TÜV Association

# Sampling

## Alternative proposal

# General

Sampling of Technical Documentations is a key component in verifying the safety and performance of medical devices.

A minimum level of systematic assessment is necessary to ensure product safety and thus patient safety.

We believe the current approach is in general appropriate. There is only a lack of proportionality; in particular, manufacturers with few products - mostly micro and small businesses - are disproportionately burdened compared to manufacturers of a wider range of products, which are mostly medium-sized and large enterprises.

In our view, there is no need to amend the MDR and IVDR. The desired policy objective of reducing the scope of Technical Documentation assessments, particularly for SMEs, can be achieved much more quickly by revising the requirements set forth in the document MDCG 2019-13 rev. 1.

TÜV VERBAND

# General

Given the political commitment to reduce the scope of Technical Documentation assessments, we are making this proposal, which we believe sets minimum requirements with regard to patient safety. If the scope of the sampling is reduced any further, systematic assessment will no longer be possible.

This proposal does not take into account the European Commission’s proposals regarding Well-Established-Technologies (WET). We assume that there will be no reduction in the scope or number of reviews for Technical Documentations for implantable Class IIb and Class III devices that are assumed to be WET. The proposals therefore refer to the assessment of Technical Documentations for Class IIa and non-implantable Class IIb, as well as Class B and Class C products.

# Current requirements - MDCG 2019-13 rev. 1

**4.1.1. Sampling prior 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 IVDR8), 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 during surveillance**

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 of the technical documentation 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% 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.

# Commission proposal MDR

**Article 1 (43) (a), new subparagraph – Article 52 MDR**
‘By way of derogation from the first subparagraph, class III devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group.’;

**Annex I (5) (q) (ii), new fourth indent – Annex VII (4.5.2) (a) fourth indent MDR**
~~‘draw up and keep up to date, for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and’~~
‘clearly identify, for class IIa and class IIb devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III,’

**Annex I (7) (a) section 2.3, new third and fourth paragraphs – Annex IX (2.3) third and fourth paragraphs MDR**
~~Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with Sections 4.4 to 4.8. In choosing representative samples, the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 105 and in particular the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.~~
~~If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.~~
‘Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annex II and III, as specified in Sections 4.3 to 4.8 for a representative device. ‘

**Annex I (7) (e) new section 3.5 – Annex IX (3.5) MDR**
~~In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the second paragraph of Section 2.3.~~
~~In the case of class III devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.~~
In the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, during the surveillance assessment the notified body may include a ‘for-cause’ assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.
In the case of class III devices, with the exception of well-established technology devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.’;

# Commission proposal IVDR

**Annex II (5) (s) (i) (2), new fourth indent – Annex VII (4.5.2) (a) fourth indent IVDR**

~~'draw up and keep up to date, for class B and class C devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and'~~

'clearly identify, for class B and class C devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III, and,'

**Annex I (6) (a) section 2.3, third and fourth paragraphs replaced by – Annex IX (2.3) third and fourth paragraphs IVDR**

~~Moreover, in the case of class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 4.4 to 4.8. In choosing representative samples the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 99 and in particular, the novelty of the technology, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken. If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of tits decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.~~

'Moreover, in the case of class B and class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annexes II and III, as specified in Sections 4.3. to 4.8., for a representative device selected as follows:

– for class B devices, one device;

– for class C devices, one device per generic device group.

In choosing the representative device, the notified body shall apply a risk-based approach, taking into account the principle of proportionality and in particular, the novelty of the technology, the novelty of the analyte and/or marker being detected, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose, the application by the manufacturer of harmonised standards or CS for the device and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative device taken.

The notified body may include a 'for-cause' assessment of the technical documentation of additional representative devices on duly justified grounds identified during the quality management system assessment.

