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from diagnosis to cure

Results: Market composition of *in vitro* diagnostic medical devices (IVDs)

CAMD* Survey Coordinated by MedTech Europe 8 – 28 July 2021

*EU Competent Authorities for Medical Devices (CAMD)

7 September 2021

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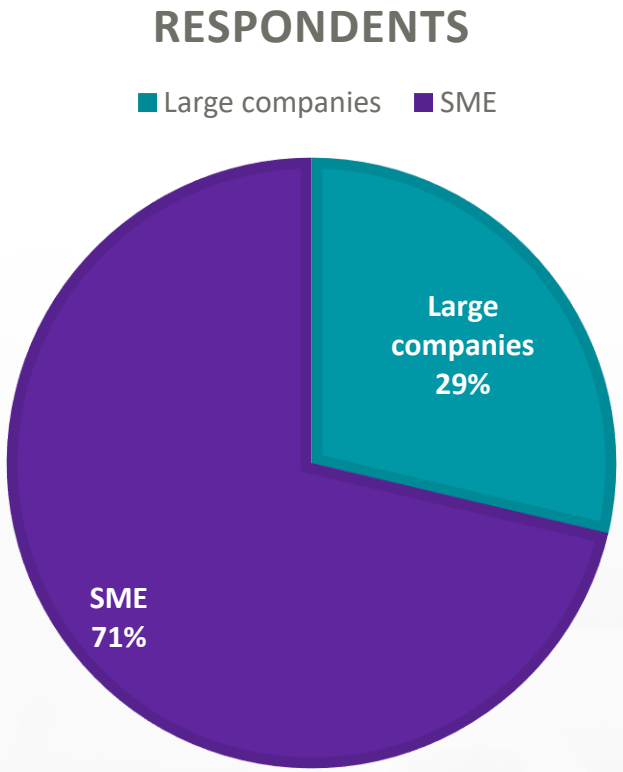
Who responded to the survey?

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

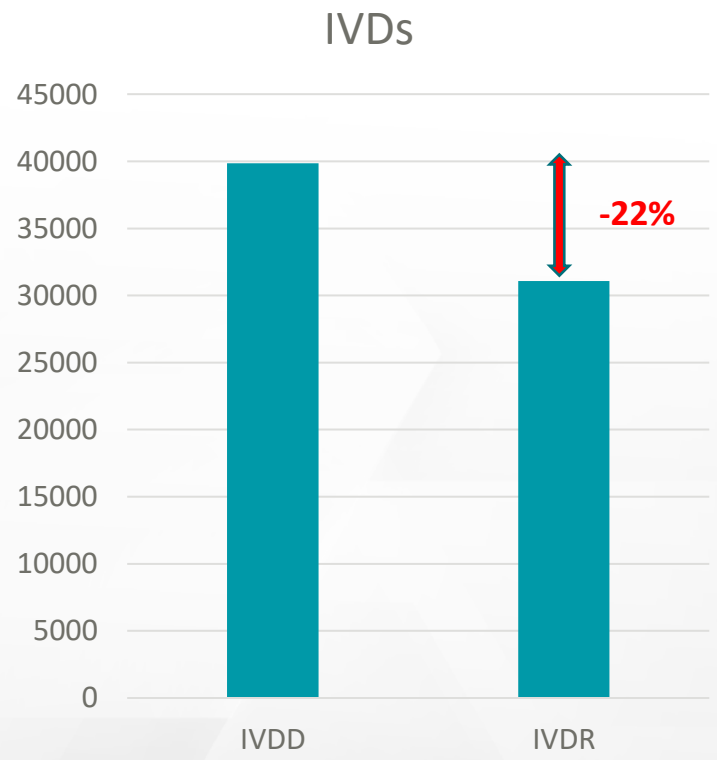
IVDs on the market under IVDD and IVDR

	IVDD	IVDR	Loss
Number of IVD devices	39.844	31.118	-8.726

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 10*.

