MedTech Europe
from diagnosis to cure

Annex: Transition to the IVD Regulation - MedTech Europe Survey Results for October 2022

IVD Survey Coordinated by MedTech Europe 30 September – 27 October 2022

February 2023

Disclaimer: how to use this slide deck

- This presentation is the **annex** to the **IVD survey report** published by MedTech Europe under this link. The IVD survey report together with this annex, summarise the findings from the second annual survey which MedTech Europe run to assess the state of the IVD market transition to the IVD Regulation.
- This slide deck contains aggregated quantitative and qualitative data obtained from the survey. Some slides contain data which is correlated to company size. Where appropriate, comparison has been made to the 2021 survey findings and to the European Commission survey of Notified Bodies on applications and certifications (October 2022).
- 7 slides were added as background information, at the end of this slide deck. These include details on the number of devices per device class.

Key takeaways

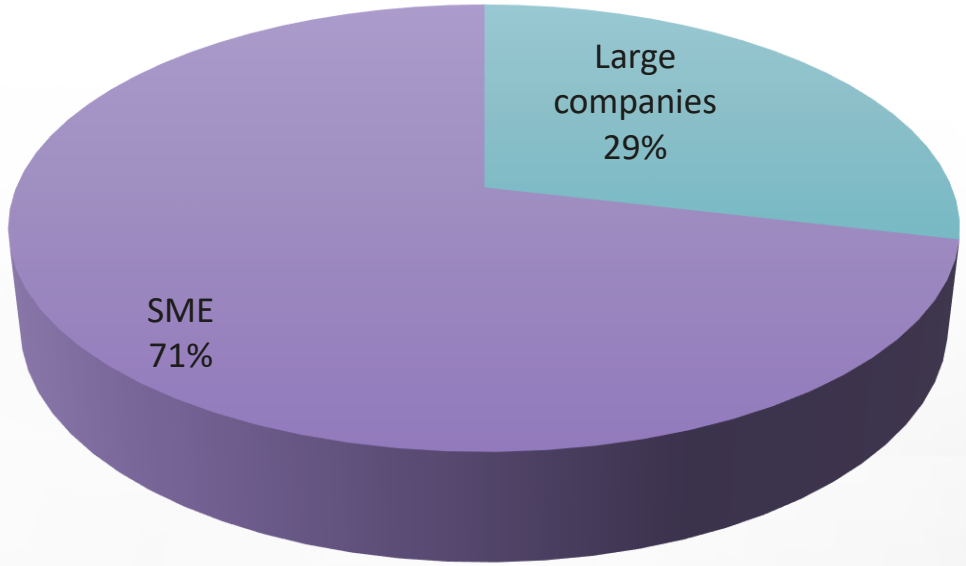
- **~91% of companies benefitted from the January 2022 amendment providing extended transitional periods.**
- **IVD manufacturers are in transition to the IVD Regulation.** Out of total IVDR expected devices (26.597), 34% already are CE marked. ~94% of large companies and 47% of SMEs have an agreement in place with at least one Notified Body, indicating that they have started the process to transition to IVD Regulation.
- **Certification bottlenecks are still possible leading up to May 2025.** 51% of Class D legacy devices belong to manufacturers who do not have an agreement in place with a Notified Body.
- **Access to a Notified Body has improved since July 2021 but remains a significant issue especially for SMEs.** 53% of SMEs and 6% of large companies *do not have an agreement* with a Notified Body designated under the IVDR.
- **17% of today's devices will be discontinued – in most cases due to the cost of CE-marking under IVD Regulation**
- **The length of different conformity assessment phases varies hugely. Efficiencies can be gained in reducing time-to-certification and increasing predictability of the system at every stage of conformity assessment**
- **IVD Regulation will impact early access to innovative medical tests in Europe**. There is a 28% drop in manufacturers who would prioritise the EU for first product launches

Who responded to the survey?

Respondents	110*
SME	77
Large companies	33

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

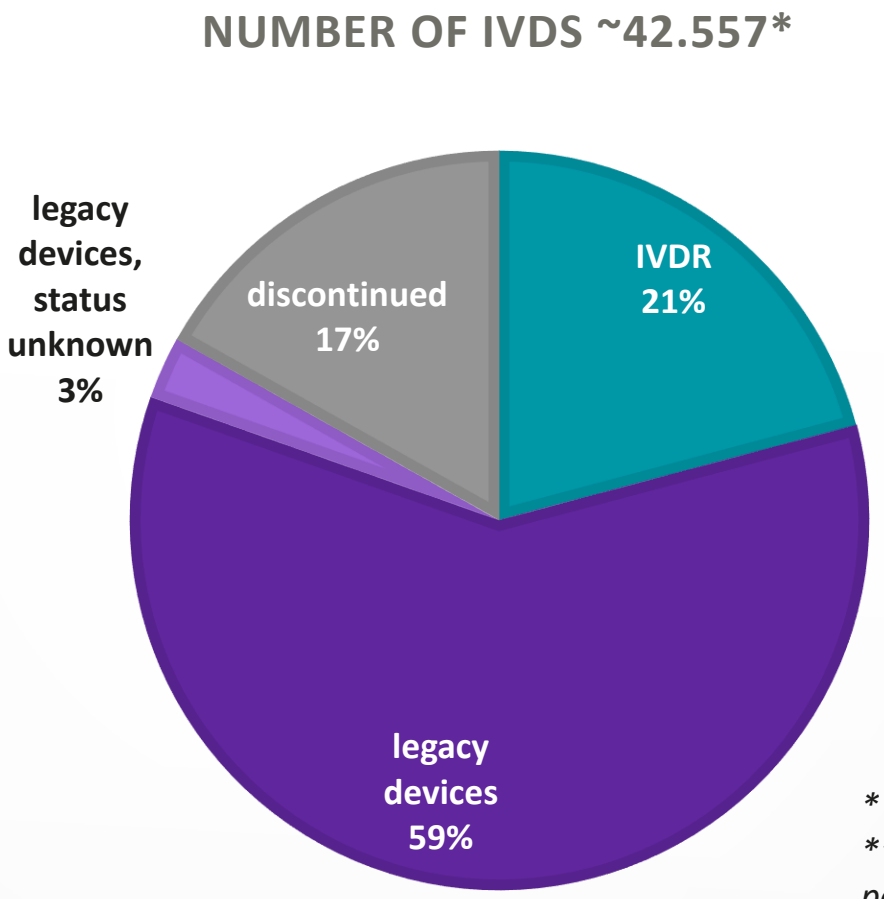
Respondents represent ~75% market revenue share**



