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Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation

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Update of footnote number 10

1 Introduction

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) establish the requirements for sampling of Class IIa / Class IIb and Class B / Class C devices for the assessment of the technical documentation.

Article 52(4) and (6) of the MDR and Article 48(7) and (9) of the IVDR establish the need to assess the technical documentation of at least one representative device per **generic device group** (for Class IIb and Class C) and for each **category of devices** (for Class IIa and Class B) prior to issuing the certificate.

Section 2.3 and 3.4 of Annex IX of both Regulations (and section 10 of Annex XI of the MDR) defines that the quality management system assessment has to be accompanied by the assessment of technical documentation for devices selected on a representative basis.

Section 4.5.2(a) of Annex VII of both Regulations[1] 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.

Section 4.5.2(b) of Annex VII requires 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).

2 Scope

This guidance is intended to define the requirements of sampling for Class IIa and Class IIb devices under the MDR and Class B and Class C devices under the IVDR for the purpose of assessing the technical documentation.

This guidance defines and further elaborates on the sampling criteria and use of such criteria for drawing up and maintaining a sampling plan.

In addition, this guidance clarifies the tasks to be performed by the notified body including the applicability of Chapter II of Annex IX of both Regulations and the extent of the technical documentation assessment.

See Section 5.3 for exemptions for specific types of devices.

[1] Hereafter referred to as “Annex VII” for both, the MDR and the IVDR.

3 Definitions

The Regulations do not contain definitions of certain terms applicable to sampling, and in some instances certain definitions given cannot be used on an operational level. Therefore, **only for the purpose of this guidance** the following definitions apply:

3.1. Category of devices: category of devices should be understood as the relevant MDA/MDN codes (MDR) or IVR codes (IVDR) according to Regulation (EU) 2017/2185 on the codes for the designation of notified bodies.

3.2. Generic device group[2]: is to be understood:

- in respect of the MDR[3,4] as the 4th level of the European Nomenclature on Medical Devices (EMDN) [5, 6] (i.e. combination of one letter plus 6 digits), and
- in respect of the IVDR as the 3rd level of the EMDN (i.e. combination of one letter plus 4 digits respectively) in combination with the most appropriate IVP code.

3.3. Device range: device range is to be understood as all “device categories" for Class IIa and Class B devices and all “generic device groups” for Class IIb and Class C devices covered in a certificate.

3.4. Device: device should be understood as the device(s) associated with one Basic UDI-DI[7].

3.5. QMS certificates: QMS certificates are EU quality management system certificates (MDR and IVDR), EU quality assurance certificates (MDR) and EU production quality assurance certificates (IVDR) issued by notified bodies as a result of conformity assessments.

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[2] "A set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics" (Art. 2 (7) MDR and Art. 2(8) IVDR).
[3] In cases, where the 4th level for the MDR does not exist the notified body should use the next higher level.
[4] If the notified body considers that for a particular device level 4 for the MDR/level 3 for the IVDR is not sufficiently specific to define a generic device group, it can use the next lower level if available.
[5] EMDN nomenclature can be found currently at:
http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_15_file.pdf
[6] In case where more than one EMDN code applies to one device, only the most appropriate one of these EMDN codes will be assigned for sampling purposes. The technical documentation related to that particular device will be assessed in its entirety.
[7] As defined in MDCG 2018-1 v2 Guidance on BASIC UDI-DI and changes to UDI-DI.

4 Sampling criteria

The Regulations establish minimum requirements for sampling prior to issuing the certificate and during its validity. The notified body will ensure that these requirements will be complied with when drawing up a sampling plan. In addition, other considerations have to be observed in order to ensure an adequate coverage of devices on a representative basis.

4.1. Quantitative Sampling Criteria

4.1.1. Sampling <u>prior</u> to issuing a QMS certificate

The Regulations establish the need for the notified body to assess technical documentation for a number of devices prior to issuing the QMS certificate:

- For Class IIb and Class C the technical documentation of at least one representative device per generic device group (as per Article 52(4) of the MDR and Article 48(7) of the IVDR). This means that the notified body should assess how many generic device groups as per 3.2 are covered in the application (how many nomenclature's 4th levels for MDR / 3rd levels in combination with applicable IVP codes for the IVDR[8]), select per group at least one representative device covered by a Basic UDI-DI and assess the technical documentation for the device(s) selected.
- For Class IIa and Class B the technical documentation of at least one representative device per category of devices (as per Article 52(6) of the MDR and Article 48(9) of the IVDR). This means that the notified body should asses how many categories of devices as per section 3.1, (how many MDA/MDN or IVR codes), are covered by the manufacturer's application, select per category at least one representative device covered by a Basic UDI-DI (MDA/MDN or IVR code) and assess the technical documentation for the device(s) selected.

