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MedTech Europe Survey Report

MedTech Europe Survey Report analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies

**Survey commissioned by the Competent Authorities for Medical Devices
(CAMD) Task Force on Certification Capacity Monitoring**

Survey data was gathered during 8 – 28 July 2021

Executive summary

At least 22% of IVD tests on the market today will be discontinued. In addition to this, **many more IVDs will be lost if no urgent solutions are found** to address the existing transition issues to the IVD Regulation.

The added loss is **avoidable and preventable**.

The highest **proportionate loss of IVDs will come from small and medium sized manufacturers**, many of whom make niche products in smaller volumes and who may be more prone to run out of business.

The **lack of a sufficient number of operational Notified Bodies** is the first obstacle that manufacturers face on their way to certification.

Key figures:

The survey represents an estimated **90%** market revenue coverage.

An unavoidable decrease of up to **22%** of IVDs (when comparing the devices under IVDD and the total number *intended* to be CE marked under IVDR).

A **~10-fold** or **736%** increase in the number of tests needing Notified Body certificates.

As few as **24%** will remain on the market in the worst-case projection (many of these would be the lowest risk class A which cannot be used independently but only coupled with devices of higher-class B, C and D reagents).

Only **47%** of manufacturers have a contractual agreement with a Notified Body to assess and certify their quality management systems and IVDs under the new IVDR; moreover, such a framework agreement does not yet guarantee that the Notified Body can cover and assess all manufacturers tests within the regulatory deadline of May 2022.

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Introduction

To align with significant developments in technology and healthcare over the last 20 years, the European Union has revised laws governing *in vitro* diagnostic medical devices (IVDs). The existing IVD Directive (IVDD) was first published in 1998 and will be replaced by the new IVD Regulation (IVDR) on 26 May 2022. The new EU regulation on IVDs entered into force in May 2017 at the same time as the new regulation for non-IVD medical devices. At that time, the priority for the EU was to ensure a robust, transparent and sustainable regulatory framework and maintain a high level of safety, while supporting innovation for medical devices *and* IVDs.

The new regulations were intended to progressively replace the existing directives after a transition period of three years for medical devices (extended to four years due to the COVID19 pandemic) and five years for IVDs. The IVD sector was given two years more than the MD sector (now reduced to one year) to reflect the more significant and profound shift in the new IVD regulatory requirements requiring significantly more infrastructure and capacity than ever before.

Many more IVDs would be covered by the scrutiny of Notified Bodies and would need a new (or renewed) certificate under the regulation. Early estimates suggested an 80:20 split - 80% of devices did not need a certificate under the IVDD and 20% did. It was expected that the IVDR would reverse this to 20:80 – 20% of devices would not need a certificate and 80% would. The results of this survey show that even this was an underestimate: the actual split is 92:8 under the IVDD and 22:78 under the new regulation. In essence, under the IVD Regulation, ten times more devices will need a certificate from a Notified Body - 78% of the total on the market, compared to only 8% of the total under the IVD Directive.

Because of this major shift in the number of devices needing certificates, Notified Body capacity is critical to the success of the EU IVDR. However, designation has been slow and uncertain. **There were 18 Notified Bodies designated to the existing IVDD¹ but only 6 Notified Bodies are designated to the IVDR², most of them recently.** On the other hand, there are 22 Notified Bodies newly designated to the Medical Devices Regulation³.

¹ NANDO listing for IVD Directive 98/79/EC https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20

² NANDO listing for IVDR 2017/746 https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

³ NANDO listing for MDR 2017/745 https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

At the time of writing, we are now only less than 9 months before the date of application – a hard stop for the majority of IVDs with no grace period or (for practical reasons) sell-off provision to rely on. Although the Commission's joint implementation plan⁴ for IVDR addresses some of the work still to do, we hope these survey results will impress on the Competent Authorities and the European Commission that much time and effort is still needed to ensure that EU IVD medical tests do not fall off a cliff-edge. In particular, a viable infrastructure and necessary time to complete certification for all categories of IVDs should be provided.

As ever, industry stands by ready to support the full and proper implementation of this regulation.

