MedTech Europe
from diagnosis to cure

Sampling under IVDR

MedTech Europe proposal for a more risk-based approach

30/07/2025

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Executive Summary

The *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) established requirements for Class B and Class C professional laboratory-use devices[i] for the assessment of the technical documentation through sampling during the certificate lifetime. As per current Medical Devices Coordination Group (MDCG) 2019-13 REV. 1 guidance[ii], sampling under IVDR for Class B and Class C devices should be proportionate to the total number of devices under that certificate. It is expected that 15% of technical documentation is reviewed per representative group[1] of devices during each five years cycle which Notified Bodies may reduce to 5%.

In this Reflection Paper, MedTech Europe argues that, given the composition of the IVD market, the current sampling criteria over the certificate lifetime for Class B and Class C devices is not proportionate when compared to the portion of sampling for highest risk Class D devices. The vast majority of IVDs on the European Union (EU) market are Class B devices (~66% of total) and Class C devices (~26% of total)[iii,2]. Given such a large market share, mandating a sampling of 15% which repeats every certification cycle, has a high burden on IVD manufacturers, especially Small and Medium-Sized Enterprises (SME), because it affects Class B and Class C devices disproportionally. In addition, sampling is a major new requirement for the IVD sector since most IVDs are undergoing conformity assessment and sampling under IVDR for the first time.

Assessment of technical documentation requires significant resources for Notified Bodies and, therefore, implies significant resources for manufacturers. The average sampling costs per one technical file assessment during initial certification audit can round up to 38K EUR, which may constitute approximately ~35% of total fees the manufacturer pays to Notified Body for one IVDR QMS certification[iv]. However, these costs can be higher than 35% because they depend on the number of generic device groups a manufacturer has, for each of which they have to sample at least 1 technical file. In addition, the average number of samples taken for technical file assessment is higher under IVDR (5.2) as compared to Medical Devices Regulation (EU) 2017/745 (MDR) (2.5) which is likely to result from the current sampling criteria, more extensive Notified Body scope designation codes for IVDs than medical devices and more grouping categories for IVDs[iv]. Most importantly, according to the Gesundheit Österreich GmbH (GÖG) survey, the spike in costs is one of the most important reasons for IVD manufacturers having stopped or planning to stop production, marketing, and supply of some IVDs to the EU market[v]. Hence, the burden of sampling needs to be considered to ensure that diagnostics remain available for patients and laboratories, as well as to ensure a high level of safety and performance.

MedTech Europe calls on the MDCG to adopt a risk-based rather than quota-based sampling approach for Class B and Class C devices. This Reflection Paper illustrates how a risk-based, rather than arbitrary quota approach, could significantly reduce burden stemming from duplicative sampling which has little added value to ensuring device safety and performance as compared to other more valuable means (e.g. annual surveillance, change notification etc.). More specifically,

[1] Device category for Class B and generic device group for Class C
[2] Note, self-tests and near-patient tests (which are not sampled) make up only a small proportion of these groups

we argue that the current sampling approach is not risk-proportionate, as it results in Notified Bodies dedicating a disproportionate amount of time to sampling activities for lower risk devices. While the recent update to MDCG 2019-13 REV. 1, which has introduced the possibility of reducing sampling to 5% beyond the first certification cycle, has partially relieved the burden on the IVD sector, this might be a temporary approach until the overall ongoing revision of this guidance document will be published. We therefore take the opportunity to argue that a more risk-proportionate approach should be considered. Note that this paper mostly addresses sampling during surveillance rather than sampling during initial certification.

Below, we provide simulations which show the impact of sampling on the IVD sector and explain why the current sampling criteria should be amended without compromising device safety and performance.

The impact of IVDR sampling criteria

To illustrate the impact of sampling on manufacturers, we present simulations which demonstrate that the sampling criteria of 15% is excessively burdensome, has little value for device safety and performance and is not risk proportionate for Class B and Class C devices. We also present a simulation for lower sampling percentage for these devices and formulate a more risk-based proposal for sampling under IVDR.