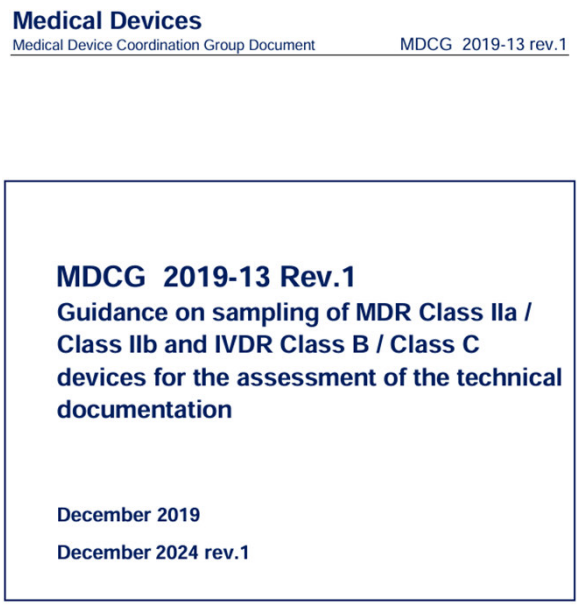
If the quality management system and the technical documentation of the assessed representative device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.';

**Annex II (6) (e) new section 3.5 – Annex IX (3.5) IVDR**

~~In the case of class C devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 of for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3.~~

In the case of class B and class C devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.';

# Basic requirements




The Commission proposal reduces the sampling of Technical Documentations to a level, that a systematic assessment would not be possible. Product safety and thus patient safety is at risk!

Following the provisions set out in MDCG 2019-13 rev. 1, the sampling should be based on

- quantitative and
- qualitative criteria

both

- prior to initial certification and
- during surveillance activities.

These criteria need to

- focus on being representative of the intended use and
- subsequently the safety aspects related to them.

The MDCG-approach for classes IIb and IIa and for class B and C (which in some cases is only a prolonged application time or "higher" invasiveness), shall be replaced by a risk-based approach focusing on the intended use and the related safety aspects.

# Alternative proposal MDR

The separation into generic device groups (class IIb using EMDN codes level 4) and categories of devices (class IIa using MDA/MDN codes) should be replaced by

- applying level 3 EMDN codes for class IIb and IIa.

The notified body shall assess

- at least one sample of the level 3 EMDN code,
- applying a risk approach that prioritizes class IIb products over class IIa in the same EMDN code

prior to issuing an EU certificate referencing this group of devices.

For the sampling during surveillance, after issuing the certificate:

- every year at least one representative sample of the EMDN level 3 code – subdivided by active and non-active devices and independent of the risk-classification in IIa and IIb - shall be subject to the technical documentation assessment,
- as long as the assessments in the last 3 years did not cover the same product (Basic UDI-DI).
- Within the first three-year cycle, at least 15% of devices shall be sampled. Depending on performance, the percentage share may be reduced to 10% or 5% or increased to 10% or 15% in the following three-year cycles

Further, we would remove requirements sampling an entire Basic UDI-DI to one device only.

In addition, the notified body may include ‘for-cause’ assessments of technical documentations of representative devices where the notified body has identified potential concerns.

# Alternative proposal IVDR

To conduct sampling based on level 3 EMDN codes does not make sense: After all, there are only six groups at the third level for reagents. The separation into generic device groups (class C using 3rd level of the EMDN (i.e. combination of one letter plus 4 digits respectively) in combination with the most appropriate IVP code) and categories of devices (class B using IVR codes) should be replaced by

The notified body shall assess prior to issuing a QMS certificate:

- A set of all Class B and C products is formed, and this set is assigned to the IVR categories. From these IVR categories, the technical documentation of at least one product is initially reviewed.

