Initial Survey Report 12 August 2021

(Final survey report expected by early September)

CAMD Survey – Market composition of *In vitro* Diagnostic Medical Devices (IVDs)

Survey coordinated by MedTech Europe

MedTech Europe
from diagnosis to cure

‘Take home’ messages:

The survey predicts a significant loss of IVDs from EU and global markets for use in the care and treatment of patients.

Some loss is unavoidable, but much is avoidable. All the loss is predictable.

Lack of regulatory infrastructure is the most common reason given – particularly Notified Body capacity.

The survey in numbers:

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 products needing Notified Body certificates

As few as **32%** of IVDs remaining on the market in the worst-case projection (many of these would be class A which rely on the availability of corresponding class B, C and D reagents)

Only **47%** of manufacturers have an agreement with a Notified Body (which itself is not a guarantee that all their products are covered under that agreement)

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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 3 years for medical devices (extended to 4 years due to the COVID19 pandemic) and 5 years for IVDs. The IVD sector was given 2 years more than the MD sector (now reduced to 1 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. 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 78:22 under the new regulation.

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 IVDD[1] but only 5 Notified Bodies are designated to the IVDR[2], most of them recently.** On the other hand, there are 22 Notified Bodies newly designated to the Medical Devices Regulation[3].

We are now only 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 plan[4] 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

[1] NANDO listing for IVD Directive 98/79/EC https://ec.europa.eu/growth/tools-cdatabases/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
[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

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.

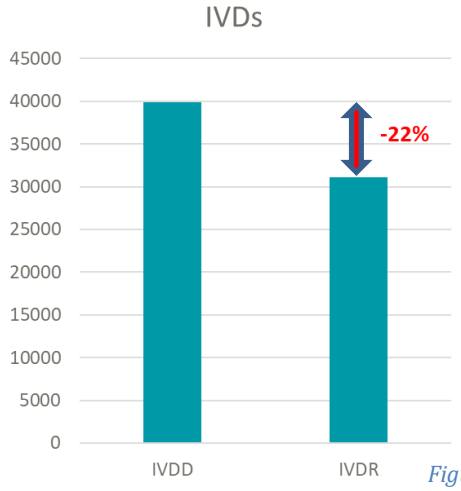
Between 8th and 28th July 2021, the survey was sent to all IVD manufacturer members of MedTech Europe. National Associations were encouraged to invite their own member manufacturers to participate. Only one submission per manufacturer was allowed. The numerical results have been aggregated. Each respondent has granted us permission to share this data with CAMD and the European Commission. The Commission may in turn share these results with the national IVD competent authorities of the Member States.

115 manufacturers participated in the survey[5]. 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.

This report should be considered together with the accompanying slide deck presentation in Annex I which contains all the data which has emerged from the survey and the details of calculation. In Annex II we included

Summary of results

Number of products intended to be transitioned across from IVDD to IVDR



Manufacturers are hoping to transition up to 31067 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.

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.

Figure 1 Some IVDs will be unavoidably lost in the transition to IVDR

[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

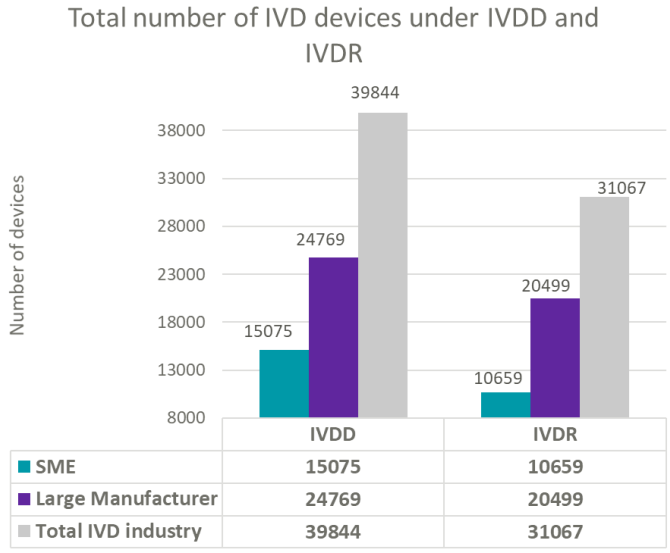


Figure 2 SMEs will lose a greater proportion of their market

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

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).

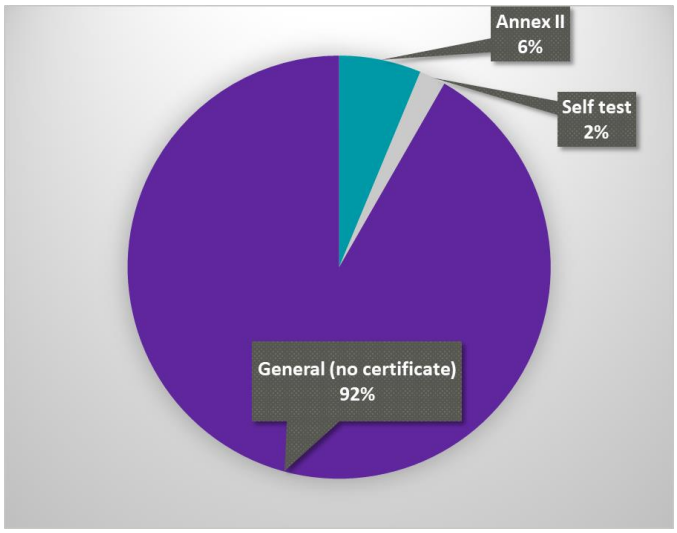


Figure 3 Few IVDs have certificates under IVDD

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. 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).

[6] 92% (36542/39844)
[7] 8% (3302/39844)

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	3.305 (8%)
IVDR	24.346 (78%)

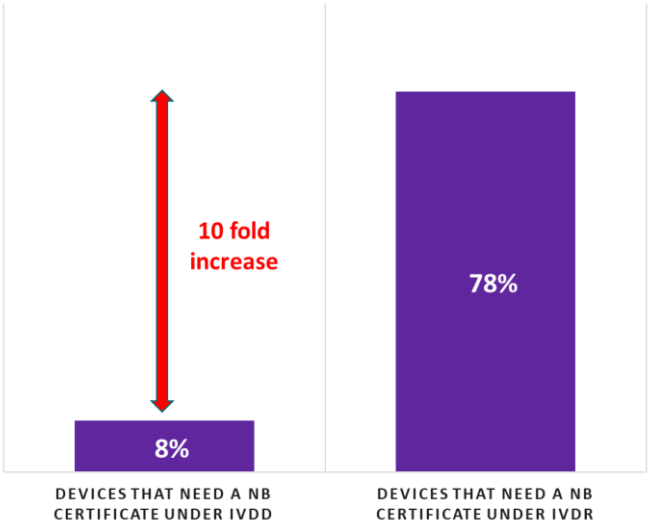


Figure 4 Many more new certificates are needed for IVD regulation

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 22%[11] of IVDs will not be covered by a certificate by the May 2022 date of application. This leaves 66%[12] of all IVDs where certification either is ongoing or where the respondent has not provided information about their status.