Survey Methodology

In preparation for the imminent transition to a new regulatory framework for IVDs, EU Competent Authorities for Medical Devices (CAMD) commissioned MedTech Europe to run a survey of the IVDR market.

Between 8th and 28th July 2021, the survey was sent to all IVD manufacturer members of MedTech Europe. National Associations were encouraged to invite their own member manufacturers to participate. Only one submission per manufacturer was allowed. The numerical results have been aggregated and are being published in conformity with the legal disclaimer. MedTech Europe has shared an initial report with CAMD and the European Commission on 12 August. In that report, we also included individual, anonymised comments regarding the Notified Body and IVDR transition – such individual comments are not being published as part of this report, however, MedTech Europe summarises the themes under the section entitled, 'IVDR transition – individual comments made by respondents'.

115 manufacturers participated in the survey⁵. This represents an estimated market revenue coverage of 90%. Most respondents (82) were Small and Medium-sized Enterprises (SME) with 33 responses from larger manufacturers.

Summary of Results

Number of Products Intended to be Transitioned Across from IVDD to IVDR

Manufacturers are hoping to transition up to 31118 IVDs into the new regulation compared with 39844 IVDs under the existing Directive. This represents an unavoidable drop of 22% of IVDs that will be no longer be available to health services for patient care.

⁴ Joint implementation and preparedness plan for Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_joint-impl-plan_en.pdf

⁵ compared with 65 responses (80% of market share) in the IVDR market readiness survey coordinated during January-February by MedTech Europe on behalf of the European Commission

The greatest proportionate loss will come from SME manufacturers many of whom make niche products and who may be less able to endure loss of business.

It is not clear to what extent EU and global health systems are prepared for this unavoidable loss.

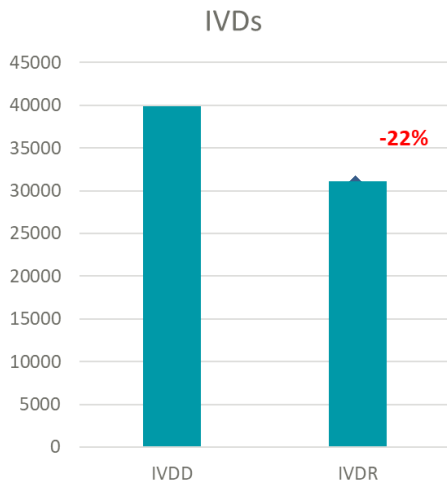


Figure 2 Some IVDs will be unavoidably lost in the transition to IVDR

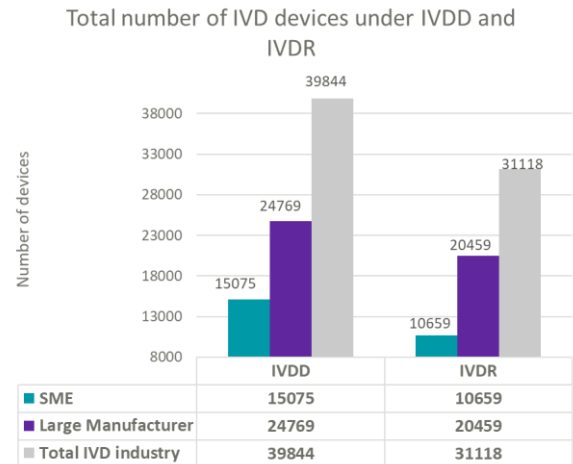


Figure 1 SMEs will lose a greater proportion of their market

Transition of Existing Certification under IVD Directive (98/79/EC) to the New IVD Regulation (2017/746) – the ‘grace period’

Currently 92%⁶ of IVDs do not need to have a certificate from a Notified Body. Certificates are only required for 8%⁷ of IVDs listed in Annex II of the IVD Directive (IVDD) or which are intended for self-testing. If the Notified Body who issued the certificate agrees, then the manufacturer may be able to make use of a ‘grace period’ up to May 2024 set out in the transitional provisions in article 110(3) of the IVD Regulation (IVDR).