See next slide for breakdown by company size



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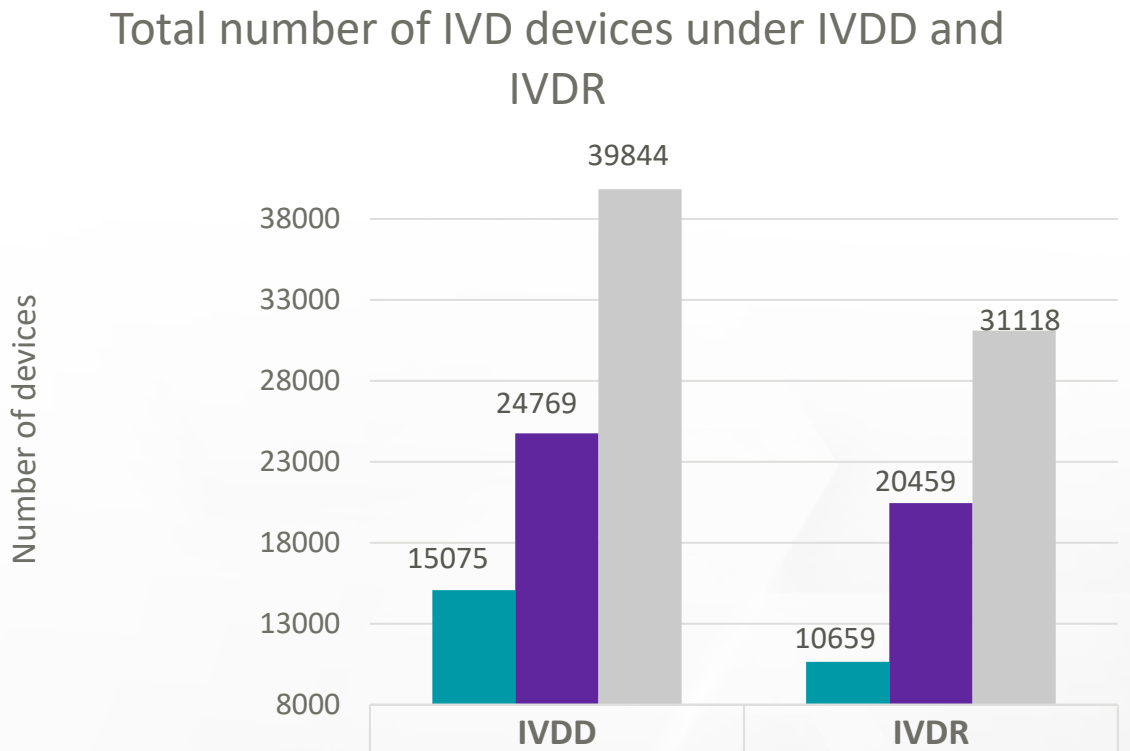
Number of IVD's on the market under IVDD and IVDR by company size

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



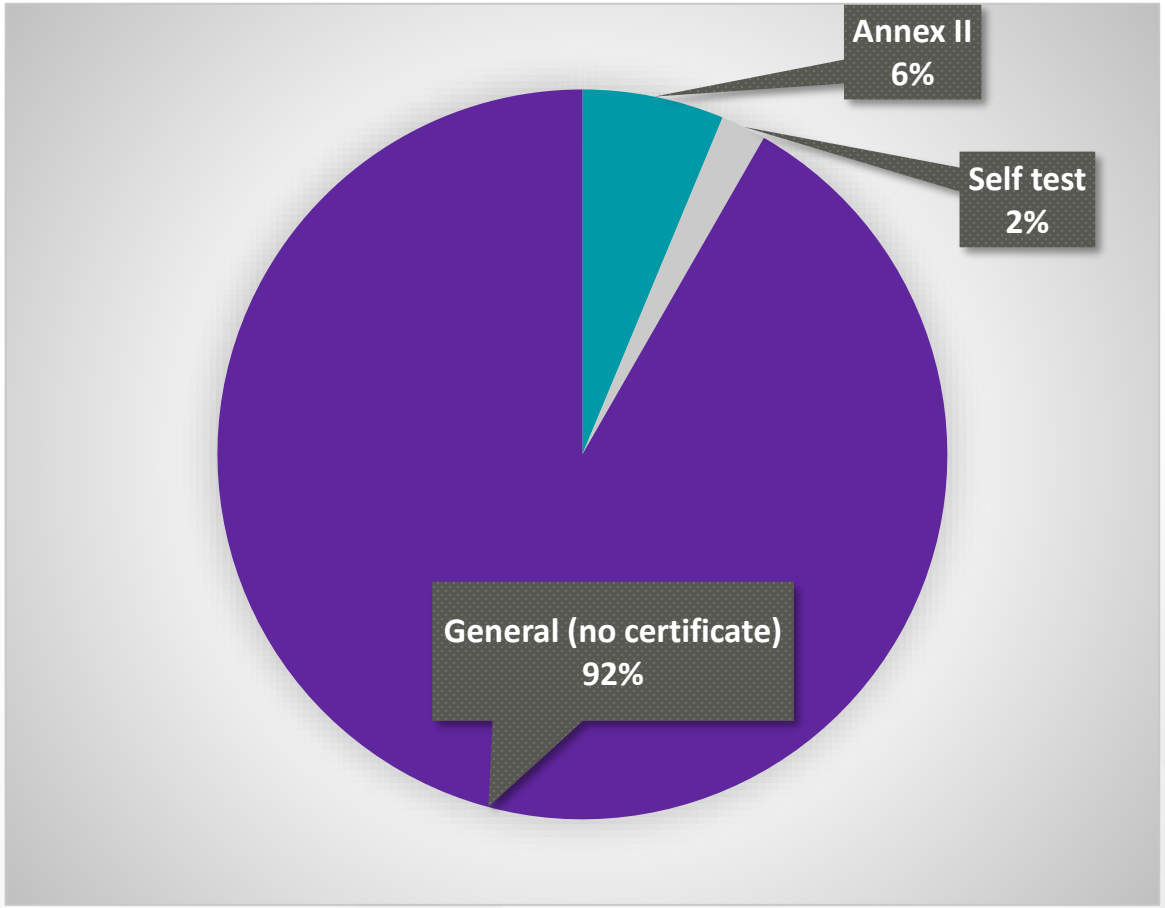
	IVDD	IVDR	
SME	15075	10659	(-29%)
Large Manufacturer	24769	20459	(-17%)
Total IVD industry	39844	31118	-8726