*Compared to 115 respondents in the last survey of this type July 2021, which covered 90% market revenue share

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

IVDs on the market in 2022 and how they will transition



*Total estimated IVDs: ~42.557 **		
IVDD legacy devices** 26.048	IVDR total expected 26.597 IVDR certified 9.131	(to be) discontinued 7.378*** status of 1.204 IVDD legacy devices is unknown

** Representing ~75% share of market revenue*

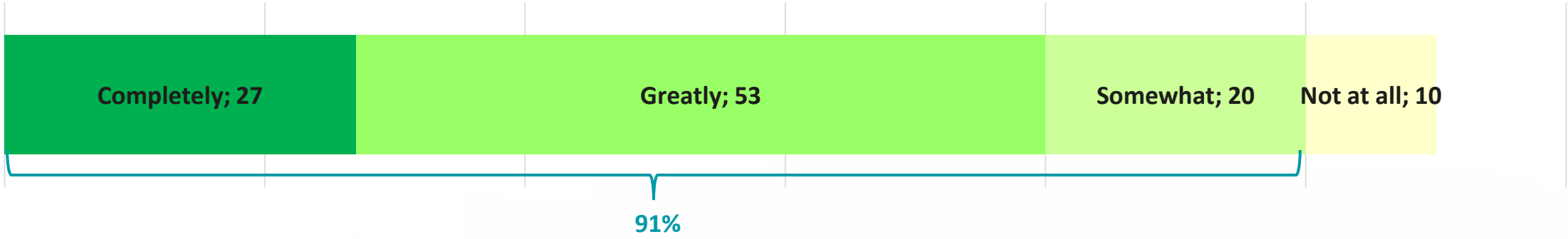
*** 'Legacy devices' refers to IVDD devices being placed on the market under the extended transitional periods*

**** It is unknown when will the devices be discontinued (some may already have been discontinued). For the purpose of estimating the total IVD market, these devices were counted.*

Key Takeaway

~91% of companies were helped by the January 2022 amendment providing extended transitional periods

To what extent has the amendment relieved pressure on your company, i.e., ensured a predictable production schedule and secure supply of IVDs to customers? (select one that applies)



- 91% of manufacturers indicated they were helped by the Amending Regulation (EU) 2022/112, which provided extended transitional periods to the IVD Regulation (EU) 2017/746 (IVDR)
- While this perhaps is not a surprising finding*, it does show that the strong perception of IVD manufacturers is, that the legislative measure brought significant relief and restored production and availability of IVDs to patients, laboratories and healthcare systems

**July 2021 MedTech Europe survey data showed that Notified Body certificates had not yet been issued for 88% of IVDs which needed them. This was consistent across all classes.*

Key Takeaway

Certification bottlenecks still are possible leading up to May 2025

Minimum certification workload to be completed by May 2025

		Self tests	Near Patient Tests	Companion Diagnostics	First-launch	Significantly changed
Class D	1.188				87	60
Class C		597	689	52	209	83
Class B		249	267		226	246
Class A					102	102
Total	**1.188**	**846**	**956**	**52**	**624**	**491**

The minimum workload which must be completed by Notified Bodies by May 2025 is considerable:

- Notified Bodies have confirmed they have 544 applications open* for various device classes, which should be considered as minimum ongoing work (more applications should be expected by May 2025). Most are for Class B and C devices
- 1.188 Class D devices require EU QMS and EU TDA certification. At least 1.551* IVD Directive certificates expire before 2025.
- 1.115 devices are expected to be first-launch or significantly changed and will need CE-marking in the next 12-18 months. It is unknown how many will require only EU QMS or also EU TDA certification
- Conformity assessment for Class C must start well in advance of May 2026, especially for self-tests, near-patient tests and companion diagnostics since these need both EU QMS and EU TDA certification
- Oversight activities related to devices already certified under IVDR must be undertaken. This survey did not quantify that workload; however, it should represent considerable ongoing and annual work (including surveillance assessment, review of PSUR, review of summary of safety & performance, vigilance activities, management of change notifications, and more)

European Commission survey of applications and certifications (Oct 2022)