The simulation of total costs for the IVD sector presented in this paper is based on data from the GÖG survey[iii] on the monitoring of the availability of devices and MedTech Europe IVDR and MDR survey[iv].

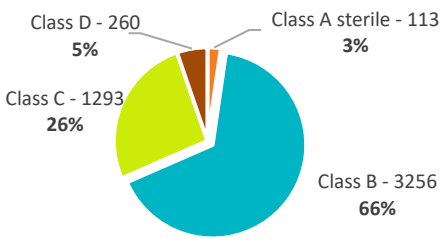
This simulation aims to answer the questions:

- **What is the cost burden on the IVD sector based on the current sampling approach defined in MDCG 2019-13 REV. 1?** The current approach sets out a 15% sampling for all applicable IVDR Class devices under Notified Body surveillance, which may be reduced to a minimum of 5% (based on the decision by Notified Body and until the overall ongoing revision of MDCG 2019-13 guidance document will be published). At least one technical file is required to be sampled at annual surveillance visits.
- **How would the cost burden on the IVD sector change if the sampling approach defined in MDCG 2019-13 REV. 1 is reduced?** Here a simulation considers the impact of having technical files picked up only on the basis of risk for Class B, i.e. no automatic quota during surveillance, 5% sampling for Class C devices during surveillance, and a maximum of 5% instead of 15% as a default sampling percentage for initial sampling (at least for devices with stable post-market surveillance and vigilance (PMSV) data).

For the simulation, the following assumptions are used:

1. The average cost paid by manufacturers to Notified Body for the assessment of technical file for sampled devices presented in MedTech Europe IVDR and MDR survey results is used as an estimate of technical documentation review (average cost – 37,853 EUR)[iv].
2. Even though the total absolute number of devices in the GÖG survey data does not represent the whole IVD market, the distribution percentage by Classes reflects the IVD market with Class B devices constituting over half and Class

Figure 1 Approximate total number of IVDs on the EU market per class



C devices a third of the IVD market in the EU (see figure 1)[iii]. It should be noted that the actual figures may exceed those reported in the GÖG survey.

Impact of CURRENT % for technical documentation sampling under IVDR

Sampling during one certification cycle: Based on the current MDCG 2019-13 REV. 1 guidance, technical documentation of Class B and Class C devices needs to be sampled and reviewed based on 15% sampling criteria which may be decreased to a minimum of 5%. In practice, 5% instead of 15% sampling has been used *de facto* for the first certification cycle by most Notified Bodies, and MDCG 2019-13 REV. 1 note 10 now allows the use of 5% sampling until the overall ongoing revision of this guidance document will be published. Therefore, we chose to use 5% sampling in the simulation for one certification cycle. For the highest risk Class D devices, the regulation specifies that all technical documentation needs to be reviewed (100% sampling).

Table 1 and Figure 2 present the estimated costs of one certification cycle for the whole IVD sector based on EU market composition from the GÖG survey. If the average cost from MedTech Europe survey is considered as a representative average amount charged by Notified Bodies per one technical documentation review (~38K EUR), the total costs for sampling for the whole IVD sector would amount to 6.1mln EUR for Class B devices, 2.4mln EUR for Class C devices and 9.8mln EUR for Class D devices. Thus, most of the sampling cost burden for the IVD sector falls on the highest risk Class D devices.

Table 1 Current costs for 1st certification cycle: minimum sampling of 5% for Class B and Class C devices

Class	Cost per TD review by NB[iv]	Sampling criteria (%)	# of IVDs on EU market[iii]	# of TDs auto-reviewed by NBs	Investment for TDs review	Invest-ment %
Class B	37,853 EUR	5%	3,256	163	6,162,468 EUR	34%
Class C	37,853 EUR	5%	1,293	65	2,447,196 EUR	13%
Class D	37,853 EUR	100%	260	260	9,841,780 EUR	53%
			Total:	**488**	**18,451,444 EUR**	**100%**