For the 92% of IVDs who cannot apply for a certificate under the IVDD, manufacturers have no grace period and must fully apply IVDR from May 2022.

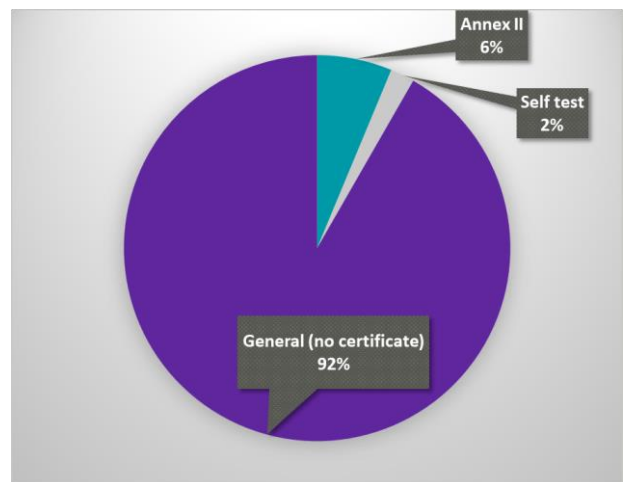


Figure 3 Few IVDs have certificates under IVDD Directive

⁶ 92% (36542/39844)

⁷ 8% (3302/39844)

The ‘sell-off’ provision in article 110(4) for devices already in the supply chain will be of very limited value to reagents (class B, C and D IVDs) that tend to have a limited shelf-life and so move through the supply chain very quickly. The ‘sell-off’ period is more important for products with a longer shelf-life (e.g., instrumentation, the vast majority of which do not require certification under the IVDR).

Number of new certificates needed for IVDR

As a result of IVDR, 78%⁸ of devices will need a new certificate (including those needing to renew existing certificates). This represents a 736%⁹ increase in IVDs needing a certificate compared with the IVDD. This data is important for understanding how much more Notified Body capacity is needed to support the certification process under the IVDR.

	Number of devices that need a certificate
IVDD	3.302 (8%)
IVDR	24.346 (78%)

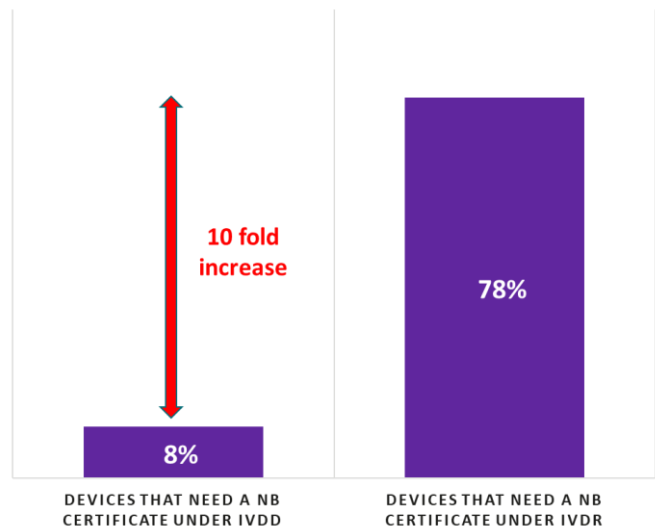


Figure 4 Many more new certificates are needed for IVD regulation

Certification status for IVDR

New certificates have already been issued for 12%¹⁰ of IVDs that will need them for IVDR. Manufacturers are predicting that at least 28%¹¹ of IVDs will not be covered by a certificate by the May 2022 date of application. This leaves 60%¹² of all IVDs where certification either is ongoing or where the respondent has not provided information about their status.