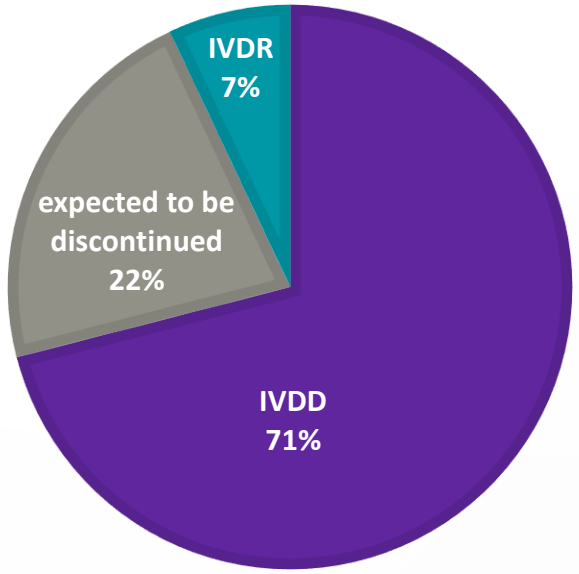
Key Takeaway

IVD manufacturers are in transition to the IVD Regulation.

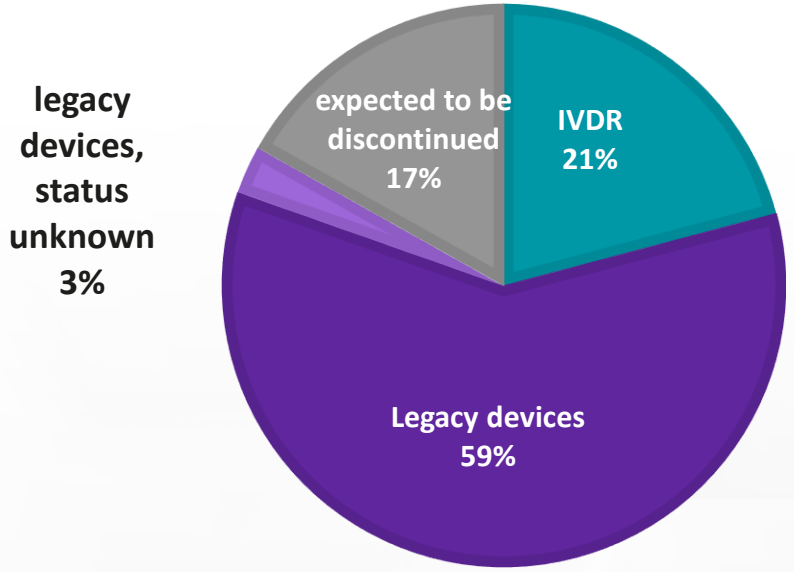
Work must continue to certify 66% of devices expected under the IVD Regulation.

Total IVD market in transition to the IVD Regulation: Comparison of IVD Market in 2021 vs. 2022

IVD MARKET 2021
(90% MARKET REVENUE COVERAGE)



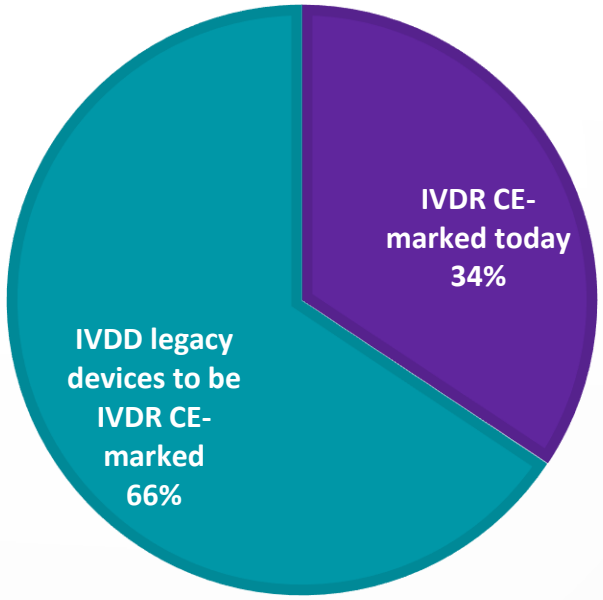
IVD MARKET 2022
(75% MARKET REVENUE COVERAGE)



- There has been a 3-fold increase in IVDs which are CE-marked under IVDR since July 2021
- The percentage of devices expected to be discontinued remains roughly equivalent, considering the relative market share represented for each survey year *(90% market revenue share in 2021 vs. 75% market revenue share in 2022)*
- For 2021, the category 'IVD Directive' includes class A devices. For 2022, the category 'legacy devices' should not include class A non-sterile