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



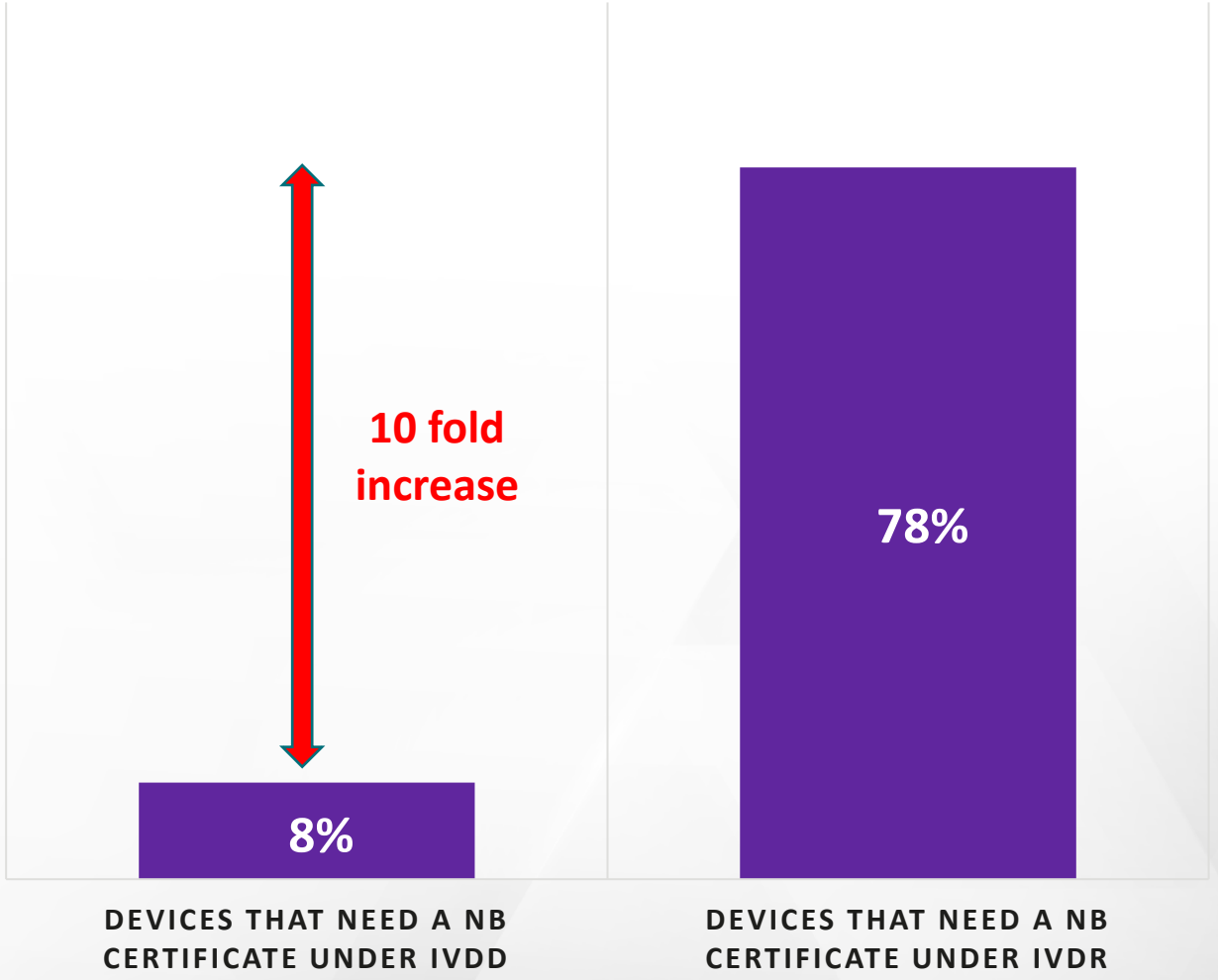
**transitional provisions under IVDR Art 110(3)*

The number of devices that need a Notified Body certificate

	Number of devices that need a certificate
IVDD	3.302 (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