⁸ 78% (24346/31067)

⁹ 736% (24346/33302)

¹⁰ 12% (2878/24346)

¹¹ 28% (6874/24346)

¹² 60% (14584/24346)

Number of devices for which an IVDR certificate was issued up to date	Number of devices where no information was provided if IVDR certificate will be issued on time	Number of devices for which the IVDR certificates will not be issued by May 2022
2878	14584	6874

Figure 5 There is still uncertainty about how many certificates will be issued in time

While the survey data indicates that 21%¹³ of manufacturers have no issues in completing certification, it can be expected that some of the ‘60%’ category hoping to be certified will be at varying degrees of risk of not being certified on time. This is because we are nine months from the date of application; Notified Bodies predict anything from 10 to 14 months for a new certificate to be issued. Ideally ~six months are needed after the certificate is issued for the manufacturer to manufacture and label the device, communicate the availability of test menus to laboratories and healthcare professionals, provide the device to the supply chain and ensure consistent availability for the user. Up to 12 months may be needed for registering the device for export to international markets.

Additional certification procedures are needed for some IVDs

For some IVDs, additional processes are needed before Notified Bodies can issue the required certification. These IVDs include class D IVDs, companion diagnostics and devices for self-testing or near-patient testing. All such devices each require individual EU technical documentation assessment; Class

Class D IVDs	Self-tests	Near Patient Tests	Companion Diagnostics	Total
1261	588	1467	170	3486

Figure 6 Some IVDs need additional certification

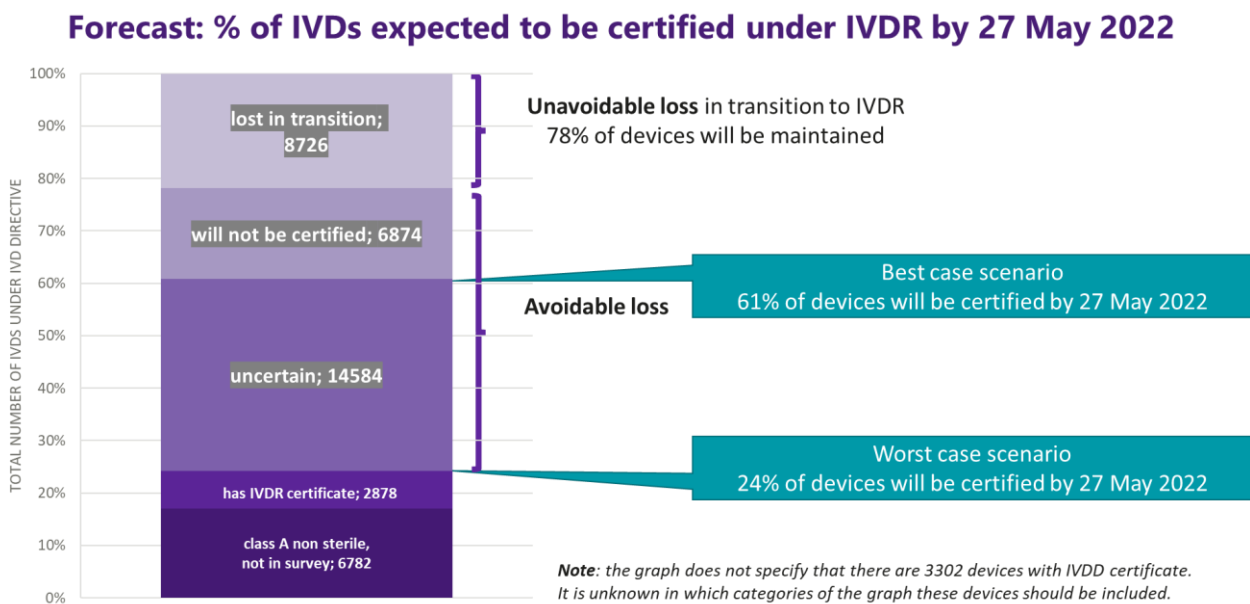
D and companion diagnostics further require the intervention of additional specific bodies during the certification process. It is possible that these IVDs will be disproportionately affected by delays to certification due to the increased Notified Body workload and lack of capacity. In a recent publication, TEAM NB have [raised uncertainty](#) that class D devices will be certified by May 2022 due to lack of infrastructure and time needed to certify.

¹³ 21% (24/115)

Best- and Worst-Case Scenarios

In transitioning from IVDD to IVDR, manufacturers predict that as a bare minimum, 22%¹⁴ of IVDs currently on the EU market will be lost. Therefore, a maximum of 78%¹⁵ of current IVDs could possibly make the transition to IVDR, and with no immediate action, it can be expected that many more products will be lost. Here we present best-case and worst-case scenarios to detail the potential extent of the loss.