Work must continue to certify 67% of devices expected under the IVD Regulation

TOTAL NUMBER EXPECTED UNDER IVDR: 26.597



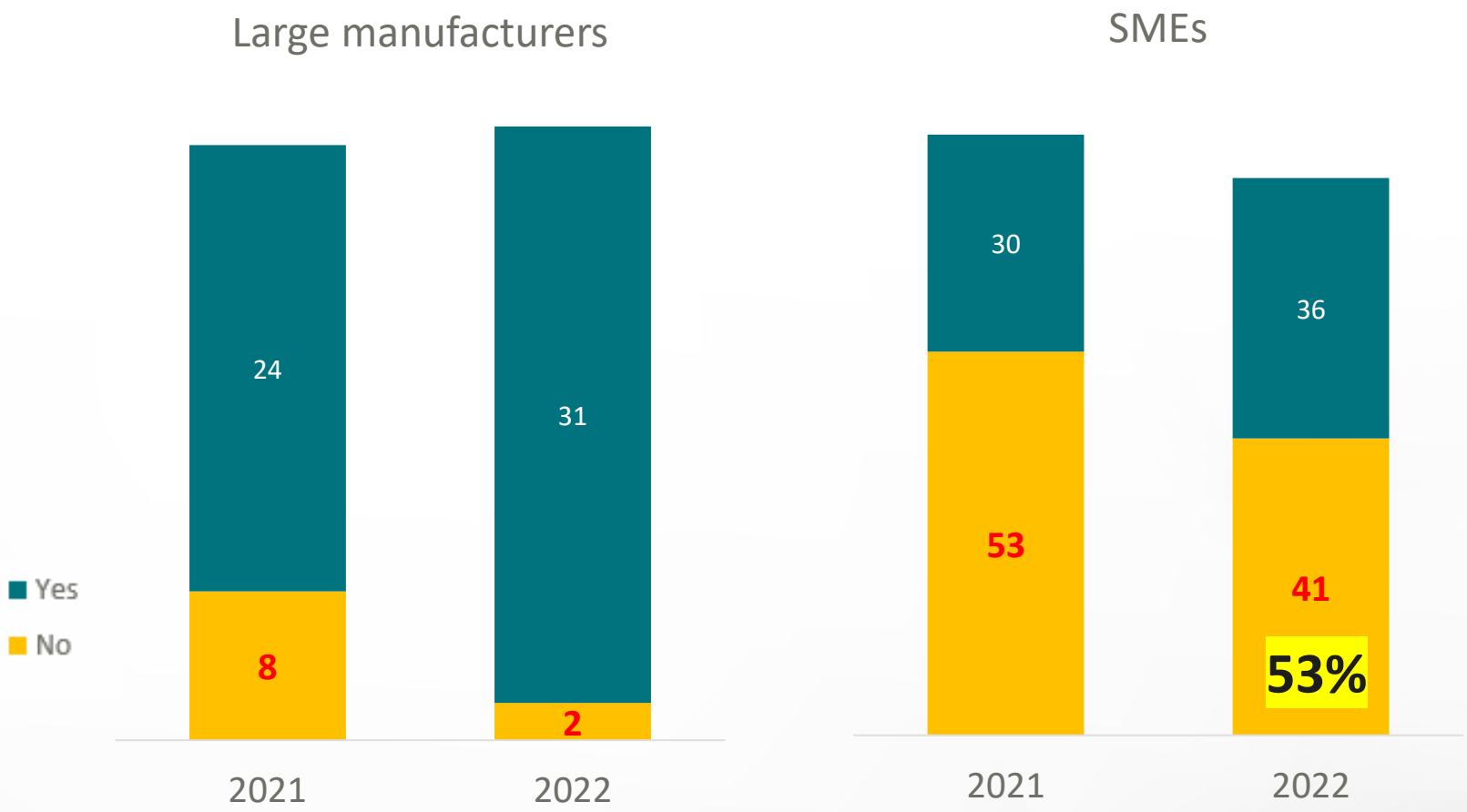
The IVD sector is making progress in its transition to the IVDR.

Out of the **total number** of devices expected under IVD Regulation, 34% already have CE-marking

Key Takeaway

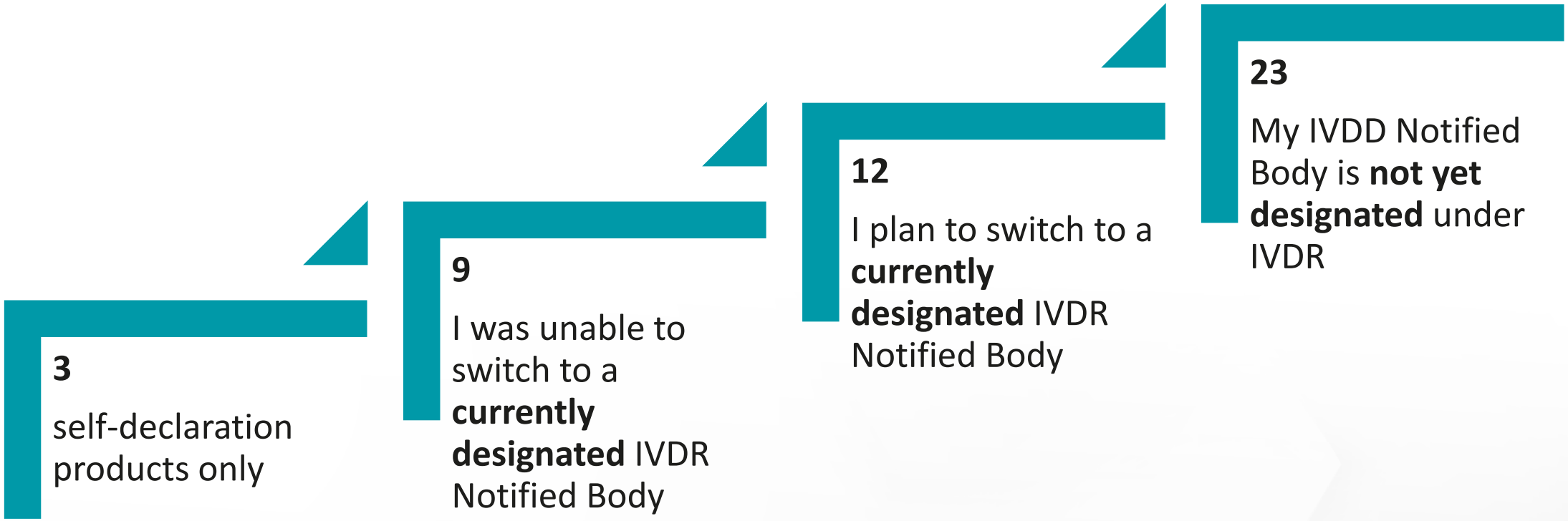
Access to a Notified Body has improved since July 2021 but remains a significant issue

Do you have an agreement with a Notified Body (NB) designated under IVDR?