For the sampling during surveillance, after issuing the certificate:

- every year at least one representative sample from each IVP Code applicable to the product's scope of application - independent of the risk-classification in B and C - shall be subject to the technical documentation assessment,
- as long as the assessments in the last 3 years did not cover the same product (Basic UDI-DI).
- Within the first three-year cycle, at least 15% of devices shall be sampled. Depending on performance, the percentage share may be reduced to 10% or 5% or increased to 10% or 15% in the following three-year cycles.
- When selecting the technical documentations to be reviewed, all IVP codes applicable to the product's scope of application should be covered.
- If a category contains both Class B and Class C products, one or more products from the higher risk class should be selected first.

In addition, the notified body may include 'for-cause' assessments of technical documentations of representative devices where the notified body has identified potential concerns.

# Key differences MDR

**Sampling on Basic UDI-DI**

Variante / Article based
Impacted by:
- ~~Intended Purpose~~
- Risk class
- Conformity assessment
- Design aspects
- Manufacturing technology

Number of different items in a group:
**HIGH**

**Sampling on EMDN**

Device / intended purpose based
Impacted by:
- **Intended purpose**
- ~~Risk class~~
- ~~Conformity assessment~~
- ~~Design aspects~~
- ~~Manufacturing technology~~

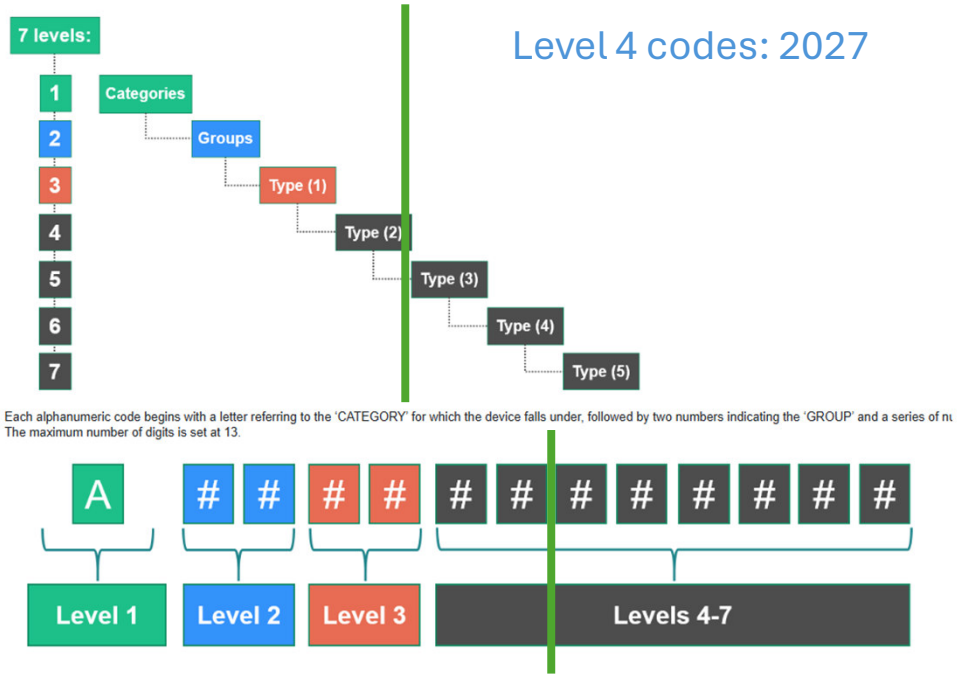
Number of different items in a group:
**MEDIUM to LOW** (depending on the level)