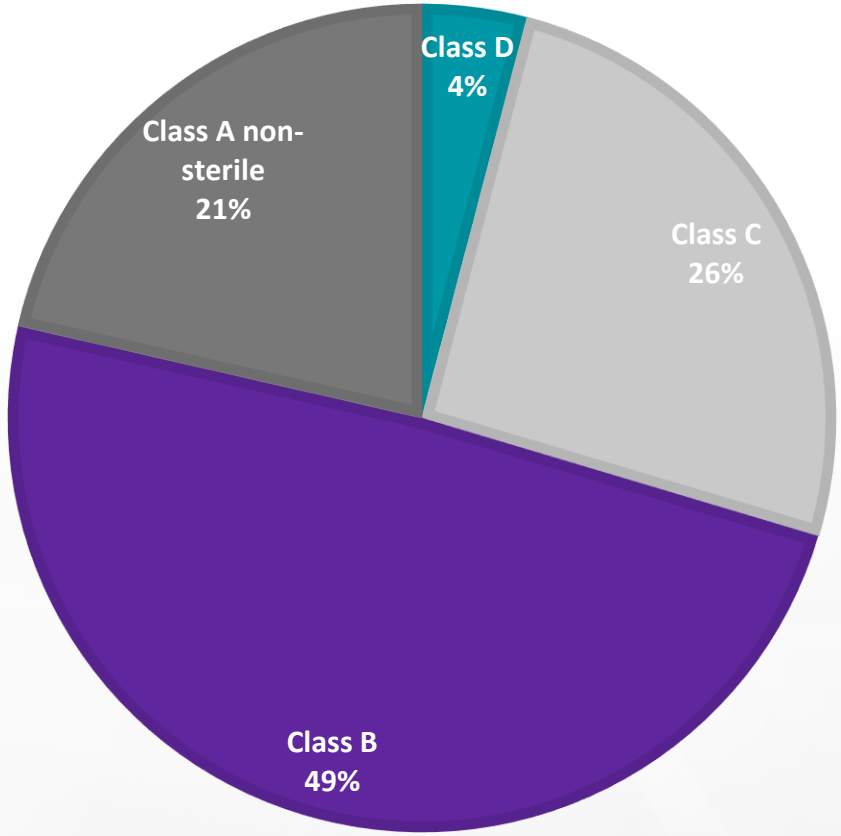


* All IVDs in class D, C, B and A (sterile) need to be covered by a QMS certificate. In addition, individual devices in Class D, for near patient testing, for self-testing and which are companion diagnostics need in addition technical documentation assessment certificate *see slide 9*
Only Class A (non-sterile) 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 31.118 devices

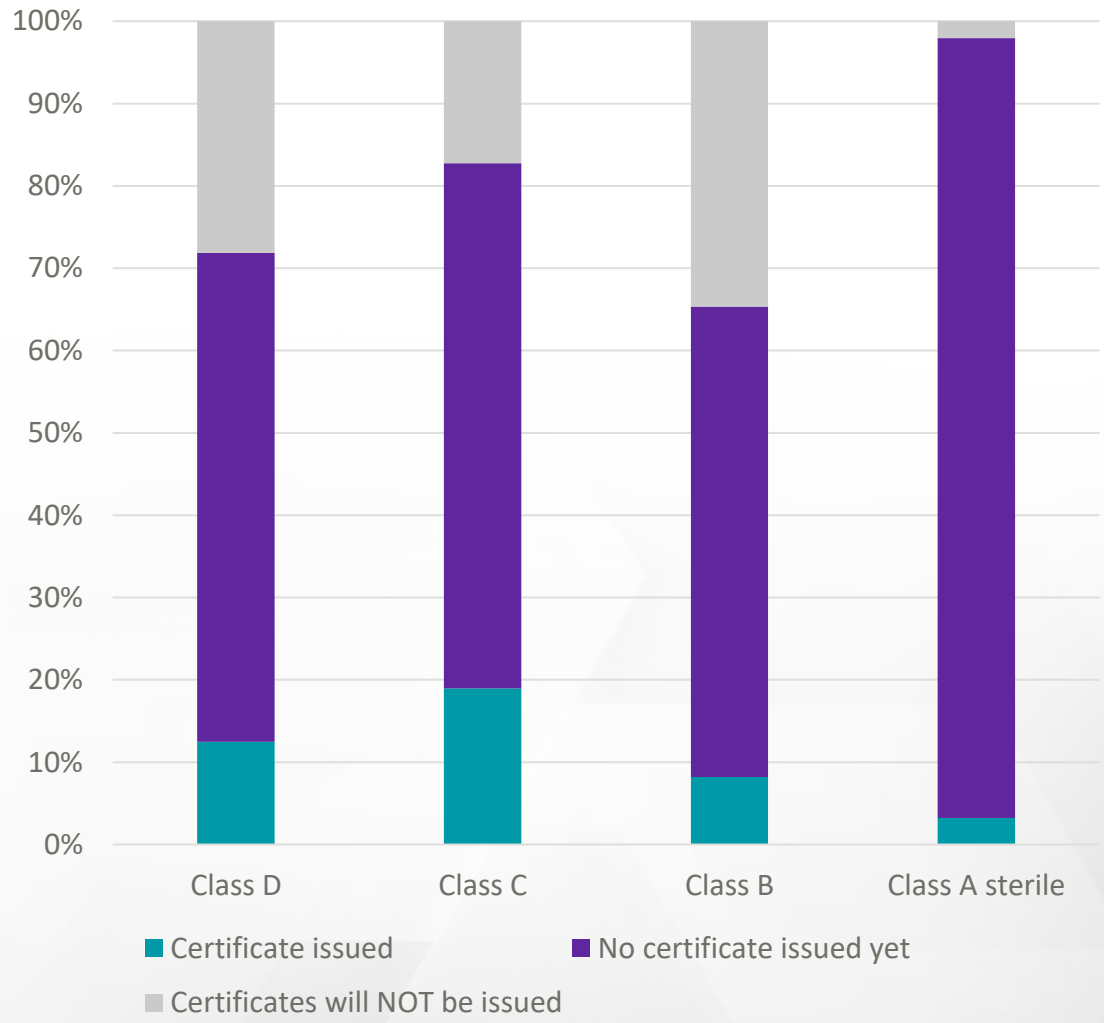


Under IVDR at least 78% of IVDs need to be covered by at least one Notified Body certificate.