- 53% SMEs do **not** have an agreement with a NB compared with 6% of large companies.
- The number of devices not covered by an agreement:
  - 6.694 legacy devices
  - 188 first-launch devices
- Having an agreement is a significant first step in transitioning to the IVDR
- Without an agreement the manufacturer cannot start conformity assessment for its devices
- Agreements may or may not cover the *full* products portfolio

Reasons for not having a Notified Body



52% would work with a **currently designated** Notified Body

48% are waiting for a Notified Body **re-designation**

Note: comments by manufacturers were grouped and included in this representation.

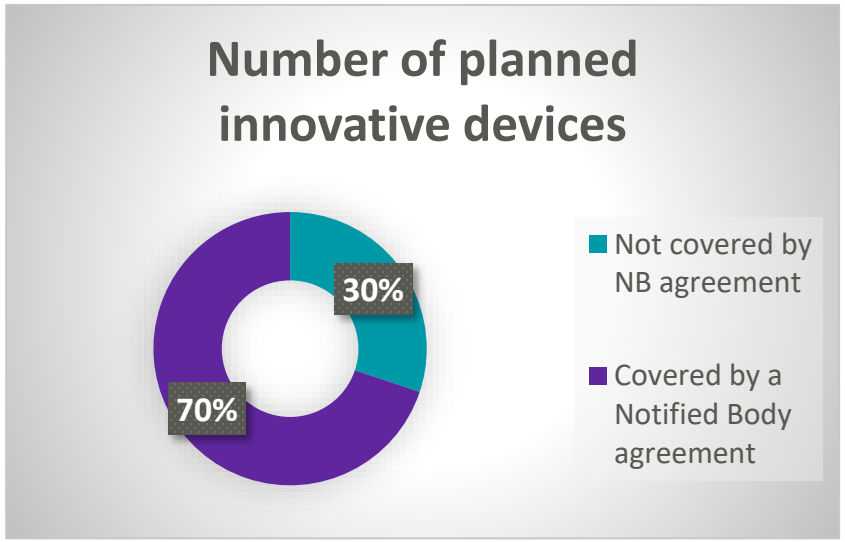
Devices where their manufacturer is ‘covered’ by at least one Notified Body

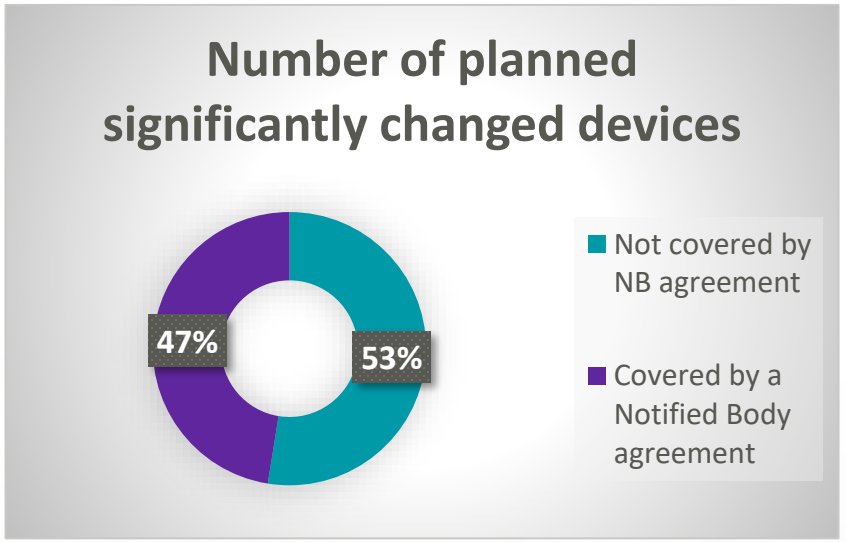
IVDD legacy devices – 26.048

- **covered by Notified Body agreement* – 19.354** 74% of the total number of legacy devices
- **not covered by Notified Body agreement* – 6.694** 26% of the total number of legacy devices

- Manufacturers (particularly with more complex portfolios) can submit applications for their devices in ‘waves’
- Notified Bodies may not always accept all applications – e.g., some did not accept class D applications until more recently

Notified Body workload for new/significantly changed devices – and the total not covered by an agreement





	First-launch (never CE-marked before)	Devices with planned significant change	Total
Total expected in next 12-18 months	624	491	1.115
Not covered by Notified Body agreement	188	258	446

- This represents certification work needed in short-term, before these 'new' devices can be placed on market
- It is probable that there will be more significant changes than expected at the time or after the survey (which asked only about planned significant changes)

Key Takeaway

Efficiencies can be gained in reducing time-to-certification and increasing predictability of the system at every stage of conformity assessment

EU Quality Management System certification – pre-review stage

1.Please state the typical duration in months, from the moment you **sent your submission for your very <u>first</u> application** until the **review start**.

months	1	2	3	4	5	6	7	8	9	12	14	18
responses	42%			26%			32%					

2. Please state the typical duration in months, from the moment you **sent your submission for your <u>second</u> application** until **the review started**.