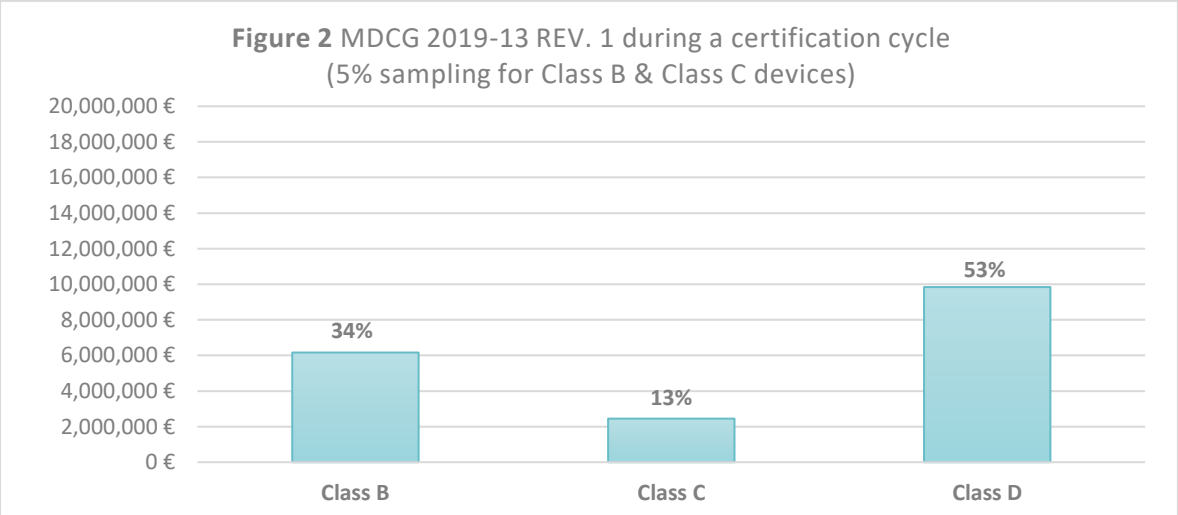
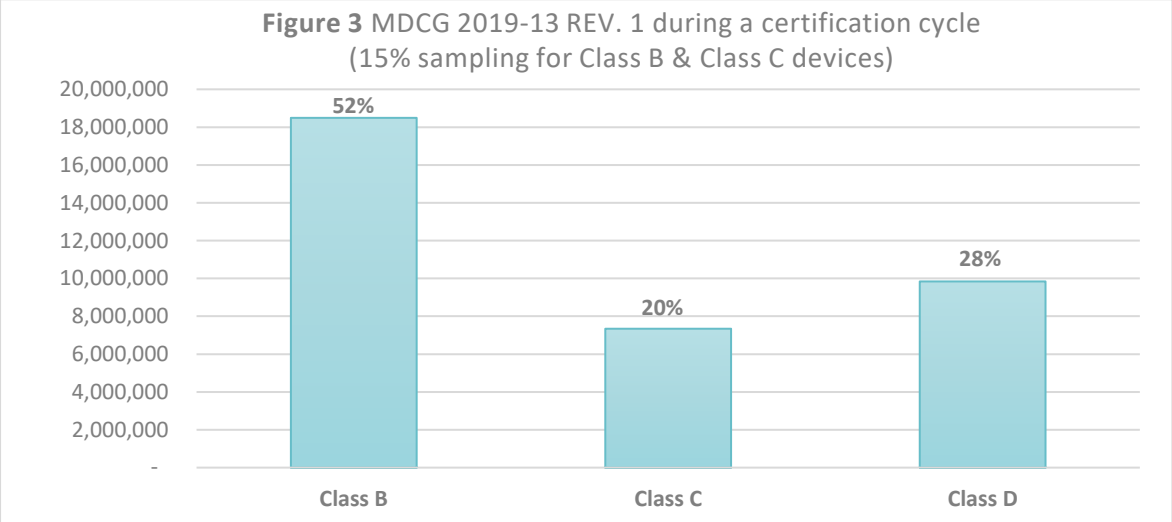