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

Current IVDR certification status by class

	#devices for which a certificate was issued	#devices where no information provided if certificate will be issued on time	#devices for which the certificates will not be issued by May 2022
Class D	156	743	352
Class C	1491	5011	1356
Class B	1220	8508	5159
Class A sterile	11	322	7
Total	**2878**	**14584**	**6874**



Notified Body certificates have been issued for only 12% of devices.

All* IVD classes are negatively impacted. **Class D, C, B, A sterile.*

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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*

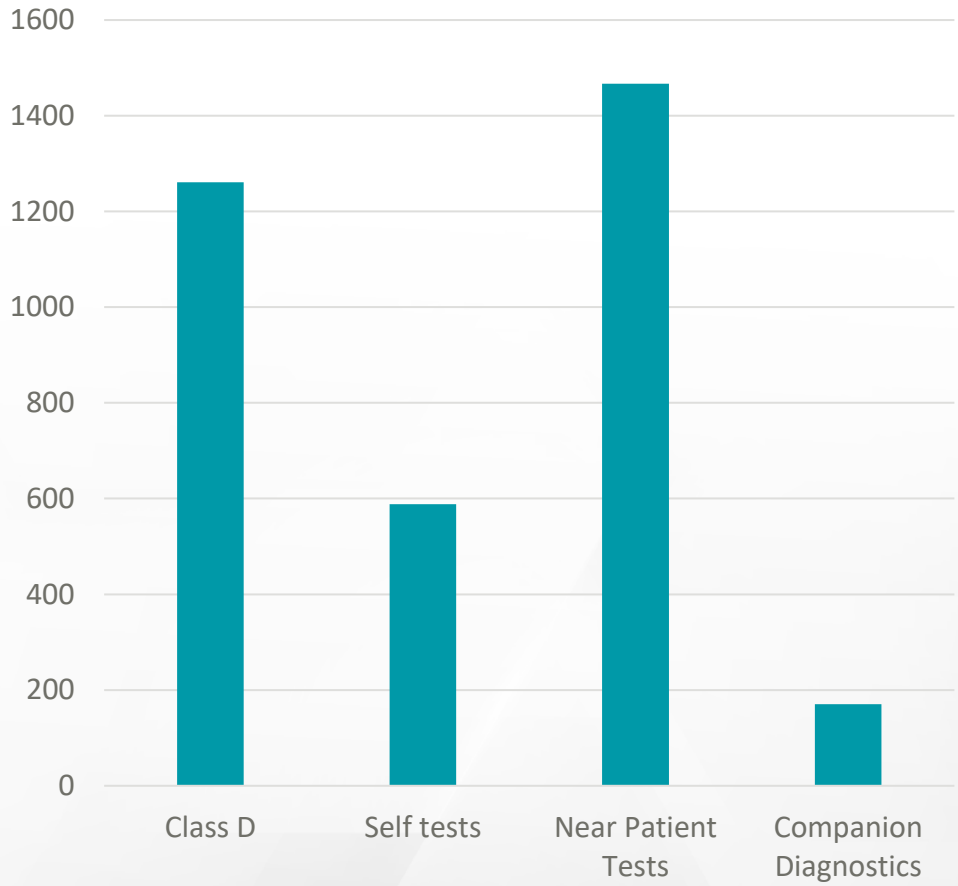
Number of IVDR products needing additional individual technical documentation assessment certificates

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

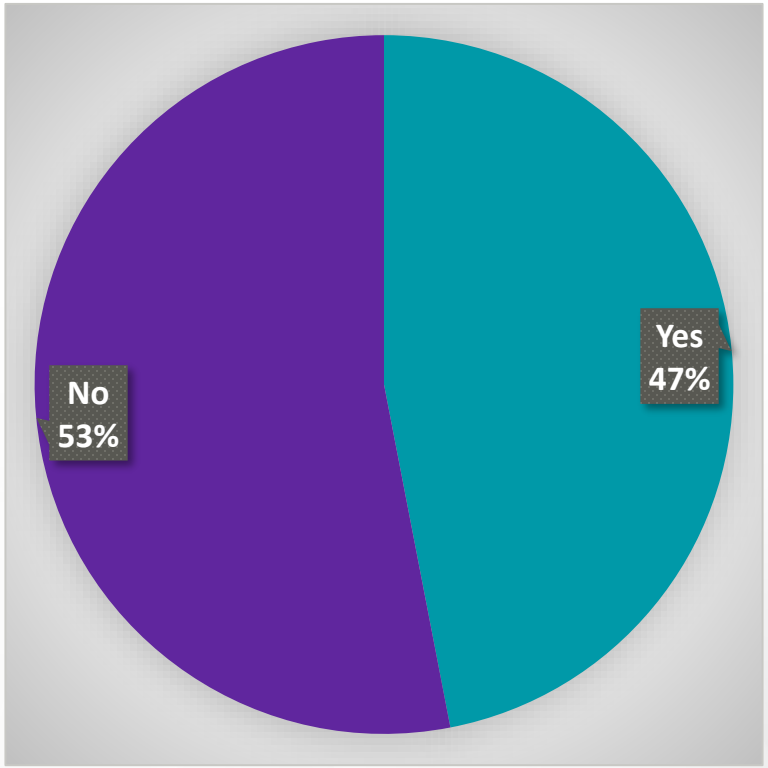
This is a separate workload for Notified Bodies. These devices need both EU QMS certification and technical documentation assessment certification.