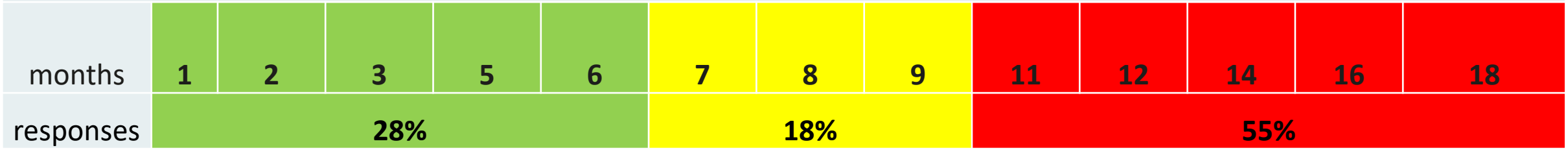
months	1	2	3	4	5	7	10	12	15	16	17	18	>20
responses	28%			17%		55%							

- The application must pass its completeness check (at least) before the review can start
- Some respondents reported that the second application took less time to start; for some this pre-review stage lasted longer
- Different reasons provided by respondents for why the pre-review phase may take longer than 3 months include:
  - ❑ Lack of Notified Body capacity meant service was slow or interrupted
  - ❑ Additional MDCG guidance – and therefore specified requirements – were introduced since first application
  - ❑ COVID travel restrictions affected ability to hold audit
  - ❑ 43% of respondents indicated that a change of device category or generic device groupings was needed

Only respondents with at least one EU QMS certificate were asked these questions. Only the typical duration was asked, rather than duration per certificate issued. Answers were not linked to a specific Notified Body. Experiences differ between Notified Bodies.

EU Quality Management System certification – review start to certificate issued

3. What is the typical duration in months from **review start** until the issuance of the **recommendation for certification**?

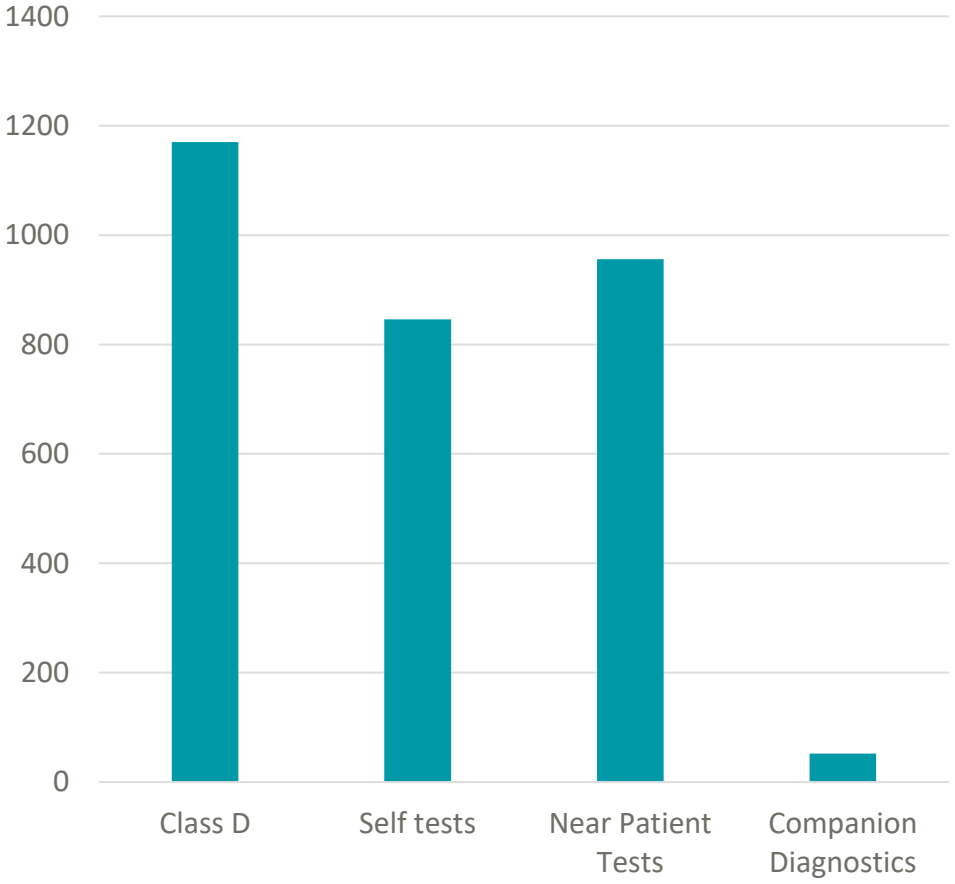


	Number of months to **issue** the EU QMS Certificate following recommendation for certification*					
Number of months	0	1	2	3	6	8
% manufacturers (total 10 responses)	10%	10%	10%	20%	40%	10%

- 55% of EU QMS certificates took between 11 and 18 months from review start until recommendation for certification
- 60% of certificates take a lengthy 3-6 months to be issued, following the recommendation for certification
- Given that the European Commission survey on applications and certifications indicates that 56% of EU QMS certificates take 6-12 months, it might be assumed that this time period covers review start until recommendation for certification, and might not (fully?) include the completeness check nor issuance of certificate

**Respondents were asked about the average time from review to certification*

Number of IVDR products needing EU Technical Documentation Assessment (EU TDA) certificates



- 11% of all IVDs expected under IVDR will need a Notified Body EU TDA certificate
- This is a separate workload for Notified Bodies. These devices need both EU QMS and EU TDA certification

Class D	Self tests	Near Patient Tests	Companion Diagnostics	Total
1.188	846	956	52	3.042

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EU Technical Documentation Assessment certification – timelines

Duration from when you **sent your application** until the **review start**?

months	1	2	3	4	6	12	15
%	41%			35%		24%	

Duration from **review start** until **issuance of the recommendation for certification**?