	Certificate issued	No certificate issued yet	Certificates will not be issued by May 2022
Total	**2878**	**16112**	**5356**

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

[8] 78% (24346/31067)
[9] 736% (24346/3305)
[10] 12% (2878/24346)
[11] 22% (5356/24346)
[12] 66% (16112/24346)

While the survey data indicates that 21%[13] of manufacturers have no issues in completing certification, it can be expected that some of the '66%' category hoping to be certified will be at varying degrees of risk of not being certified on time. This is because we are 9 months from the date of application; Notified Bodies predict anything from 10 to 14 months for a new certificate to be issued. Ideally ~6 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

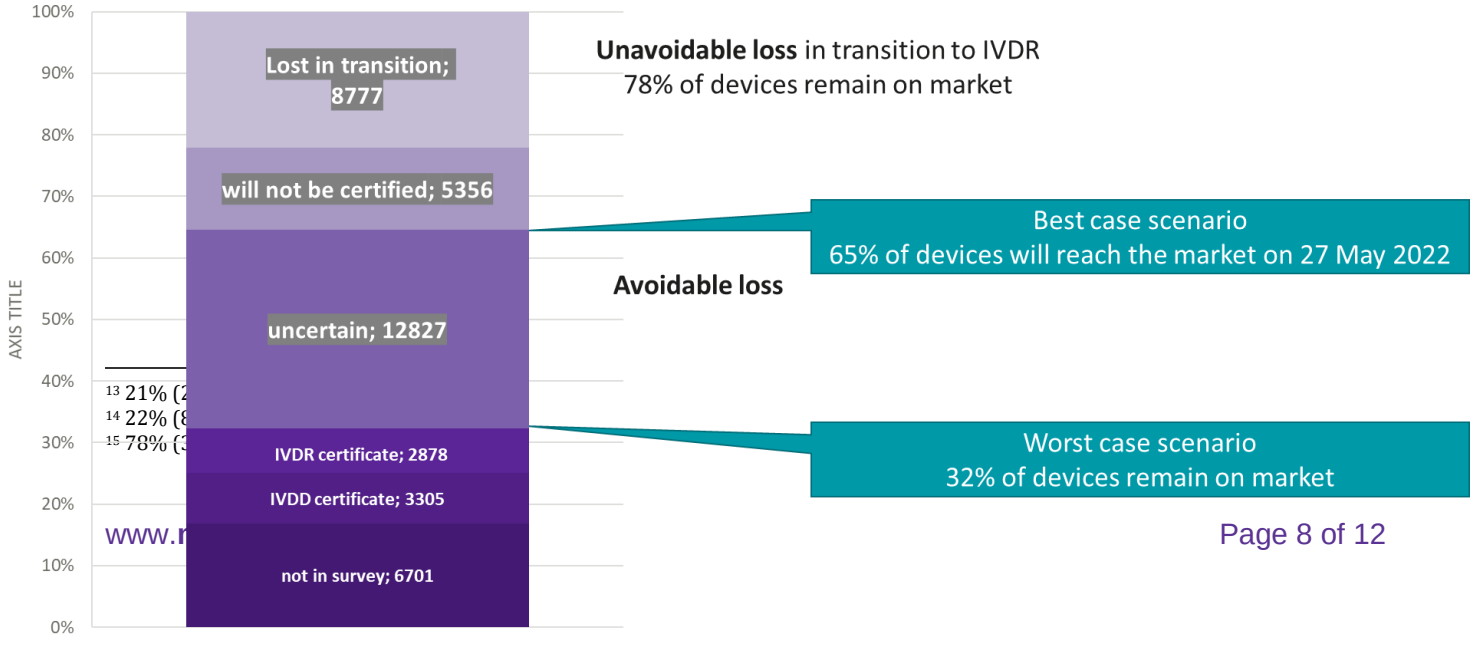
For some IVDs, additional processes are needed before Notified Bodies can issue the required certification. These IVDs include class D IVDs, companion diagnostics and devices for self-testing or near-patient testing. All such devices each require individual EU technical documentation assessment; Class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

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

Figure 6 Some IVDs need additional certification

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.



[13] 21% (2
[14] 22% (8
[15] 78% (3

Figure 7 Best- and worst-case scenarios

There are three 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 have an existing IVDD certificate and may be eligible for the grace period;
3) IVDs that already have a new IVDR certificate.

We calculate that these three groups represent up to 32%[16] of the IVD market in the EU. 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 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].

Even in the best case if no further action is taken, we predict that 35%[18] of the IVD market in the EU will almost certainly not be available from May 2022[19].

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**
Not yet designated	29%	The manufacturer is working with a Notified Body under IVDD that has not yet been designated under IVDR
Response times delayed	26%	The manufacturer has experienced a delay in Notified Bodies responses

[16] 32% (12884/39844)
[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.
[18] 35% (14133/39844)
[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)

Application not accepted	20%	The manufacturer submitted an application to Notified Body(ies) and the application has been rejected or not accepted
Will not meet May 2022 deadline	15%	The Notified Body has warned the manufacturer that they will not get certification for some or all products before May 2022
Selective certification	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.

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 – general comments

Finally, the survey looked at IVDR transition more generally. In addition to infrastructure, manufacturers commented on the risk to supply continuity in the EU and globally. 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' set out 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.

Conclusion

70% of all clinical decisions are made using IVDs[22]. 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 68% of IVDs will be lost to EU and global health services.

[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&timestamp=1572452853776#:~:text=It%20is%20estimated%20that%2070,nation%20should%20not%20be%20underestimated.

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.

This report is followed by one annex, please see next pages:
Annex I – slide deck containing the raw aggregated data

The Annex II – CONFIDENTIAL – comments received by respondents (these are individual comments which were shared exclusively with CAMD and the European Commission).

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.

For more information, visit www.medtecheurope.org.

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MedTech Europe
from diagnosis to cure

Annex I

CAMD* Survey Market composition of *in vitro* diagnostic medical devices (IVDs)

Coordinated by MedTech Europe 8 – 28 July 2021

*EU Competent Authorities for Medical Devices (CAMD)

12 August 2021

regulatory@medtecheurope.org

How to read this slide deck

- **115 IVD manufacturers participated in the survey representing over 90% of the total European IVD market in terms of revenue. Participants answered more than 20 questions providing granular data about the number and status of IVD devices under the IVD Directive and IVD Regulation.**

- **This slide deck contains raw, aggregated and detailed quantitative and qualitative data obtained from the survey and should be considered together with the accompanying *Survey Initial Report* which is an in-depth analysis. Some slides contain data which is correlated to company size**

- **A brief analysis is offered on each slide to provide context and aid in understanding the data.**

Executive Summary

This survey predicts a significant loss of IVDs from the market, affecting most risk classes and categories. This loss is predictable and avoidable.

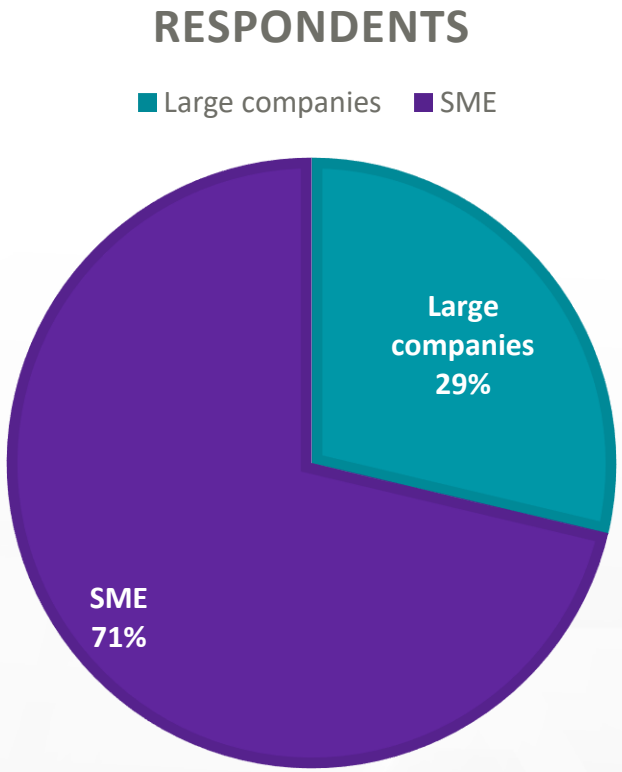
The lack of IVDR infrastructure is the main reason stated for this expected loss

This survey indicates the need for action on the IVDR regulatory framework and approaching date of application. This (legal) action should apply to IVDs of all classes: D, C, B and A

Who responded to the survey?