Table 2 and Figure 3 illustrate the estimated sampling costs for the entire IVD sector, assuming Notified Bodies opt for a 15% sampling during a certification cycle. The total costs for sampling would amount to 18.4mln EUR for Class B devices, 7.3mln EUR for Class C devices and 9.8mln EUR for Class D devices. In this case, most of the cost burden for the IVD sector falls on the lowest Class B devices subject to technical documentation review, and the costs for Class C devices seem to be close to those charged for sampling of Class D devices.

These figures show that the total costs for sampling under IVDR based on 15% sampling criteria during a certification cycle are not proportionate to the risk Class (i.e. the lower the Class – the more time the Notified Body spends on sampling).

Table 2 Current costs during a certification cycle: minimum sampling of 15% for Class B and Class C devices

Class	Cost per TD review by NB[iv]	Sampling criteria (%)	# of IVDs on EU market[iii]	# of TDs auto-reviewed by NBs	Investment for TDs review	Invest-ment %
Class B	37,853 EUR	15%	3,256	488	18,487,405 EUR	52%
Class C	37,853 EUR	15%	1,293	194	7,341,589 EUR	20%
Class D	37,853 EUR	100%	260	260	9,841,780 EUR	28%
			Total:	**942**	**35,670,774 EUR**	**100%**



In addition, for device groups with few or very similar devices which have already been sampled, such sampling criteria implies continuous sampling and re-sampling of the same devices, especially for manufacturers either with small device portfolios or device groupings with few devices.

Impact on Small and Medium-Sized Enterprises

While the simulations above provide a general estimation for the entire IVD sector in the EU, it is important to stress that Small and Medium-Sized Enterprises (SMEs) make up around 90% of the medical technology industry[vi] and, given their turnover, the impact on SME organisations may be significantly higher than on large manufacturers. Based on the EU definition of SMEs[vii] and MedTech Europe survey data[iv], the total 5-year external regulatory costs paid to Notified Body to obtain, maintain and re-certify IVDR Quality Management System certificate[3] may constitute between ~1% and ~6% of the total turnover for medium-sized organisations, between ~6% and ~29% – for small organisations and ~29% or more – for micro organisations (see Table 3). Sampling and likely re-sampling of the same devices (given small SME portfolio) may therefore markedly increase the post-market regulatory burden on smaller organisations.

[3] For most Class B and Class C devices only Quality Management System certification is applicable

Table 3 The total 5-year external regulatory costs paid to Notified Body to obtain, maintain and re-certify IVDR Quality Management System certificate

SME turnover[vii]	5-year external manufacturer's regulatory IVDR costs[4,iv]	5-year external manufacturer's regulatory IVDR costs as a % of turnover
Medium-sized enterprise: **10 - 50 million EUR**	585,718 EUR	~1% – ~6%
Small enterprise: **2 - 10 million EUR**	585,718 EUR	~6% – ~29%
Micro enterprise: **≤ 2 million EUR**	585,718 EUR	≥ ~29%

Why does the current sampling approach have little added value?

Simulation data show that sampling costs for Class B and Class C devices may become disproportionately high. Sampling of technical documentation holds value only when it demonstrably contributes to increased device safety and performance. While some measures and criteria established through IVDR and MDCG guidance documents are necessary and essential to fulfilling the main objective of the IVDR to ensure a high level of safety and health in the EU, there are several important reasons why a high percentage of sampling for Class B and Class C devices is not among those essential measures:

