Sampling

For Assessment of Technical Documentation According to IVDR Annex IX

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Introduction
Articles 48(7) and (9) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) establish the requirement to assess technical documentation of at least one representative device per generic device group (Class C) and for each category of devices (Class B) prior to issuing a certificate to a manufacturer.

Sections 2.3 and 3.4 of Annex IX define that the quality management system assessment has to be accompanied by assessment of the technical documentation for devices selected on a representative basis.

Section 4.5.2(a) of Annex VII requires the notified body to prepare a sampling plan for assessment of the technical documentation prior to the QMS audit.

In December 2019, the Medical Devices Coordination Group (MDCG) published MDCG 2019-13 on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for assessment of the technical documentation, defining the requirements for sampling of Class B and Class C devices for the purpose of assessing the technical documentation.

Revision 1 of the guidance was published in December 2024 to modify the the requirements for sampling frequency.

Which devices are sampled?
Technical documentation of Class D, companion diagnostic, self-testing and near-patient testing devices is not subject to sampling, as these devices are issued a technical documentation assessment certificate in addition to the quality management system certification.

Class A devices that are not sterile are not subject to notified body assessment. It is the responsibility of the manufacturer of these devices to establish the quality management system and maintain the technical documentation for the devices.

Class B and Class C devices that are not intended for self-testing, near-patient testing or as companion diagnostics are assessed on a representative basis, i.e. sampled.

How is sampling performed?
The manufacturer submits a complete list of devices they wish to certify under the IVDR, including their classification and categorization / grouping to TÜV SÜD.

We will create a sampling plan including a schedule defining which technical documentation to assess from each Device Category (DC) and Generic Device Gorup (GDG) for initial and surveillance assessments. The plan is initially created for 5 years and is subject to change in the event of changes to the device portfolio or other inputs. The sampling plan is not shared with the manufacturer in advance to ensure representative sampling.

Sampling is not random, but the sampling plan is created using a risk-based approach.

What is a Device Category and a Generic Device Group?

Class B	**Device Category** IVR Code according to Regulation (EU) 2017/2185
Class C	**Generic Device Group** 3rd level of European Nomenclature of Medical Device (EMDN) consisting of 1 letter and 4 digits plus the most appropriate IVP code per Regulation (EU) 2017/2185

Examples of Device Categories (Class B, IVR code)

IVR 0605	Devices intended to be used for monitoring of levels of medicinal products, substances or biological component
IVR 0606	Devices intended to be used for non-infectious disease staging
IVR 0607	Devices intended to be used for detection of pregnancy or fertility testing
IVR 0608	Devices intended to be used for screening, determination or monitoring of physiological markers
IVR 0609	Other devices to be used to define or monitor physiological status and therapeutic measures
IVR 0701	Devices which are controls without a quantitative assigned value
IVR 0702	Devices which are controls without a qualitative value

All Class B devices that share the same IVR code are grouped together in a single device category.

Examples of Generic Device Groups (Class C, EMDN + IVP code)

EMDN Code	EMDN Code Title	IVP Code	IVP Code Topic
W0101	Clinical Chemistry	IVP 3002	Biochemistry
W0101	Clinical Chemistry	IVP 3013	Spectroscopy
W0102	Immunochemistry (Immunology)	IVP 3001	Agglutination
W0102	Immunochemistry (Immunology)	IVP 3007	Immunoassays
W0103	Haematology / Haemostasis / Immunohaematology / Histology / Cytology	IVP 3006	Flow Cytometry
W0103	Haematology / Haemostasis / Immunohaematology / Histology / Cytology	IVP 3007	Immunoassays
W0104	Microbiology (culture)	IVP 3014	Cell function
W0105	Infectious Immunology	IVP 3007	Immunoassays
W0105	Infectious Immunology	IVP3011	NAT / NGS
W0106	Genetic testing	IVP 3004	Chromosomal analysis
W0106	Genetic testing	IVP 3011	NAT / NGS

For Class C devices, devices in the same EMDN group can be further subdivided into multiple generic device groups based on different IVP codes. Conversely, devices sharing the same IVP code can be subdivided into multiple generic device groups based on different EMDN codes. This results in a more granular grouping based on the application and the technological characteristics of devices.

How many devices are sampled?

Prior to Initial Certification
- At least one sample per Device Category and Generic Device Group

During First Certification Cycle
- At least 5% of each GDG and DC
- At least 1 TD per year

During Following Certification Cycles
- At least 15% of each GDG and DC
- At least 1 TD per year
- May be reduced to a minimum of 5% pending final revision of MDCG 2019-13

How TÜV SÜD can help

TÜV SÜD is the first Notified Body to issue an IVDR certificate. As one of the world's largest EU Notified Bodies for all types of medical devices covered by EU directives and regulations, TÜV SÜD is designated as a full-scope Notified Body under the IVDR.

Our experts' experience and expertise make TÜV SÜD your partner of choice to bring your innovative in vitro diagnostic medical devices to the EU market, providing a full range of certification and testing services to ensure global market access.

We work collaboratively with our partners to ensure access to critical innovative diagnostic technologies for patients and providers.

Contact us to discuss your needs for IVDR certification.

Related services

TÜV SÜD provides the following related services
- IVDR Certification
- EN ISO 13485 certification
- Testing services including EMC and NRTL testing
- Medical Device Single Audit Program (MDSAP)

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