Respondents	115* representing a rough estimated market revenue coverage of 90%**
SME	82
Large companies	33

More SMEs responded than large companies. This reflects the IVD industry in the EU.



*Compared to 65 respondents in the last survey of this type in January-February 2021

**MedTech Europe estimations based on The European IVD Market Statistics Report 2020

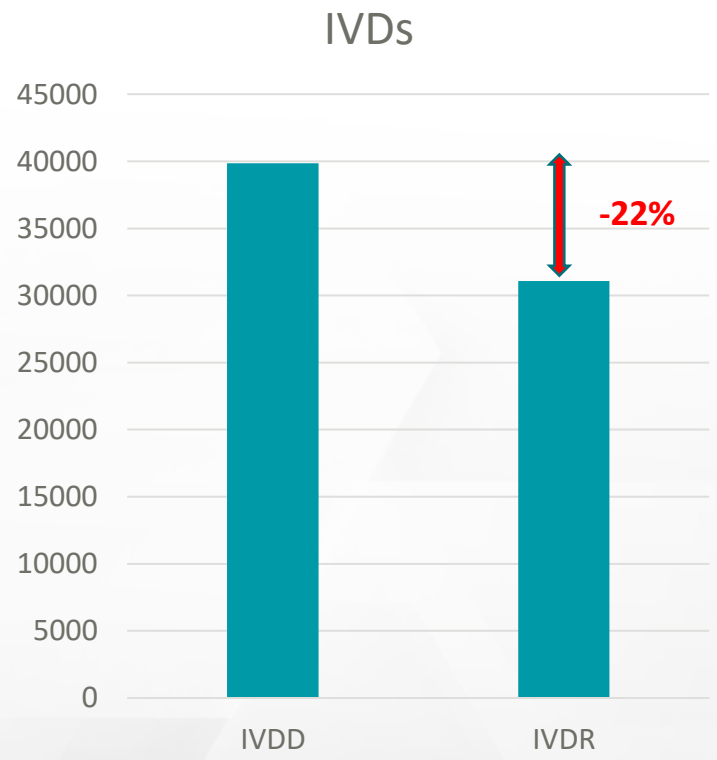
IVDs on the market under IVDD and IVDR

	IVDD	IVDR	Loss
Number of IVD devices	39.844	31.067	-8.777

The number of IVDs intended to be available to EU health services under IVDR will drop by 22%.

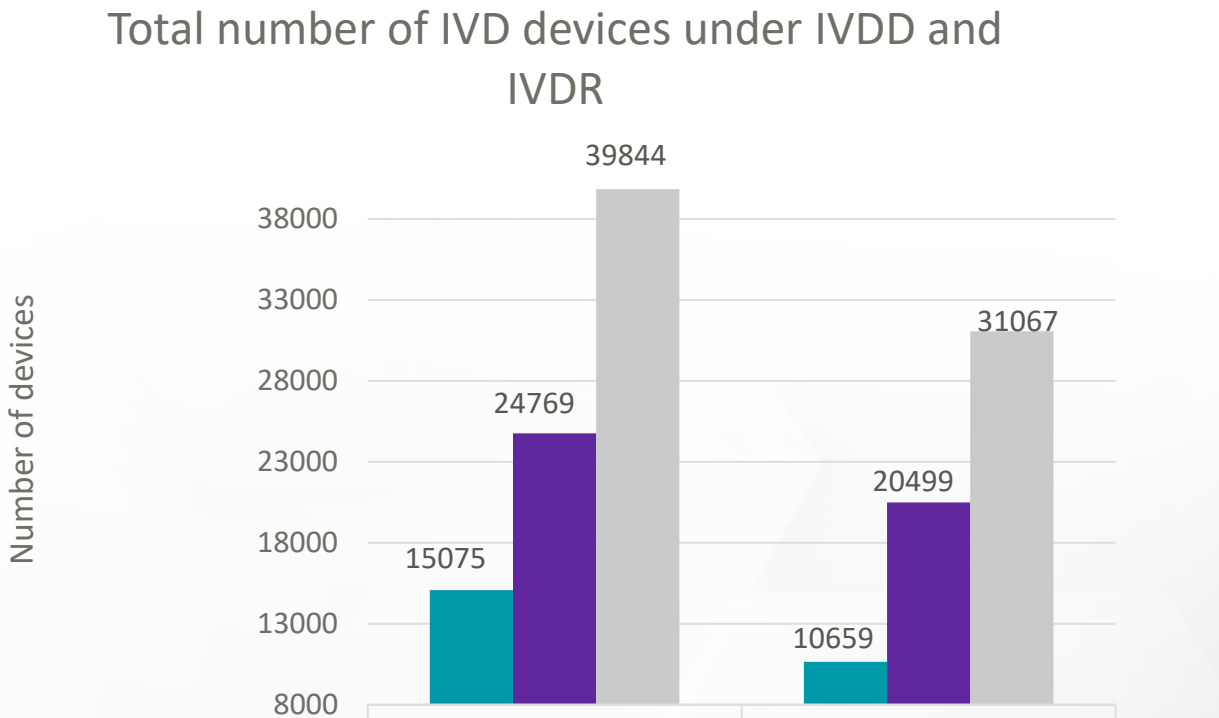
31.067 is the total number of devices *intended* to be CE marked under IVDR. Other data from the survey indicates that not all 31.067 IVDs will be CE marked on 26 May 2022. Therefore, a much greater disruption should be factored in for health services *see slide 11*.