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



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.

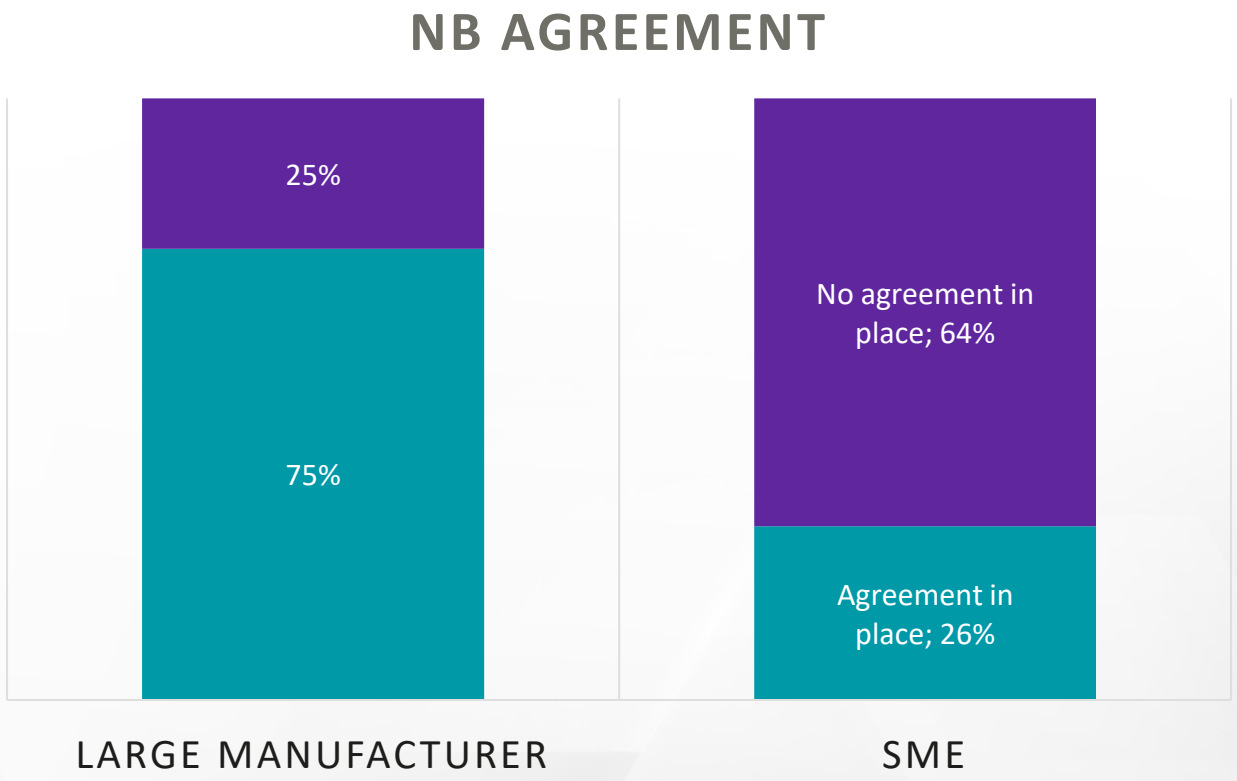
Agreements may or may not cover the *full* products portfolio by providing certification *on time* for May 2022.