1. The purpose of sampling is not to check devices but manufacturers' QMS compliance	As per IVDR section 4.5.2(a,b) of Annex VII, the purpose of technical documentation via sampling review is to assess manufacturers' Quality Management System (QMS) – not the performance of the device. Sampling criteria should be proportionate to ensuring a robust QMS.
2. Technical documentation is already sampled and reviewed for ISO 13485	Technical documentation review, as it is currently defined under MDCG 2019-13 REV. 1 guidance, is an additional layer on top of sampling for technical documentation review performed for International Organisation for Standardisation (ISO) QMS standard for medical devices 13485[5]. A high percentage of technical documentation reviews for Class B and Class C devices offers limited additional benefits for device safety, as many of these aspects are already addressed through compliance with ISO 13485.
3. 15% of technical documentation review has little added value for Class B and Class C devices with stable PMSV data	Many Class B and Class C devices that are being sampled and reviewed are devices with stable PMSV data that have long been on the EU market with no or few vigilance cases (e.g. devices regularly used and tested as part of clinical practice in routine diagnostics). Technical documentation review exceeding 5% is justified for devices associated with an increased risk (e.g. due to increased number of incidents, major QMS non-conformities, etc.). However, it provides limited added value for devices supported by stable PMSV data. Redirecting Notified Body's resources toward files that present increased risk would be a more effective way to enhance patient safety.

[4] The number provided for 5-year external manufacturer's regulatory IVDR costs here excludes internal manufacturer' regulatory IVDR costs (e.g. full-time equivalent (FTE)/personnel costs)
[5] ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

4. A holistic and proactive post-market surveillance system under IVDR ensures that the issues with devices are caught on time	IVDR establishes systemic and interconnected processes of post-market surveillance and vigilance reporting to proactively collect and review experience gained from devices placed on the EU market (e.g., trend reporting, periodic safety update report, post-market surveillance report, post-market performance follow-up, change notification, etc.), all of which feed into Performance Evaluation and risk management of the device. This experience supports the early identification of any need for corrective or preventive actions, thereby contributing to the continued safety of devices available in the public health system. The enlarged, more frequent and more detailed reporting obligations under the IVDR provide an additional layer of safety indication, to which a high percentage of technical documentation sampling for Class B and Class C devices adds limited value.
5. Similarity of devices in the same group	Where devices in the same generic device group or device category are highly similar or based on the same technology, quota-based sampling becomes a highly duplicative activity.

The impact of ADAPTING % for technical documentation sampling under IVDR

As discussed above, sampling is only one of several IVDR tools to assess the safety and performance of devices on the EU market, and it often duplicates other, more effective means (e.g. annual surveillance, change notification, etc.). This redundancy raises questions about the need for a high % of sampling for Class B and Class C devices among other PMSV tools under IVDR. At the least, the sampling rate should be reduced for devices that have been on the EU market for an extended period and are supported by stable PMSV data.

MedTech Europe recommends that the sampling approach under the IVDR would be significantly more risk-proportionate if the following changes were implemented (either through MDCG 2019-13 REV. 1 guidance revision or via an implementing act):