See next slide for breakdown by company size



Number of IVD's on the market under IVDD and IVDR by company size

SME manufacturers expect to lose the greatest share (29%) of their products when considering which IVDs they will keep from IVDD to IVDR



	IVDD	IVDR	
SME	15075	10659	-4416
Large Manufacturer	24769	20499	-4270
Total IVD industry	39844	31067	-8777

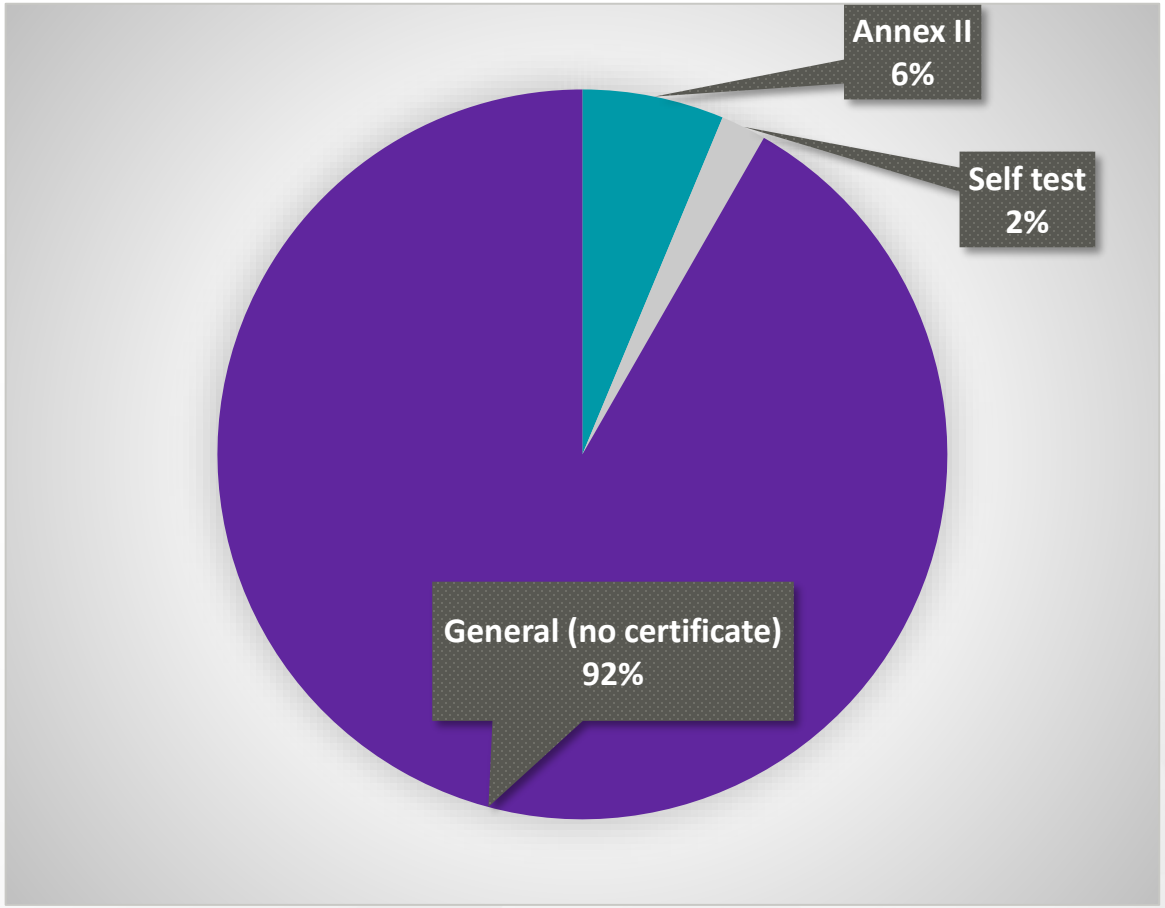
The number of devices which have a Notified Body certificate issued by category (IVDD)

	Number of devices
Annex II certificate	2.501
Self-test certificate	801
General (no certificate)	36.542
Total	**39.844**

92% of all IVDs currently do not need to have a Notified Body certificate under IVDD

Only 8% of all IVDs currently have a Notified Body certificate under IVDD and could potentially make use of the 'grace period'* until May 2024

See slides 8 and 9



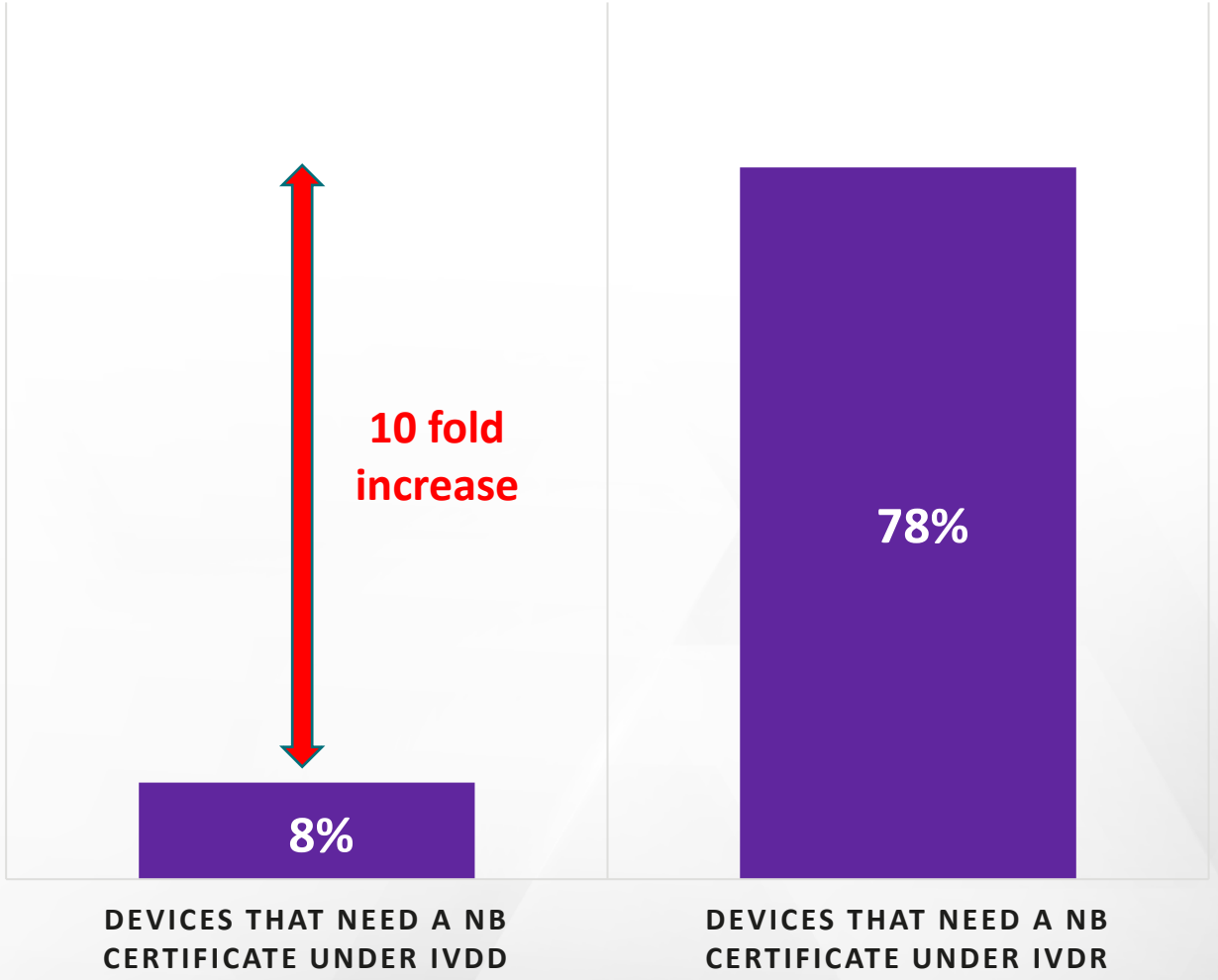
**transitional provisions under IVDR Art 110(3)*

The number of devices that need a Notified Body certificate

	Number of devices that need a certificate
IVDD	3.305 (8%)
IVDR	24.346 (78%)

The percentage of devices requiring a NB certificate climbed from 8% to almost 80% of the total devices from IVDD to IVDR.