**Sampling on MDx Code**

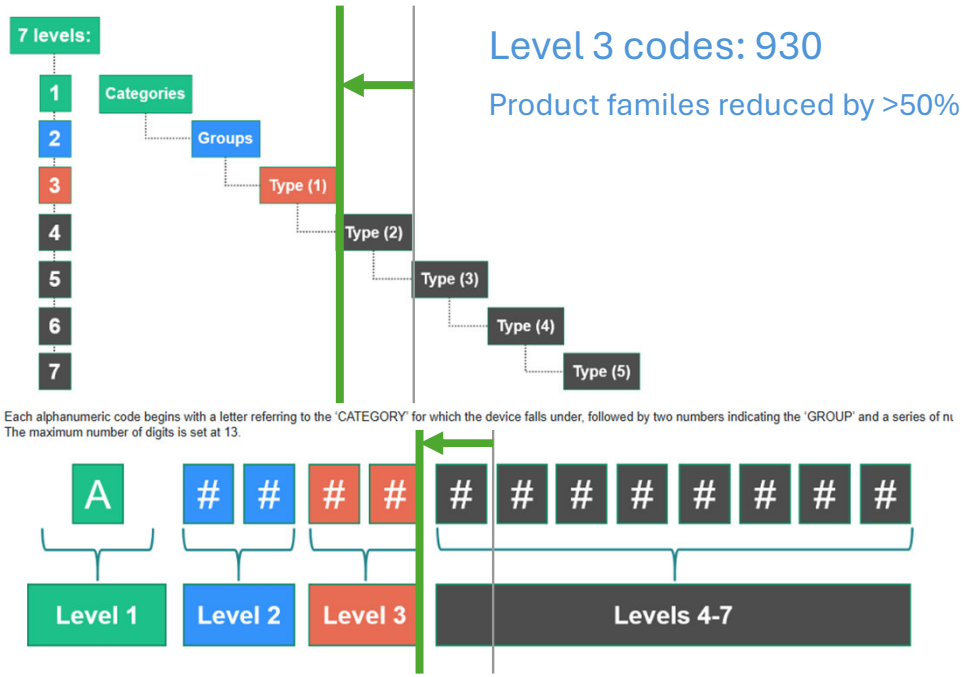
Application / Risk based
Impacted by:
- ~~Intended purpose~~
- ~~Risk class~~
- ~~Conformity assessment~~
- ~~Design aspects~~
- ~~Manufacturing technology~~
- **Application**
- **Risk**
- **Energy application**
- **Invasiveness**

Number of different items in a group:
**MEDIUM**

# EMDN levels MDR




MDCG 2019-13 identifies a “Generic device group” by the 4th level (i.e. combination of one letter plus 6 digits).




Use the 3rd level (i.e. combination of one letter plus 4 digits) rather than the 4th level.

Graphic Source: European Medical Device Nomenclature (EMDN)

# Key differences IVDR

| Sampling today | Sampling alternativ proposal |
|---|---|
| Classes B and C treated seperately:<br>• Class B sampling IVR code<br>• Class C sampling EMDN code + IVP | Merging classes B and C<br>➔ sampling IVR code |
| Sampling groups = 26 + x | Sampling groups = 22 |

Impact:

- Initial certification:
  - The number of groups determines the number of initial TD assessments - hence the greatest impact here.
  - Benefit for manufacturers: Reduction in initial effort and, consequently, simplification.
  - Although the Notified Body (NB) conducts fewer initial checks, it still performs a reasonable number of assessments to initially certify a QMS.
- Surveillance cycle:
  - Provided we maintain the percentage distribution of BUDIs throughout the cycle, the proposal has an effect on the total number of samples to be drawn.
  - Advantage: continued systematic coverage of the scope based on the quantitative and qualitative sampling criteria.