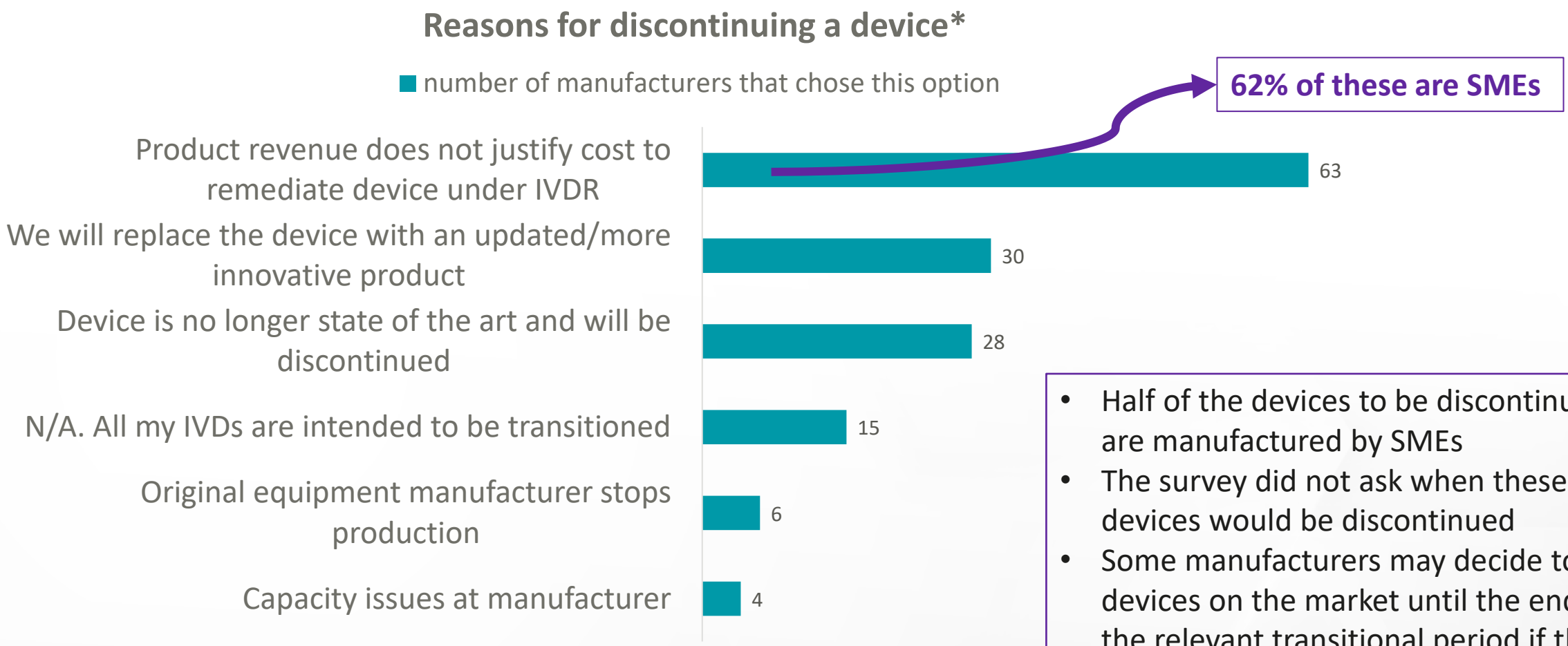
	2	5	6	7	8	9	10	14	>20
%	25%			38%			37%		

- Efficiencies can be gained in the duration before the review starts: ideally this should not last more than 3 months
- 41% indicated that the time to start the review (including completeness check) took less than 3 months, for most respondents this phase lasted longer, ranging from 4-6 months for 35% and 12-15 months for 24% of cases

Key Takeaway

17% of today's devices will be discontinued

Manufacturers to discontinue 7.378 devices – 17% of today's market



- Half of the devices to be discontinued are manufactured by SMEs
- The survey did not ask when these devices would be discontinued
- Some manufacturers may decide to keep devices on the market until the end of the relevant transitional period if they were being discontinued due to the cost of the IVD Regulation

**Respondents could choose more than one option*

Key Takeaway

IVD Regulation will impact early access to innovative medical tests in Europe: there is a 28% drop in manufacturers who would prioritise the EU for first product launches

What geography would you prioritize for a first regulatory approval before and after the IVDR Date of Application, 26 May 2022?

		Australia	Canada	China	EU	Other	UK	US
SME	Before IVDR				**69**	7	1	
	Since IVDR		1		**53**	6	4	5
Large	Before IVDR	1		1	**27**	1		3
	Since IVDR	1		1	**16**	5		10
SME and Large	Before IVDR	1		1	**96**	8	1	3
	Since IVDR	1	1	1	**69**	13	4	15

- Although Europe remains a preferred market, there is a significant, **28% drop** in prioritizing EU market for the first regulatory approval since 26 May 2022. Many respondents would move to the US or other jurisdictions.
- The 'Other' category includes respondents who are undecided or will wait to see which major jurisdiction is the most efficient, reliable and or cost efficient.