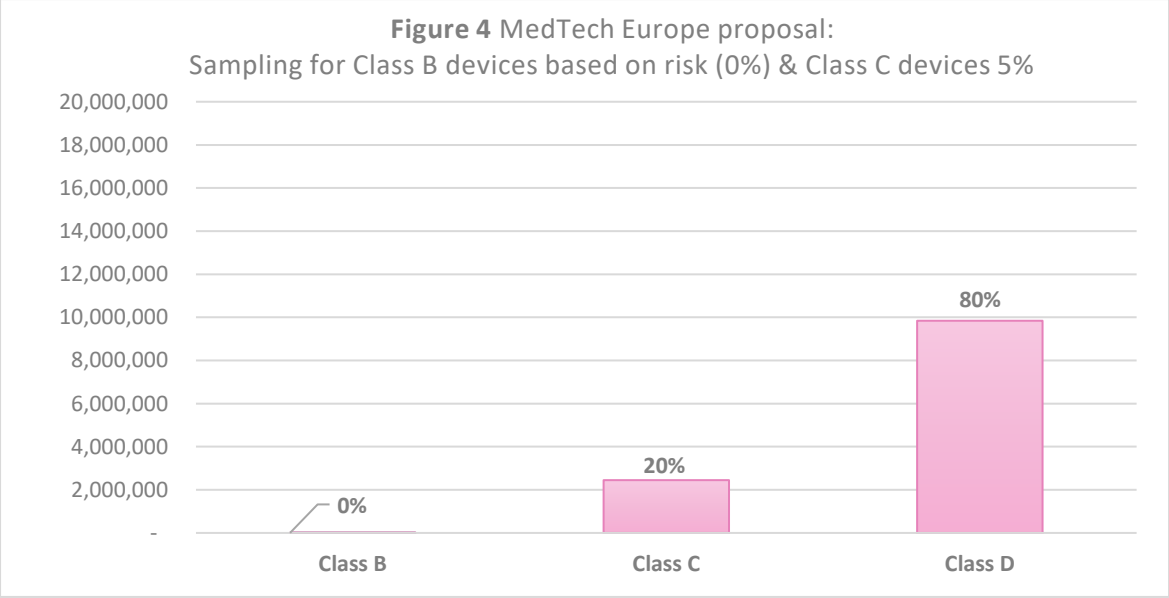
1.	**Adopt 5 % as the default recommended sampling %**	Since 5% instead of 15% sampling has already been used *de facto* for the first certification cycle by most Notified Bodies, we suggest that this should be made a default recommended sampling percentage for initial sampling, at least for devices that have been on the EU market for a prolonged period and are supported by stable PMSV data.
2.	**No sampling for Class B devices after 1st certification cycle**	After the first certification cycle, automatic technical documentation sampling should be removed for Class B devices. Instead, Notified Bodies should initiate sampling based on increased risk.
3.	**5% sampling for Class C devices**	For Class C devices, sampling should be set at 5%.
4.	**No re-sampling for generic device groups and device categories with few or similar devices**	For generic device groups and device categories with few or similar devices which already have been sampled, further sampling should not be required – even during annual surveillance visits – unless triggered by a concern arising from PMSV data.
5.	**Higher % of sampling only when it adds value**	A higher sampling percentage should be considered only when it adds meaningful value for safety and performance of devices (e.g. innovative devices and devices with unstable PMSV data).

As demonstrated in the simulation below, introducing a more risk-based sampling criteria for devices that have been on the EU market for an extended period with stable PMSV data would significantly reduce the overall cost burden on the sector, while enhancing the risk-proportionality of the system. This approach would notably lower both costs and administrative burden for manufacturers, especially SMEs, and support a more efficient allocation of Notified Bodies' resources.

Table 4 and Figure 4 illustrate the projected impact of MedTech Europe's proposal on sampling burden in the IVD sector following the first certification cycle. Under this model, the total costs for sampling would amount to 0 EUR for Class B devices (unless the need for sampling is triggered based on criteria like device being innovative or having unstable PMSV data), 2.4mln EUR for Class C devices and 9.8mln EUR for Class D devices. In such scenario, most of the cost burden for the IVD sector falls on the highest Class D devices, followed by Class C devices and it is the least burdensome on Class B devices. Such an outcome reflects a more risk-aligned approach and reduces unnecessary burden for devices with similar profiles.

Table 4 Current costs AFTER 1st certification cycle: 0% for Class B and minimum of 5% for Class C devices

Class	Cost per TD review by NB[iv]	Sampling criteria (%)	# of IVDs on EU market[iii]	# of TDs auto-reviewed by NBs[6]	Investment for TDs review[7]	Invest-ment %
Class B	37,853 EUR	0%	3,256	Based on risk	Based on risk (0 EUR)	(0%)
Class C	37,853 EUR	5%	1,293	65	2,447,196 EUR	20%
Class D	37,853 EUR	100%	260	260	9,841,780 EUR	80%
			Total:	**325**	**12,288,976 EUR**	**100%**



[6] Regardless of sampling criteria including for Class B, the Notified Body still should have discretion to review technical documentation based on risk arising from PMSV activities or novelty of technology.
[7] Please consider that the estimation reflects only the costs from one unit and not the entire organization (this would be much higher for entire organisation).