This can be read as ~10-fold or 736% increase in the number of IVDs needing at least 1 Notified Body certificate* from IVDD to IVDR *(see slide 7)*

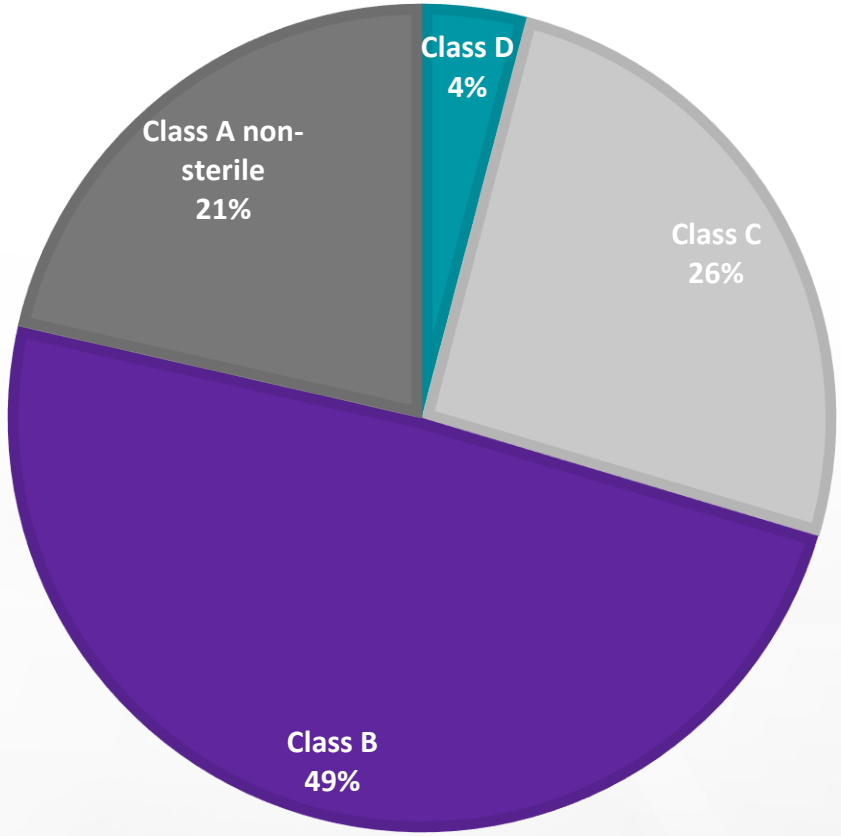


* All IVDs in class D, C, B and A (sterile) need to be covered by a QMS certificate. In addition, individual devices in Class D, for near patient testing, for self-testing and which are companion diagnostics need in addition technical documentation assessment certificate *see slide 10*
Only Class A (non-sterile) do not need to be covered by a Notified Body certificate.

Breakdown per class under IVDR

	Percentage of devices by class
Class D (Highest risk)	4%
Class C	25%
Class B	49%
Class A sterile	0,01%
Class A non sterile*	~21%

Total IVDR 31.067 devices



**the number of class A non sterile devices is an approximation; there was no specific question for this type of device in the survey*

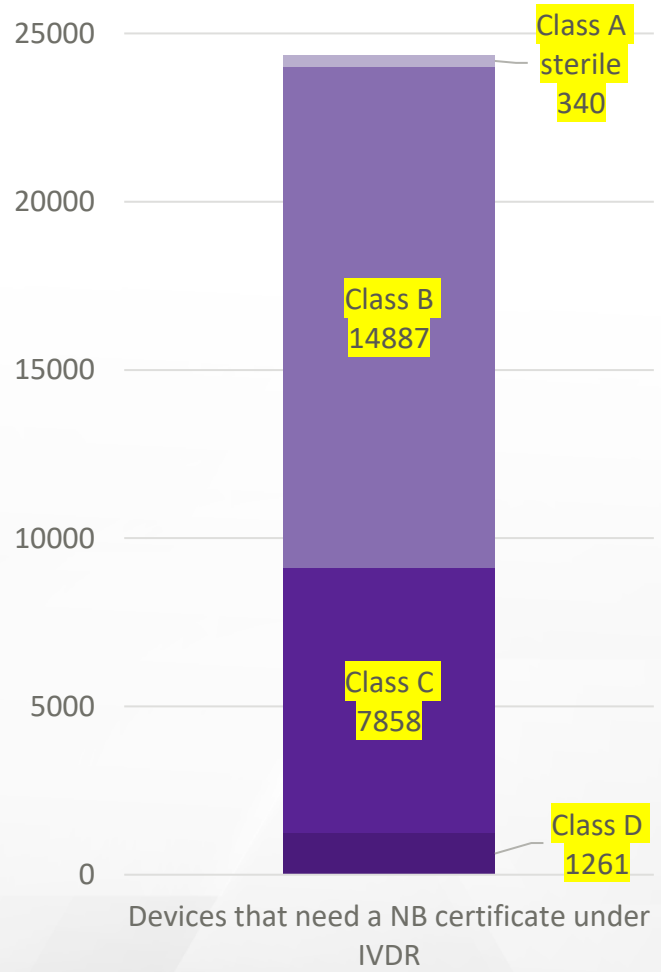
The number of devices that will need to be covered by at least one Notified Body certificate in IVDR (by class)

	Number of devices that will need at least one NB certificate
Class D (Highest risk)	1.261
Class C	7.858
Class B	14.887
Class A sterile*	340
Class A non sterile	-
Total	**24.346**

*Class A non-sterile do not need Notified Body certification for IVDR

At least 78% of IVDs need to be covered by at least one Notified Body certificate. This slide shows how this workload is distributed by class.

