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Sampling

for Assessment of Technical Documentations according to IVDR Annex IX

Introduction

Article 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 (for Class C) and for each category of devices (for Class B) prior to issuing a certificate to a manufacturer.

Section 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 draw up and keep up to date, **a sampling plan** for the assessment of Technical Documentation as referred to in Annexes II and III prior to the audit.

In December 2019 the Medical Device Coordination Group (**MDCG**) published the document "MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation" to (amongst others) define the requirements of sampling for Class B and Class C devices under the IVDR for the purpose of assessing the technical documentation.

This document also interprets Section 4.5.2(b) of Annex VII to require the Notified Body to assess the Technical Documentation **as preparation for the audit(s)**. This assessment is expected to be finalised in due time of such audit(s).

This document describes how the above requirements are implemented by **TÜV SÜD Product Service GmbH** and gives additional practical explanations/implications.

Which devices are sampled?

Technical Documentations of non-sterile Class A devices must be kept up-to-date by the legal manufacturer, however, no Notified Body is involved in its assessment. Technical Documentations of Class D, Companion

Diagnostic, Self-Testing and Near-Patient Testing devices are assessed without exception before they can be placed on the market (although not the correct term, this sometimes is called "PMA", pre-market approval).

That leaves Class B and Class C devices, here the assessment of the Technical Documentation of each device is not necessary, but devices are assessed on a representative basis, i.e. "sampled". A "device" should be understood as the device(s) associated with one Basic UDI-DI.

What does sampling mean in this context?

TÜV SÜD needs a complete list of all your devices that are within the scope of the IVDR, including classification and categorisation / grouping.

A Sampling Plan is created including, for each Device Category and Generic Device Group, a schedule defining which devices' Technical Documentations will be assessed when in the course of the certification cycle. The plan is created for 5 years initially and may change whenever there is a change to the device portfolio or due to other input.

Contrary to the common understanding of the term "sampling" and the picture on Page 1 of this document, the process is not completely random, but risk-driven. I.e. TÜV SÜD will create the sampling plan on a risk-based approach, as far as possible.

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 on Medical Devices (EMDN, former Italian CND), consisting of 1 letter and 4 digits plus most appropriate IVP code

Examples for Device Categories (Class B, IVR code)

Excerpt from COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185 of 23 November 2017:

IVR 0605	Devices intended to be used for monitoring of levels of medicinal products, substances or biological components
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 intended 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

Examples for Generic Device Groups (Class C, EDMN + IVP code)

EDMN CODE	EDMN CODE TITLE	IVP CODE	IVP CODE TOPIC
W0101	Clinical chemistry	IVP 3002	Biochemistry
W0101	Clinical chemistry	IVP 3013	Spectroscopy
W0102	Immunochemsitry (immunology)	IVP 3001	Agglutination
W0102	Immunochemsitry (immunology)	IVP 3007	Immunoassays
W0103	Haematology / Haemostasis / Immunoheamotology / Histology / Cytology	IVP 3006	Flow cytometry
W0103	Haematology / Haemostasis / Immunoheamotology / Histology / Cytology	IVP 3007	Immunoassays
W0104	Microbiology (culture)	IVP 3014	Cell function
W0105	Infectious immunology	IVP 3007	Immunoassays
W0105	Infectious immunology	IVP 3011	NAT / NGS
W0106	Genetic testing	IVP 3004	Chromosomal analysis
W0106	Genetic testing	IVP 3011	NAT / NGS

How many devices are sampled?

PRIOR TO CERTIFICATION
At least one device per generic device group and device category

DURING 1ST CERTIFICATION CYCLE
5% of devices of each GDG or DC
At least one TD per year

DURING FOLLOWING CERTIFICATION CYCLES
15% of devices of each GDG or DC
At least one TD per year

What are the practical implications of sampling, how does the process work at TÜV SÜD Product Service GmbH?

The sampling process works hand in hand with the general certification process, please see also the respective information material.

If you choose to get a conformity assessment according to Annex IX of the IVDR, we will need a list of all your IVD devices, including classification and group /category assignment. Please be aware that the number of groups / categories has a direct impact on the number of devices to be sampled.

TÜV SÜD will evaluate the list and agree or disagree with the classification and grouping/categorisation. In case there are any discrepancies, your personal Client Handler will contact you and try to resolve them.

We will then create a sampling plan for 5 years and ask you to send the Technical Documentations for the sampled devices. In case there are changes in your product portfolio or design, the plan might be adjusted to reflect these.

There is a separate document that describes the Technical Documentation Submission Requirements, please ask your personal Client Handler.

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