# Key differences IVDR

| Sampling today | | Sampling alternative proposal | |
|---|---|---|---|
| Class B (Device Category) | | Class B/C together (DeviceCategory) | |
| 1 | IVR 0503 | 1 | IVR 0106 |
| 2 | IVR 0504 | 2 | IVR 0201 |
| 3 | IVR 0505 | 3 | IVR 0202 |
| 4 | IVR 0506 | 4 | IVR 0301 |
| 5 | IVR 0601 | 5 | IVR 0302 |
| 6 | IVR 0602 | 6 | IVR 0401 |
| 7 | IVR 0603 | 7 | IVR 0402 |
| 8 | IVR 0604 | 8 | IVR 0403 |
| 9 | IVR 0605 | 9 | IVR 0501 |
| 10 | IVR 0606 | 10 | IVR 0503 |
| 11 | IVR 0607 | 11 | IVR 0504 |
| 12 | IVR 0608 | 12 | IVR 0505 |
| 13 | IVR 0609 | 13 | IVR 0506 |
| 14 | IVR 0701 | 14 | IVR 0601 |
| 15 | IVR 0702 | 15 | IVR 0602 |
| | | 16 | IVR 0603 |
| Class C (Generic Device Group) | | 17 | IVR 0604 |
| 1 | W0101 + IVP | 18 | IVR 0605 |
| 2 | W0102 + IVP | 19 | IVR 0606 |
| 3 | W0103 + IVP | 20 | IVR 0607 |
| 4 | W0104 + IVP | 21 | IVR 0608 |
| 5 | W0105 + IVP | 22 | IVR 0609 |
| 6 | W0106 + IVP | Sampling groups = 22 | |
| 7 | W0201 + IVP | | |
| 8 | W0202 + IVP | | |
| 9 | W0203 + IVP | | |
| 10 | W0204 + IVP | | |
| 11 | W0205 + IVP | | |
| Sampling groups = 26 + x | | | |

# Alternative proposal MDR

**Article 1 (43) (a), new subparagraph – Article 52 MDR – DO NOT CHANGE CURRENT MDR REQUIREMENTS**
~~'By way of derogation from the first subparagraph, class III devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group.';~~

**Annex I (5) (q) (ii), new fourth indent – Annex VII (4.5.2) (a) fourth indent MDR – DO NOT CHANGE CURRENT MDR REQUIREMENTS**
'draw up and keep up to date, for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and'
~~'clearly identify, for class IIa and class IIb devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III,'~~

**Annex I (7) (a) section 2.3, new third and fourth paragraphs – Annex IX (2.3) third and fourth paragraphs MDR – DO NOT CHANGE CURRENT MDR REQUIREMENTS**
Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with Sections 4.4 to 4.8. In choosing representative samples, the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 105 and in particular the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.
If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.
~~'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annex II and III, as specified in Sections 4.3 to 4.8 for a representative device. '~~

**Annex I (7) (e) new section 3.5 – Annex IX (3.5) MDR – DO NOT CHANGE CURRENT MDR REQUIREMENTS**
In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the second paragraph of Section 2.3.
In the case of class III devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.
~~In the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.~~
~~In the case of class III devices, with the exception of well-established technology devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.';~~

# Alternative proposal MDR

**Annex IX, section 2.3 new fifth', six' and seventh' paragraph – Add new and more precise requirements**

'Sampling prior to issuing a quality management system certificate:
For the sampling prior to issuing a QMS certificate at least one representative sample of the EMDN level 3 code - independent of the risk-classification in IIa and IIb - shall be subject to a full technical documentation assessment.

Sampling during surveillance after issuing the certificate:
For the sampling during surveillance every year at least one representative sample of the EMDN level 3 code – subdivided by active and non-active devices and independent of the risk-classification in IIa and IIb - shall be subject to a technical documentation assessment, as long as the assessments in the last 3 years did not cover the same product (Basic UDI-DI).
Within the first three-year cycle, at least 15% of devices shall be sampled. Depending on performance, the percentage share may be reduced to 10% or 5% or increased to 10% or 15% in the following three-year cycles.
In order to avoid unnecessary duplication of assessments, the depth of the surveillance assessments shall at least cover the post market surveillance aspects as well as Chapters I and II of Annex I of this Regulation.
Performance means the compliance to requirements, absence of negative post-market surveillance signals and maturity of the quality management system.

Additional assessments after issuing the certificate:
The notified body may perform 'for-cause' assessments of technical documentations of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data, anomalies in similar devices, non-conformities in the context of the valuations pursuant to paragraphs 6 and 7 of this section or other triggering events.'

