirements.

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