See slide 11



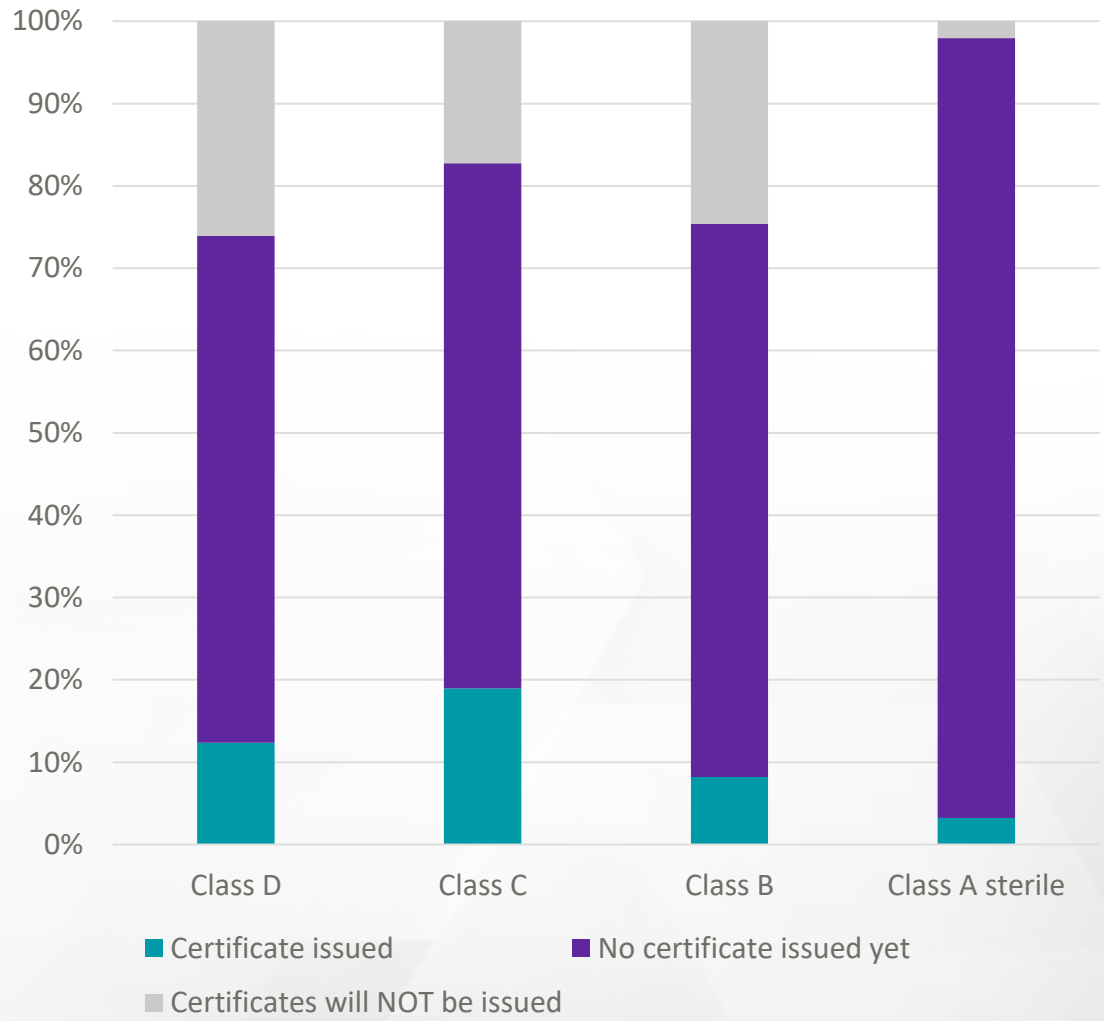
Current IVDR certification status by class

	Certificate issued	No certificate issued yet	Certificates will not be issued by May 2022
Class D	156	776	329
Class C	1491	5011	1356
Class B	1220	10003	3664
Class A sterile	11	322	7
Total	**2878**	**16112**	**5356**

Notified Body certificates have not yet been issued for 88% of IVDs. This is consistent across all classes.

The data for 'certificates will not be issued by May 2022' is an expectation today. Manufacturer comments mention the risk of non-certification so data could shift from the 2nd to the 3rd column by the end of transition.

See slide 14



In addition to a Notified Body certificate, some IVDR products need individual technical documentation assessment certificates

	IVDR Certificates required per class and type of IVD*	
	EU QMS	**EU Technical Documentation Assessment**
Class D	P	P
Self-tests	P	P
Near-patient tests	P	P
Companion diagnostic	P	P
Class B (Lab Professional use)	P grouped by device category	x
Class C (Lab Professional use)	P grouped by generic device group	
Class A (sterile)	Limited to aspects relating to establishing / maintaining sterility	x
Class A (non-sterile)	Self-certified – no notified body certificates under IVDR	

**Due to lack of popularity, type examination certificates are not included here*

Number of IVDR products needing additional individual technical documentation assessment certificates

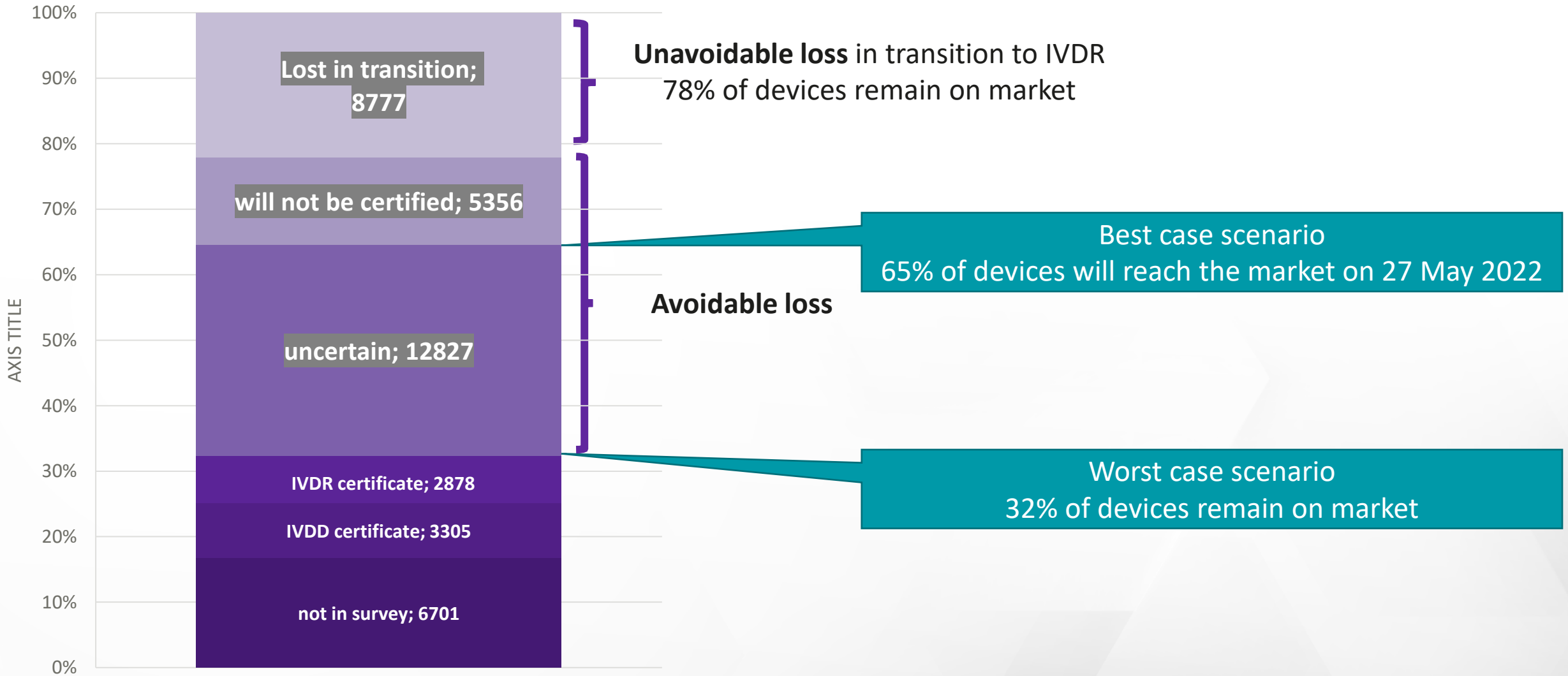
Class D	Self tests	Near Patient Tests	Companion Diagnostics	Total
1261	588	1467	170	3486

11% of all IVDs will need a Notified Body certificate for technical documentation assessment. More than half of those (NPTs, CDx, many class D) are new to this process

This is a separate workload for Notified Bodies. These devices need both EU QMS certification and technical documentation assessment certification.