# Alternative proposal IVDR

**Annex II (5) (s) (i) (2), new fourth indent – Annex VII (4.5.2) (a) fourth indent IVDR – DO NOT CHANGE CURRENT IVDR REQUIREMENTS**
'draw up and keep up to date, for class B and class C devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and'
~~'clearly identify, for class B and class C devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III, and'~~

**Annex II (6) (a) section 2.3, third and fourth paragraphs replaced by – Annex IX (2.3) third and fourth paragraphs IVDR – DO NOT CHANGE CURRENT IVDR REQUIREMENTS**
Moreover, in the case of class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 4.4 to 4.8. In choosing representative samples the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 99 and in particular, the novelty of the technology, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken. If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of tits decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.
~~'Moreover, in the case of class B and class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annexes II and III, as specified in Sections 4.3. to 4.8., for a representative device selected as follows:~~
~~– for class B devices, one device;~~
~~– for class C devices, one device per generic device group.~~
~~In choosing the representative device, the notified body shall apply a risk-based approach, taking into account the principle of proportionality and in particular, the novelty of the technology, the novelty of the analyte and/or marker being detected, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose, the application by the manufacturer of harmonised standards or CS for the device and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative device taken.~~
~~The notified body may include a 'for-cause' assessment of the technical documentation of additional representative devices on duly justified grounds identified during the quality management system assessment.~~
~~If the quality management system and the technical documentation of the assessed representative device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.';~~

**Annex II (6) (e) new section 3.5 – Annex IX (3.5) IVDR – DO NOT CHANGE CURRENT IVDR REQUIREMENTS**
In the case of class C devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 of for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3.
~~In the case of class B and class C devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.';~~

# Alternative proposal IVDR

**Annex IX, section 2.3 new fifth', six' and seventh' paragraph – Add new and more precise requirements**

'Sampling prior to issuing a quality management system certificate:
A set of all Class B and C products is formed, and this set is assigned to the IVR categories. From these IVR categories, the technical documentation of at least one representative sample shall be subject to a full technical documentation assessment.

Sampling during surveillance after issuing the certificate:
Every year at least one representative sample from each IVP Code applicable to the product's scope of application is to be reviewed - independent of the risk-classification in B and C - shall be subject to a technical documentation assessment, as long as the assessments in the last 3 years did not cover the same product (Basic UDI-DI).
Within the first three-year cycle, at least 15% of devices shall be sampled. Depending on performance, the percentage share may be reduced to 10% or 5% or increased to 10% or 15% in the following three-year cycles. When selecting the technical documentations to be reviewed, all IVP codes applicable to the product's scope of application should be covered.
If a category contains both Class B and Class C products, one or more products from the higher risk class should be selected first.
Performance means the compliance to requirements, absence of negative post-market surveillance signals and maturity of the quality management system.

The notified body may perform 'for-cause' assessments of technical documentations of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data, anomalies in similar devices, non-conformities in the context of the valuations pursuant to paragraphs 6 and 7 of this section or other triggering events.'

# Alternative proposal MDR & IVDR

Measures:

- MDR: Combination of the risk-classes IIa and IIb
- IVDR: Combination of the risk-classes B and C
- MDR: EMDN level 3 instead of level 4
- IVDR: IVR categories instead of generic device groups and categories of devices
- No duplicate assessments of a technical documentation in a defined cycle
- Performance-based reduction of the number of technical documentation assessments

The alternative proposal would result in:

- Reduction of the number of technical documentation assessments and thus costs for manufacturers
- Performance-based additional reduction of the number of technical documentation assessments
- At the same time minimum level of systematic monitoring necessary to ensure product safety and thus patient safety.
- More proportionality, in particular for manufacturers with few products compared to manufacturers of a wider range of products.
- It is still possible to assess more Technical Documentations for the purposes of product and patient safety.