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

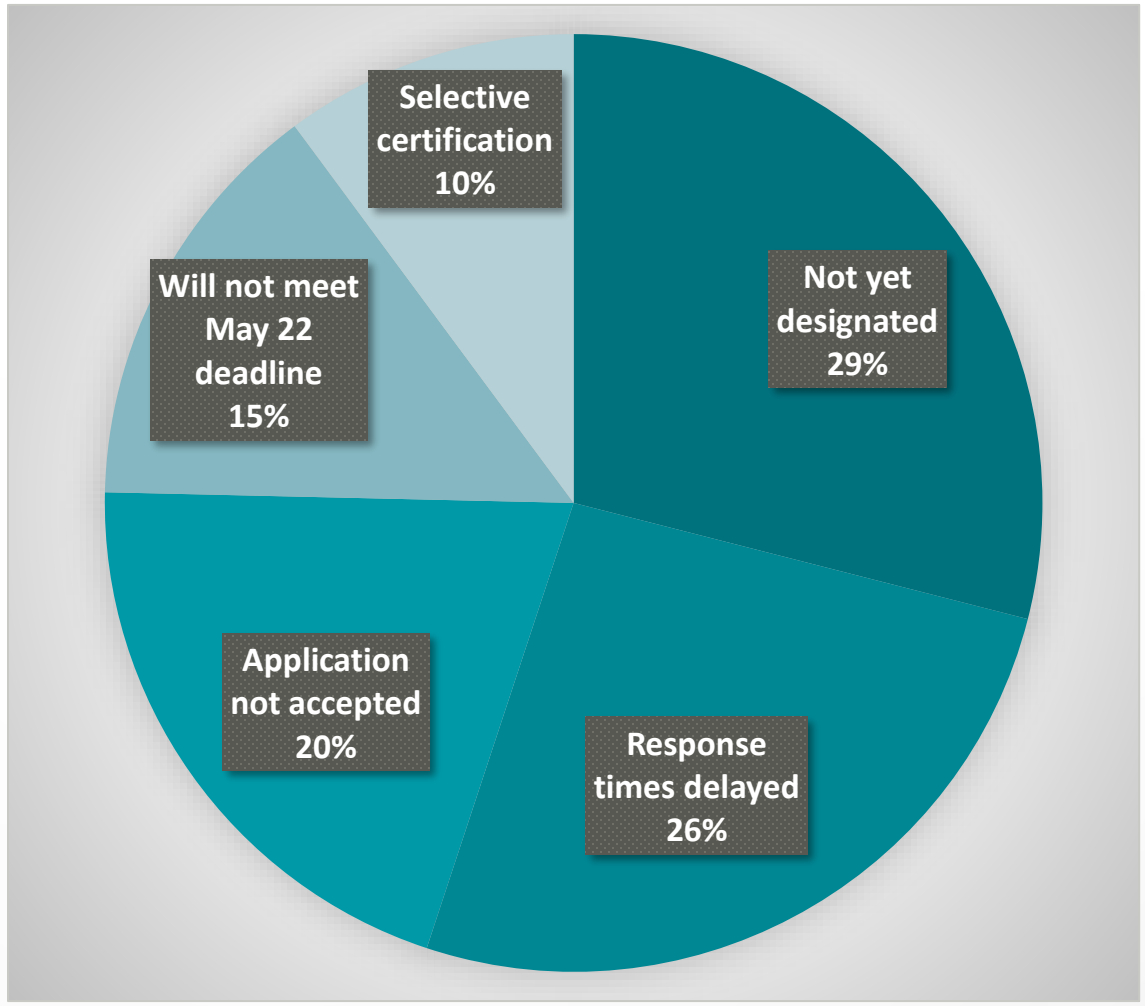
Notified Body agreements in place by company size

	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%)



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

Notified Body agreements in place by class

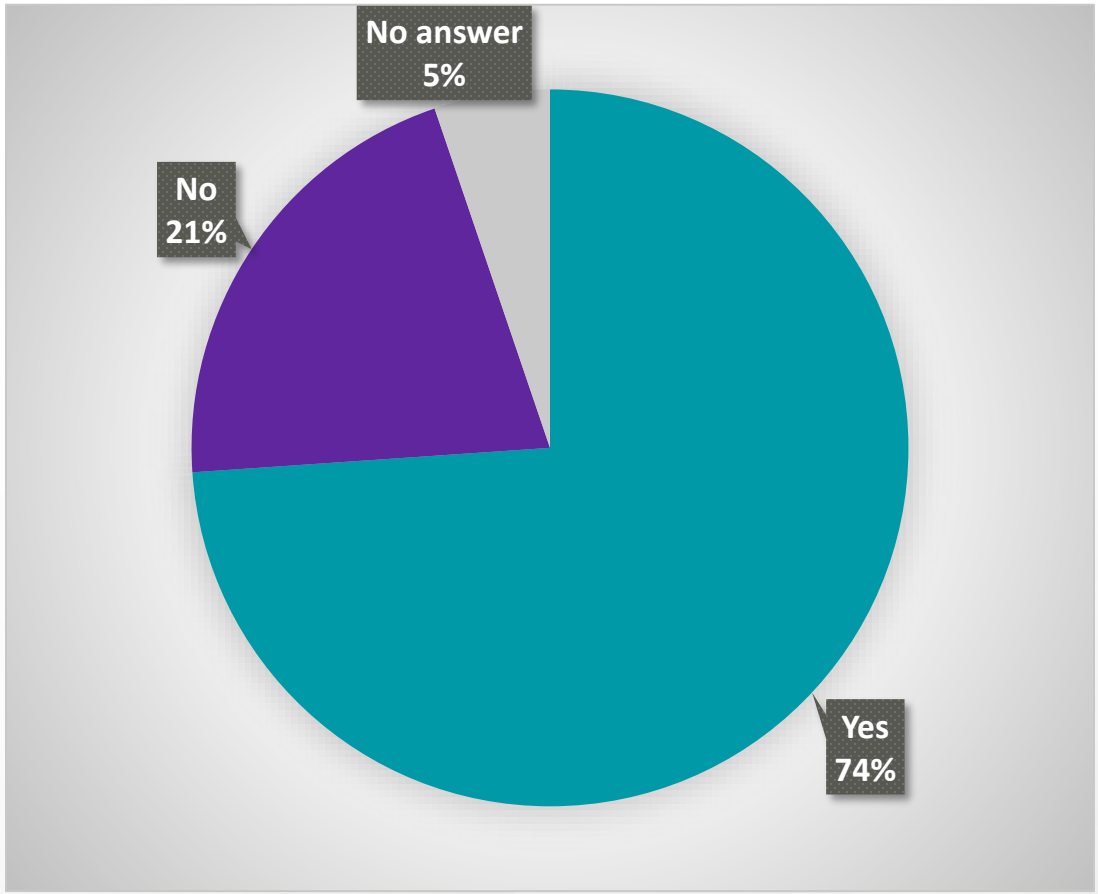
	Number of companies	Agreement in place	No agreement in place
Class D	53	29	24
Class C	92	49	43
Class B	87	45	42
Class A sterile	13	10	3

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.