Figure 7 Best- and worst-case scenarios



There are two groups of devices where there is no immediate concern regarding certification:

- 1) class A (non-sterile) IVDs that do not need IVDR certification;
- 2) IVDs that already have a new IVDR certificate.

We calculate that these three groups represent up to 24%¹⁶ of the IVD market in the EU. 3302 IVDs have an existing IVDD certificate may be eligible for the grace period; If no action is taken, in the worst case, these may be the only devices that will be available after the date of application (of course, some additional certification is to be expected by May 2022). It is important to understand that class A devices are *not* sufficient to provide IVD medical tests on their own; class A IVDs (such as instrumentation, software which only drives and influences, buffer solutions, most accessories) are almost always intended to operate in combination with one or more class B, C or D reagents and thus rely on the availability of class B, C and D devices (or in limited cases, their IVDD equivalents)¹⁷.

¹⁴ 22% (8777/39844)

¹⁵ 78% (31067/39844)

¹⁶ 24% (9660/39844)

¹⁷ If the class B, C or D device is not available then the usefulness of the class A non-sterile device becomes limited to the few situations where an IVDD version of the reagents is available following IVDR Art. 110 (3) or (4). Given that reagents tend to have a shelf-life which is measured in months, most would only be able to use Art. 110 (4) for a short period of time.

Even in the best case if no further action is taken, we predict that 39%¹⁸ of the IVD market in the EU will almost certainly not be available from May 2022¹⁹.

Obstacles to certification: Notified Body capacity

The survey provides quantitative and qualitative data on why so few IVDs will be covered by a Notified Body certificate in time for May 2022. 53%²⁰ of respondents have no agreement in place with a Notified Body. Even where agreements are in place this does not guarantee which or how many devices will be certified in time for the date of application of IVDR. 74%²¹ of respondents had observed some obstacle in starting or completing certification. Here Notified Body capacity and other lack of infrastructure were the resounding responses from manufacturers which gave comments (see Annex for comments).

Obstacle	% of responses	Meaning
<i>Not yet designated</i>	29%	The manufacturer is working with a Notified Body under IVDD that has not yet been designated under IVDR
<i>Response times delayed</i>	26%	The manufacturer has experienced a delay in Notified Bodies responses
<i>Application not accepted</i>	20%	The manufacturer submitted an application to Notified Body(ies) and the application has been rejected or not accepted
<i>Will not meet May 2022 deadline</i>	15%	The Notified Body has warned the manufacturer that they will not get certification for some or all products before May 2022
<i>Selective certification</i>	10%	Notified Bodies cannot process applications for some devices (e.g., class D, CDx or other) or has asked the manufacturer to prioritise which devices must have certificates

Figure 8 Top 5 responses for obstacles to certification

Many manufacturers have been working under the IVDD and or under ISO 13485 with Notified Bodies that have yet to be designated under the IVDR. Transitioning to a new Notified Body can take time due to the need to re-do ISO 13485 certification and adjust documentation to the new Notified Body procedural preferences.

¹⁸ 39% (15604/39844)

¹⁹ This is on top of the 22% drop when we compare the total number of devices currently on the market under IVDD versus the total number of devices which are intended to be placed on the market under IVDR.

²⁰ 53% (61/115)

²¹ 74% (85/115)

For others, the Notified Body response times to request for a contract and agreement is delayed or their requests have been rejected by the Notified Bodies which they approached. Where an agreement is in place, some manufacturers noted that their Notified Body warned them that not all products will be certified by the date of application; a prioritisation of products becomes necessary even if the manufacturer has done the necessary work to prepare the device for certification and had planned to continue supporting those products on the European and global markets.