Conclusion

While ensuring the availability of safe and effective devices in the EU is and will undoubtedly remain the main purpose of the IVDR, there are many areas in the current regulation and MDCG guidance documents which prompt improvement with regards to their ability to contribute to achieving this objective. Based on recent data from the EY survey on the Study on Governance and Innovation commissioned by the European Commission, administrative burden has been identified as a key barrier for IVDs' innovation in Europe, with SMEs being impacted the most[8]. The need for change is evident and has been backed by recent calls from the European Commission for less reporting and less bureaucracy[9].

Based on MedTech Europe proposal outlined in this paper, one area where improvement is both necessary and feasible is technical documentation sampling. MedTech Europe would like to draw the attention of regulators to the fact that the current IVDR sampling criteria should change to a more risk-based approach. As demonstrated in the simulations, the current sampling approach is not sustainable for the IVD sector. The high regulatory burden under the IVDR is already contributing to devices being discontinued, which is disproportionately impacting SMEs[iii].

More specifically, sampling requirements for Class B and Class C devices should be adjusted to a more risk proportionate approach. A more proportionate approach would involve removing automatic technical documentation sampling for Class B devices (unless prompted by PMS data) and changing sampling for Class C devices to 5% after the first certification cycle. Furthermore, there should be no further sampling of files where all devices in a group have already been sampled, or where the devices are sufficiently similar to make sampling a truly arbitrary exercise. A higher sampling proportion should only be done if it provides meaningful added value for safety and performance of devices. For Notified Bodies, this would enable a more efficient use of resources, allowing greater focus on post-market surveillance activities that offer more meaningful contributions to device safety, such as the timely assessment of changes.

Importantly, implementing these changes would not require a revision of the Regulation itself. They could be achieved through an update to MDCG 2019-13 REV. 1 guidance or via an implementing act. This makes the proposed approach both practical and immediately actionable within the current legal framework — allowing for a meaningful reduction of unnecessary administrative burden on both manufacturers (especially SMEs) and Notified Bodies without significant effort.

Finally, it is important to note that MedTech Europe is currently proposing that certification validity be extended beyond its current 5 years to better align with the actual lifetime of the device. While this paper does not address that topic in detail, it is important to ensure that sampling criteria are appropriately adjusted during the lifetime of the devices covered by EU QMS certificates, unless there are PMSV considerations requiring higher frequency of sampling.

[8] Information provided in this paragraph is based on the data from EY study on regulatory governance and innovation in the field of medical devices which was commission by the European Commission, and which was shared in MDCG meetings with stakeholders. The full report is still to be published.
[9] Statement at the European Parliament Plenary by President Ursula von der Leyen, candidate (at that time) for a second mandate 2024-2029

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.

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References

[i] Although the IVD Regulation does not specifically regulate 'professional laboratory-use' devices as a term, it is those devices which are subject to sampling under EU Quality Management System certification, given that Class D, near-patient tests and self-tests are subject to 100% technical documentation review as part of the requirement to gain Technical documentation Assessment certification.

[ii] MDCG 2019-13 Rev.1 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation, December 2024 rev.1

[iii] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices, which was commissioned by the European Commission, total IVDs undergoing IVDR conformity assessment by October 2023

[iv] MedTech Europe 2024 Regulatory Survey: key findings and insights

[v] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices, which was commissioned by the European Commission, 3 out of 5 main reasons for IVD manufacturers having stopped or planning to stop production/marketing/supply of some IVDs to the EU market are related to costs (i.e. products with low sales volumes, product revenue does not justify cost to reapprove device under the IVDR, products with low profitability)

[vi] MedTech Europe Facts & Figures 2024

[vii] Based on European Union SME definition, SME annual turnover for medium-sized organisation ≤ 50 million EUR, for small organisation ≤ 10 million EUR, and for micro organisation ≤ 2 million EUR, https://single-market-economy.ec.europa.eu/smes/sme-fundamentals/sme-definition_en