In a recent paper, Team NB have raised uncertainty that class D devices will be certified by May 2022

Certification forecast for 27 May 2022 based on data available now



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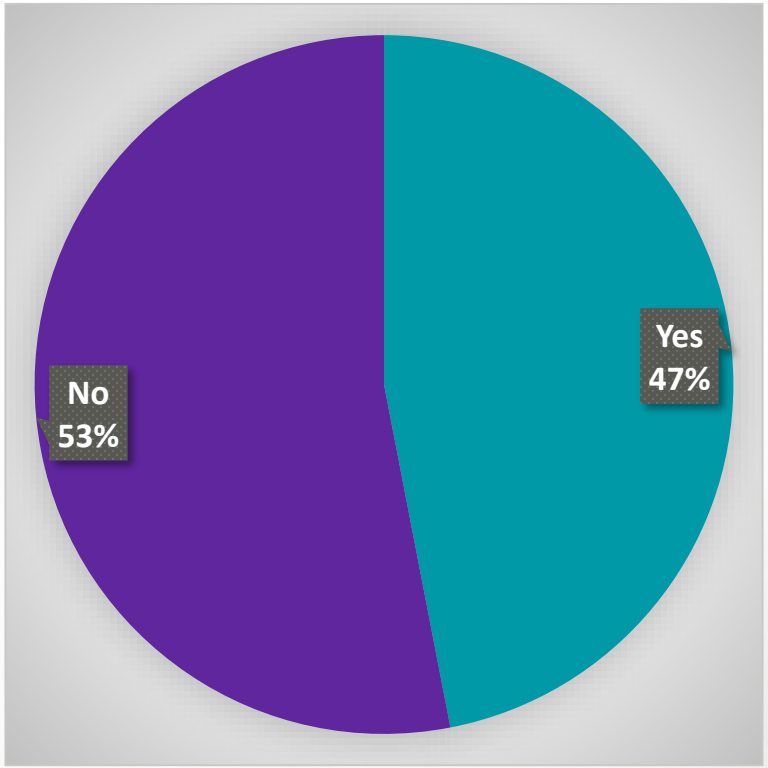
Companies with NB agreements in place

Yes (whether designated or not)	54
No	61
No answer	0



53% of respondents have no agreement in place with a Notified Body.

Without an agreement the manufacturer cannot certify its devices.

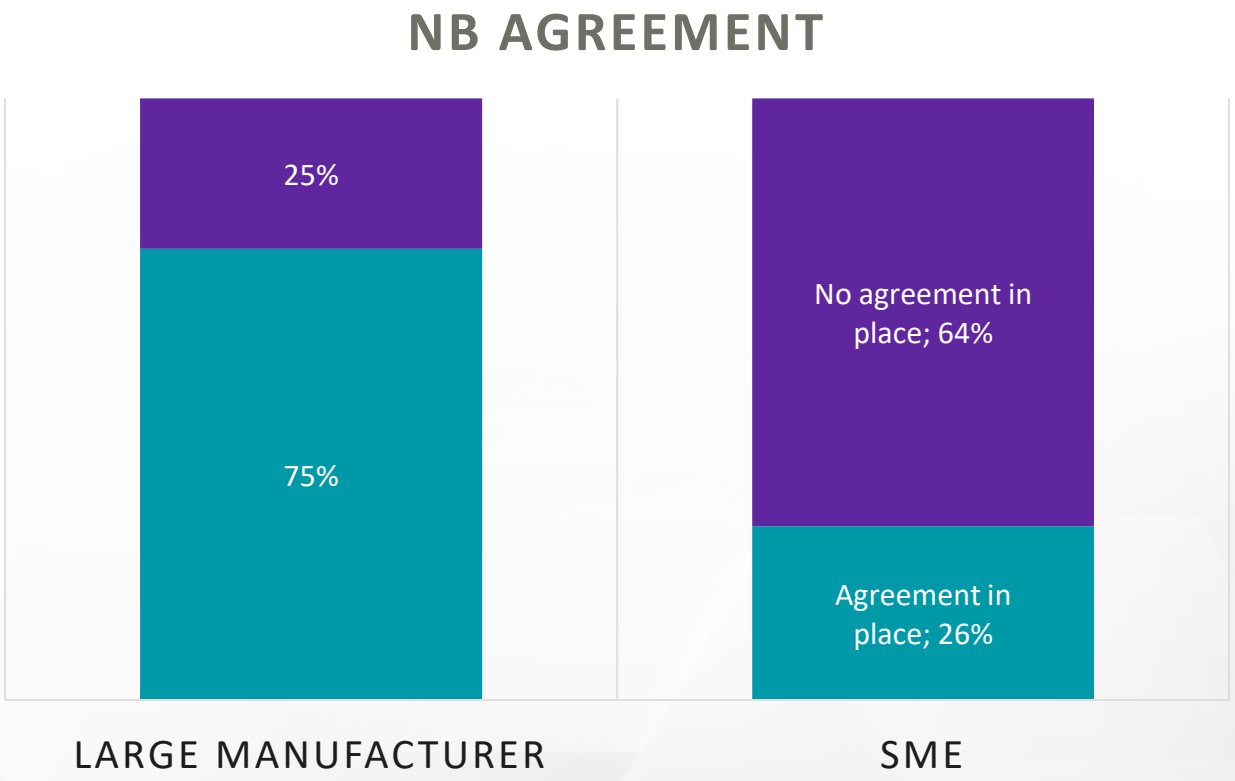
Agreements may or may not cover the *full* products portfolio by providing certification *on time* for May 2022.

Slide 18 indicates that simply having a Notified Body agreement does not guarantee that all devices will be certified on time.

Notified Body agreements in place by company size

	Large Company	SME
No agreement	8	53
Agreement	24	30

A disproportionate number of SMEs (64%) have **no** Notified Body agreement in place compared to large companies (25%)



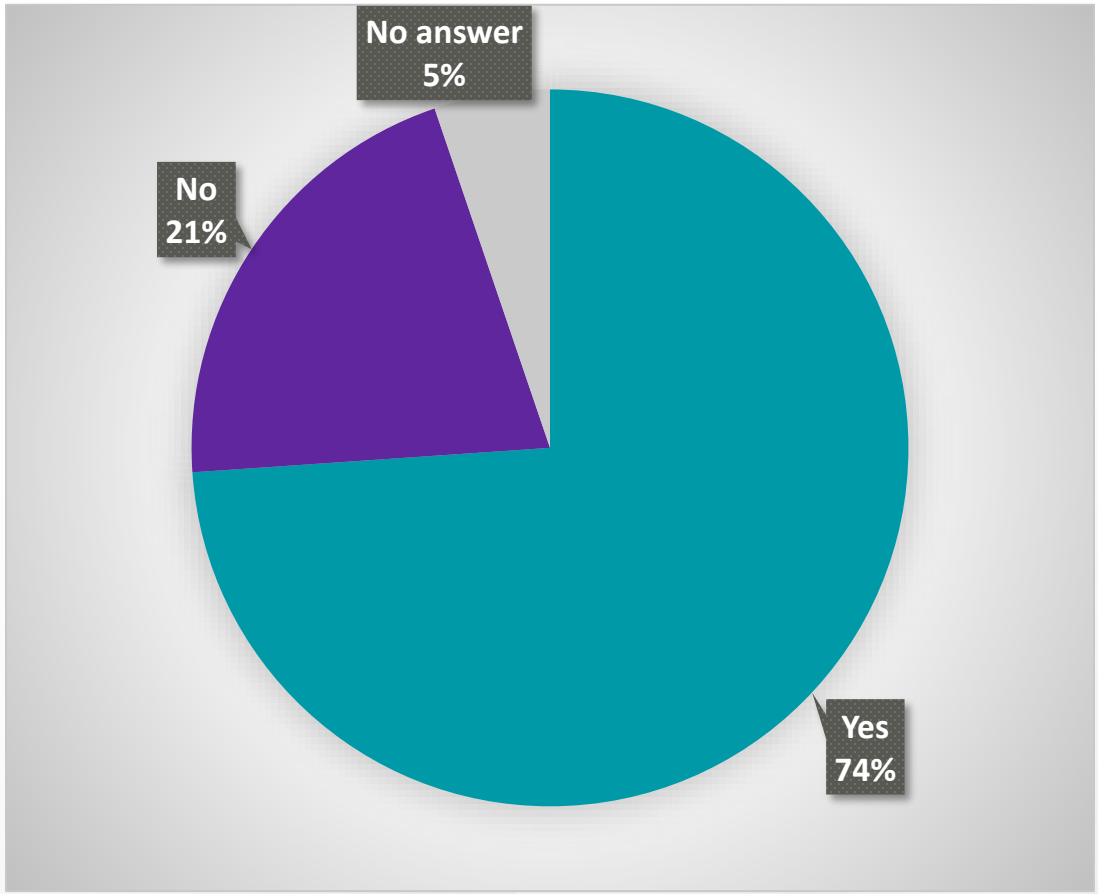
Notified Body agreements in place by class