The outcome of these assessments is an essential input for the final review according to Annex VII section 4.7 of the Regulations prior to issuing of the certificate.

4.1.2. Sampling <u>during surveillance</u>

After issuing the certificate, the notified body will continue to assess technical documentation in line with the sampling plan. Section 3.5 of Annex IX of both Regulations indicates that surveillance assessment shall also include an assessment

[8] Generic device groups for Class C devices will consist on an EMDN + an IVP code. Therefore, when different products are covered under the same EMDN but corresponds to different IVP codes, the notified body will assign the most appropriate IVDP code to each device.

of the technical documentation[9] which means that at least one technical documentation must be reviewed each year.

In addition, notified bodies will ensure that the entire device range is covered during the period of validity of the certificates as required by Section 4.5.2 (a) of Annex VII. This means that at least one device per each category, in case of Class IIa and Class B devices, and at least one device per each generic device group, in case of Class IIb and Class C devices, should be sampled and the relevant technical documentation assessed between the issue of a certificate and its expiry date.

Furthermore, in addition to the above-mentioned criteria, the number of samples to be assessed need to be selected on a representative basis (as per Annex VII 4.5.1 9th indent MDR, Annex IX 2.3 3rd paragraph MDR / IVDR, and Annex VII 4.5.1 8th indent IVDR). Therefore, in developing the sampling plan (see section 6), the notified body should also ensure that the number of devices sampled is proportionate to the total number of devices contained in the certificate. For this purpose, it is expected that 15%[10] of devices from each category and from each generic device group covered in the certificate will be sampled during its validity – taking into account the maximum validity of 5 years.

In cases where the certificate contains very few devices and the technical documentations of these have been already reviewed, it is expected that during surveillance audits the notified body will focus on the review of the technical documentation related to post-market surveillance in accordance with Annex III.

Normally, the devices to be sampled after the certificate has been issued would be spread evenly during the validity of the certificate. However, the notified body might decide to perform different numbers of reviews in a given year for different reasons (e.g. workload, vigilance concern) as long as throughout the surveillance period all initially determined assessments are performed. Such an approach is acceptable as long as the minimum requirements mentioned in the first paragraph of this section are complied with.

4.2. Qualitative Sampling Criteria

Section 2.3 of Annex IX of both Regulations establishes qualitative criteria to be used when drawing up sampling plans. While some of these criteria such as similarities in design, technology and manufacturing and sterilisation methods may be covered already by the fact that devices belong to the same category or generic device group,

[9] The follow-up of change notifications according to Section 4.9 of Annex VII (e.g. “the device range covered” in Annex IX section 2.4), and other surveillance activities as laid down in Section 4.10 of Annex VII are to be carried out in addition to sampling during surveillance.
[10] The 15% may be decreased to a minimum of 5% until the overall ongoing revision of this guidance document will be published.

all the criteria defined in Section 2.3 of Annex IX including novelty of the technology intended purpose or the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties must be individually considered when prioritising the review of one device over another. This prioritisation should take into account the inherent risk of the different devices included in the relevant category of devices / generic device group which means that, for instance, novel devices, will usually be prioritised over well-known technologies (unless there are specific concerns over the latter). Additional criteria may be also taken into consideration by the notified body[11]. As required by the Regulation, the notified body must document its rationale for the samples taken, in particular, mentioning what specific criteria have been taken into account.

It should be noted, that as long as there are devices that have not been sampled, each device should only be sampled once during the period of validity of the certificate unless vigilance cases or other information which have been brought to the notified body's attention will require it.

5 Assessment of the technical documentation

5.1. Depth of the assessment

The depth and extent of the technical documentation assessment of Class IIa / IIb and Class B / Class C devices will be the same as the depth of assessment carried out for Class III and Class IIb implantable and Class D devices.