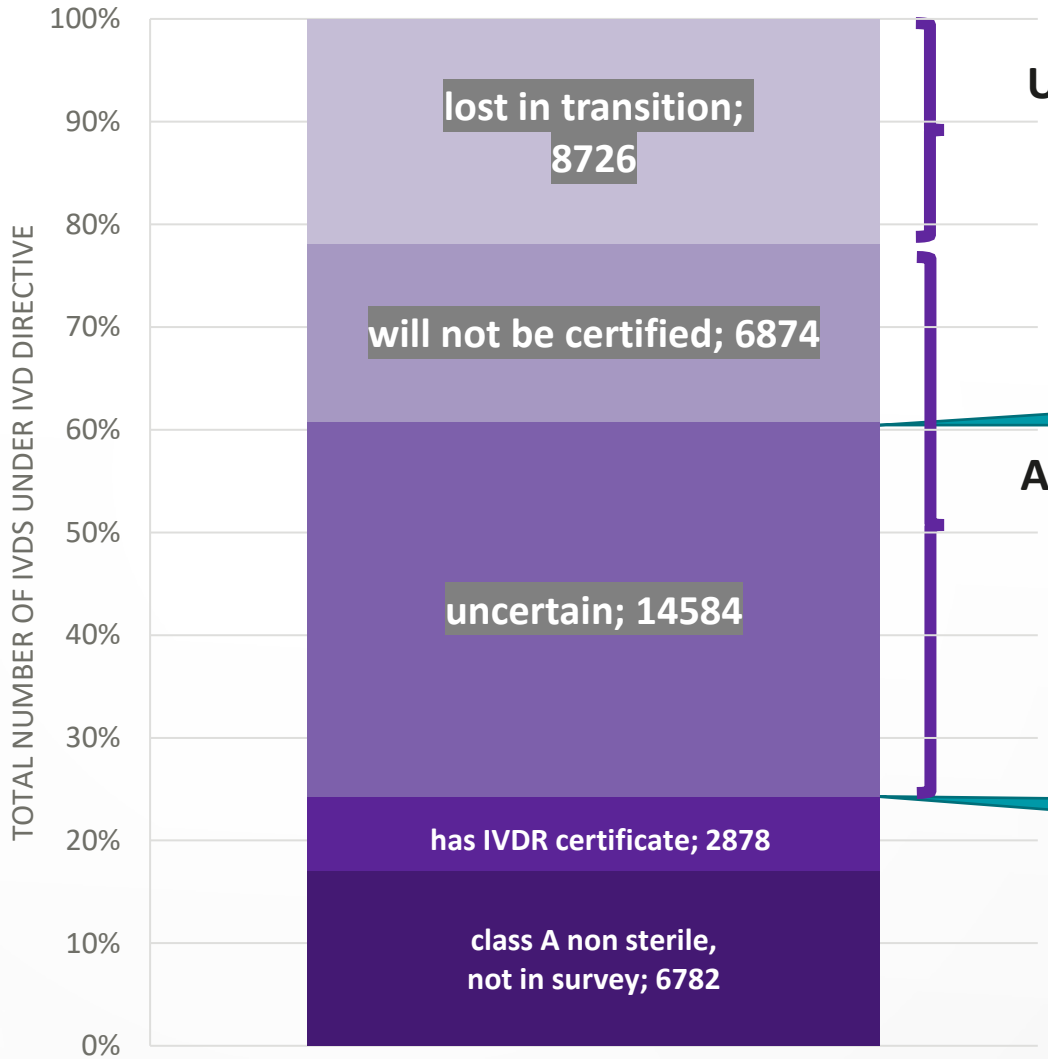


Examples of obstacles encountered during IVDR certification (for full comments, see Annex in Survey Report)

The lack of infrastructure mentioned by respondents

- Notified Bodies (see previous slide)
- EU Reference Laboratories
- EUDAMED
- IVD expert panel
- Guidance/standards/Common Specifications

Forecast: % of IVDs expected to be certified under IVDR by 27 May 2022



Unavoidable loss in transition to IVDR
78% of devices will be maintained

Avoidable loss

Best case scenario
61% of devices will be certified by 27 May 2022

Worst case scenario
24% of devices will be certified by 27 May 2022

***Note**: the graph does not specify that there are 3302 devices with IVDD certificate. It is unknown in which categories of the graph these devices should be included.*

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 76% 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.

A warm thank you to all responders and National Associations

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