	Number of companies	Agreement in place	No agreement in place
Class D	53	29	24
Class C	92	49	43
Class B	87	45	42
Class A sterile	13	10	3

Lack of NB agreements affect classes D, C and B equally.

Issues that prevent manufacturers from starting or completing certification

Yes	85
No	24
No answer	6



74% of respondents experienced some obstacle in either starting or completing certification. 21% of respondents reported that they did not have an obstacle.

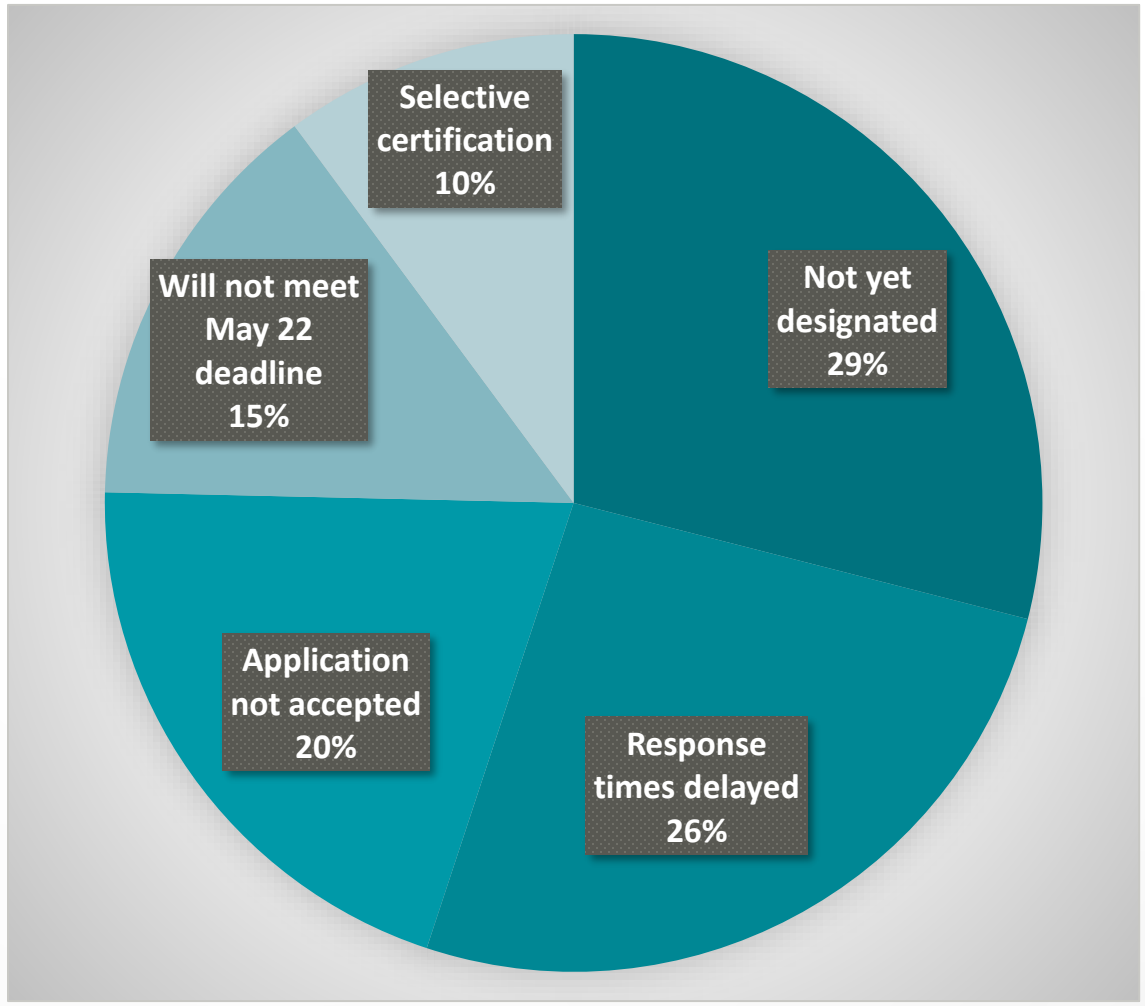
See slides 19-21 for summary of comments. Comments are included in the Survey Initial Report as an Annex.
See slide 22 for examples of comments.

Examples of obstacles encountered during IVDR certification (for full comments, see Annex in Survey Report)

The lack of infrastructure mentioned by respondents

- Notified Bodies (see following slide)
- EU Reference Laboratories
- EUDAMED
- Expert panels
- Guidance/standards (see following slide)

IVDR obstacles relating to NB capacity – top 5 responses (for full comments, see Annex in Survey Report)



Not yet designated	The manufacturer is working with a Notified Body under IVDD that has not yet been designated under IVDR
Response times delayed	The manufacturer has experienced a delay in Notified Bodies responses
Application not accepted	The manufacturer submitted an application to Notified Body(ies) and the application has been rejected or not accepted
Will not meet May 2022 deadline	The Notified Body has warned the manufacturer that they will not get certification before May 2022
Selective certification	Notified Bodies cannot process applications for some devices (e.g. CDx) or has asked the manufacturer to prioritise which devices must have certificates

IVDR obstacles – lack of guidance documents (for full comments, see Annex II in Survey Report)

Specific challenges mentioned by respondents

- Consistency of Notified Body decisions
- Extra time needed to develop own solutions
- Extra time needed to review solutions once guidance is published

Guidance documents mentioned by respondents

- Performance Evaluation
- Original Equipment Manufacturer products
- Class D scrutiny
- Companion Diagnostics
- Clinical Trial Assays

Conclusion

- This survey predicts a significant loss of IVDs from the market, from the highest risk through to the lowest risk. Much of this loss is predictable and entirely avoidable. The loss will be sharp and with short or limited replacement time for users.
- **Without immediate action by the European Commission and co-legislators, somewhere between 22% and 68% of IVDs that are currently on the market will be lost to EU and global health services.**
- The lack of IVDR infrastructure is the main reason.
- Small and medium-sized enterprises are the most affected; large manufacturers are also 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.
- This survey indicates the urgent need for action on the IVDR regulatory framework and the fast-approaching date of application.

Thank you, and stay safe

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