This means that the technical documentation of a device shall be assessed against all General Safety and Performance Requirements (Annex I) and requirements of Annex II and III. Records of the assessment shall be prepared which allow a third party to understand the functionality of the device and all aspects of the assessment including judgements made by the assessor.

It should be taken into account that every device (i.e. Basic UDI-DI) might include different variants, models or sizes. In that case, the review of the technical documentation will also include the assessment of how the differences among these have been addressed in the technical documentation and whether all of them are in line with the relevant requirements.

5.2. Applicability of Chapter II, Section 4 of Annex IX

[11] For instance, where controls or calibrators are specifically intended to be used in conjunction with a specific IVD device, these controls or calibrators will preferably be assessed alongside that device

Taking into account the wording of articles 52(4) and 52(6) of the MDR and Article 48(7) and 48(9) of the IVDR, as combined with annexes VII and IX, the tasks to be carried out by the notified body as part of the conformity assessment activities described in Chapter II, Section 4 of Annex IX comprise the complete review of the technical documentation in accordance with Annexes II and III.

In addition, the manufacturer will grant access to the technical documentation as referred to in Section 2.2 of Annex IX and the notified body will provide the manufacturer with a report on the technical documentation assessment. For Class IIa / IIb and Class B / Class C the notified body will neither require an application nor issue an EU technical documentation assessment certificate (see 5.3 for exceptions).

5.3. Additional requirements for specific types of devices under the MDR and the IVDR

For class IIb implantable devices[12], Article 52(4) second subparagraph of the MDR establishes the need to review the technical documentation in accordance with the complete Section 4 of Annex IX for every device, therefore an application as well as the issuance of an EU technical documentation assessment certificate are required. They are exempt from sampling.

According to Article 54, Class IIb active devices intended to administer and/or remove a medicinal product falling into rule 12 of Annex VIII are subject to the clinical evaluation consultation procedure prior to issuing of the certificate. These devices can be subject to sampling but according to Articles 54(3) and 55 the notified body must ensure that at least the clinical evaluation assessment report (CEAR) for each device is uploaded in Eudamed prior to issuing the QMS certificate. This means that the sampling will not apply to the clinical evaluation as it has to be assessed for every device.

Article 48 (7, 8 and 9) and Section 5 of Annex IX of the IVDR establish that class B and C devices for self-testing, near-patient testing and companion diagnostics are exempt from sampling. The manufacturer will lodge an application as per sections 5.1 (a) and 5.2 (a) of Annex IX of the IVDR, and, as described in section 5.1 (c-e) and 5.2 (a-e), the notified body will review the technical documentation of all the devices covered in the certificate and will issue an EU technical documentation assessment certificate.

5.4. Reporting

The technical documentation assessment of Class IIa / IIb and Class B / Class C devices and its reporting should follow the principles established in Annex VII and the

[12] Except for sutures, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, which are subject to sampling

applicable provisions of the conformity assessment annexes and should use or be similar to those procedures and checklists developed by the notified body for the assessment of Class III / IIb implantable devices and Class D devices.

In order to fulfil the legal requirements, the reporting requirements established in Section 4.6. of Annex VII will apply.

6 Drawing up and keeping up to date a sampling plan

According to Section 4.5.2(a) of Annex VII the notified body shall draw up and keep up to date a sampling plan. This plan should contain at least the devices covered by the certificate, their Basic UDI-DI, the generic device group (in case of Class IIb), the generic device group plus the IVP code (in case of Class C devices) or the category of devices (in case of Class IIa / Class B devices), the identifier of the respective technical documentation, the (planned) assessment dates and the status of such assessments.

The notified body should update the sampling plan whenever needed on the basis of the criteria defined in this guidance as well as on the basis of its post-certification activities laid down in Section 4.10 of Annex VII. In particular, the outcome of the screening of relevant sources of scientific and clinical data and post-market information relating to the scope of their designation, or the review of vigilance data should be taken into account.

If the manufacturer makes a change in the product range during the period of validity of the certificate, the notified body should review the sampling plan accordingly. When adding new devices to the scope of the certificate which do not fall into the already covered generic device groups / categories of devices, the initial sampling criteria (section 4.1) apply.

If the manufacturer applies for re-certification, the notified body should update the sampling plan with the samples to be assessed during the upcoming certification period according to the principles laid down under section 4.1.2 Sampling during surveillance and keep the sampling plan up to date as described above.