Obstacles to certification: other missing infrastructure

Other missing infrastructure concerns include EUDAMED, EU reference laboratories and expert panels. The pressing need for guidance documents was mentioned by many. Without guidance documents there is a greater risk of inconsistent decisions by manufacturers, Notified Bodies, and competent authorities. Manufacturers must spend time and money working out their own solutions and then check that the solutions remain valid once guidance is issued. The main guidance documents mentioned in the survey cover:

- *Performance evaluations* – to remediate existing clinical evidence or create new clinical evidence for new products.
- *OEM (“original equipment manufacturer”) products* – many IVDs are relabelled and rebranded by the legal manufacturer who places the device on the market in their own name. Some information is proprietary and original manufacturers may be reluctant to share this with the new legal manufacturer. It still isn’t clear how or indeed whether this practice can continue under IVDR.
- *Class D scrutiny* – the new classification rules mean that there will be many new class D IVDs that have never had a certificate and will be subject to additional review by an expert panel before a certificate can be issued unless common specifications are available. There will be only one expert panel for IVDs (compared with ten for medical devices). It is not clear what the expert panel will review and what is the basis for their decision making and how this works with the EU reference laboratory validation process.
- *Companion Diagnostics* – the new need for a medicines authority to review some aspects of a manufacturer’s application for a Notified Body certificate means that there is still considerable uncertainty around how the two organisations will interact with each other (e.g., what information to share, the basis for decision making and the timescales).
- *Clinical Trial Assays* – it is not clear which assays used in clinical trials of new medicines will need to meet the new IVDR requirements.

IVDR transition – individual comments made by respondents

When asked if they have challenges to start or complete IVDR certification, 74% said yes. The comments given reflect the kinds of challenges they are experiencing. These individual comments have been

anonymised and shared exclusively with CAMD. This report describes the main themes: lack of Notified Body capacity was at the top, closely followed by a general lack of regulatory infrastructure in other areas such as, expert panel, EU reference laboratories, EUDAMED, key guidances and standards, Common Specifications. COVID19 has caused disruption to clinical performance studies for new and existing devices. A focus on MDR has prevented some manufacturers from getting their IVDD certificates renewed so that they can make use of the 'grace period' provided for in the transition provisions set out in article 110. There is a lack of awareness among customers and economic operators of what the requirements and impact of IVD regulation will be. Unless customers can prepare for the anticipated attrition of IVDs, there will be a considerable interruption to clinical diagnostic services across health systems. These comments pointed to risks of supply continuity to EU and globally.

Conclusion

70% of all clinical decisions are made using IVDs²². The impact of IVDs should not be underestimated. Nor should we underestimate the impact of the loss of IVDs to EU healthcare systems. This survey predicts a significant loss of IVDs from the market, from the highest risk through to the lowest risk class of IVDs. Categories of IVD such as companion diagnostics, self-tests and near-patient tests would also be affected.

The lack of IVDR infrastructure is the main reason stated for this expected and avoidable loss. In the early days of the new regulation, it had seemed possible to create the Notified Body capacity, the guidance and other infrastructure, but with the imminent date of application there is no longer enough time.

The number of IVDs that need a Notified Body is ten-fold greater under IVDR compared to IVDD.

Without immediate action by the European Commission, somewhere between 22% and 76% of IVDs will be lost to EU and global health services.

Small and medium-sized enterprises are most likely to be affected.

Caught up in this backlog and not reported in this survey are new and emerging products that would help the EU's ambition to support innovation in medical care.

This survey indicates the urgent need for action on the IVDR regulatory framework and the fast-approaching date of application, to safeguard and support medical diagnostics in Europe.

²² BIVDA report "The value of IVDs"
[https://www.bivda.org.uk/Portals/0/documents/Reports/the_value_of_ivds_8pp_web_09052018122249%20\(23\).pdf?ver=2019-10-30-162646-720×tamp=1572452853776#:~:text=It%20is%20estimated%20that%2070.nation%20should%20not%20be%20underestimated.](https://www.bivda.org.uk/Portals/0/documents/Reports/the_value_of_ivds_8pp_web_09052018122249%20(23).pdf?ver=2019-10-30-162646-720×tamp=1572452853776#:~:text=It%20is%20estimated%20that%2070.nation%20should%20not%20be%20underestimated.)

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.

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