What impact does the IVDR have on your innovation or changes/optimization activities?

Top 3 options selected:

1. We expect a delay for the introduction of innovative medical products of our company in Europe
2. We are no longer making any changes/optimizations to our existing IVDs CE-marked under the IVDD
3. Running performance studies in Europe has become less predictable, costly or takes too much time

	Large	SME
No impact:	3	8
IVDR has enhanced our innovation or optimization activities	0	10
Our innovation projects are currently on hold:	7	19
Running performance studies in Europe has become less predictable, costly or takes too much time:	15	25
We are no longer making any changes/optimizations to our existing IVDs CE-marked under the IVDD:	16	39
We are working on selected innovations, but plan to approve them in other markets first	13	12
Our R&D budget will be reduced	3	3
Our R&D department will be relocated abroad in the medium to long term (only select if it is based in EU):	0	1
Inability to engage early with my Notified Body to explain new technologies:	4	11
We expect a delay for the introduction of innovative medical products of our company in Europe	29	42

**Respondents could choose more than one option*

- All three top options selected can be considered as representing a negative perceived impact of IVDR on innovation
- The first two options selected, show a direct impact on the product itself
- The third option selected, highlights that efficiencies must be gained in making performance studies more predictable and efficient, and less costly

Are there issues that prevent you from starting or completing certification under the IVDR?

	Large	SME	SME and Large
YES	21	34	55
NO	8	32	40
No answer	4	11	15

- 55 respondents said that they had issues with the path to IVDR certification compared to 40 who said they had no issues
- Interestingly, large companies made up most respondents who said they had issues. Large companies are almost all in process to transition to the IVDR compared to less than half of SMEs. This means that there are considerable challenges which are experienced during the transition even for manufacturers which have an agreement with a Notified Body

Conclusions

- ~91% of companies benefitted from the January 2022 amendment providing extended transitional periods
- IVD manufacturers are in transition to the IVD Regulation
- Certification bottlenecks are still possible leading up to May 2025
- Access to a Notified Body has improved since July 2021 but remains a significant issue especially for SMEs
- 17% of today's devices will be discontinued – in most cases due to the cost of CE-marking under IVD Regulation
- Efficiencies can be gained in reducing time-to-certification and increasing predictability of the system at every stage of conformity assessment
- IVD Regulation will impact early access to innovative medical tests in Europe.

*MedTech Europe's 2021 survey findings and the European Commission survey of Notified Bodies on applications and certifications (October 2022)

A warm thank you to all responders and National Associations

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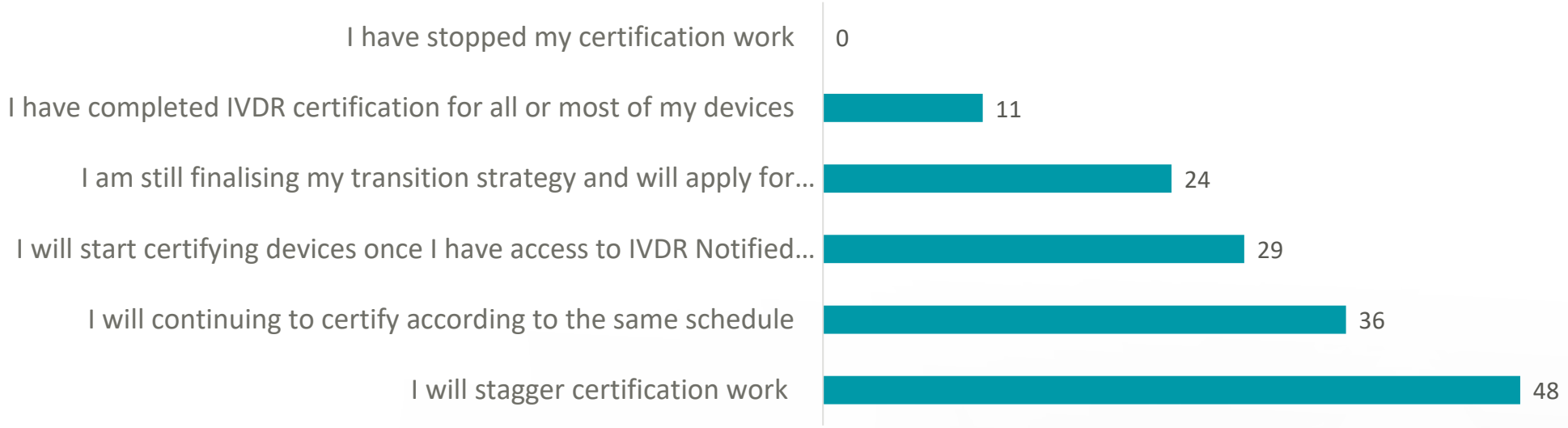
Background slides

How has the January 2022 amendment affected your transition strategy in general? (select all that apply)



- Most manufacturers should be considered as being in transition to the IVDR for their devices. No respondents said they would stop IVDR certification work and only 11 said that all or most of their certification was completed.
- 29 respondents indicated that lack of Notified Body is a block to certification. This is a surprisingly low number (given that 43 respondents do not have an agreement with a Notified Body); it is possible that some respondents without a Notified Body only indicated that they plan to stagger their work.
- 48 respondents will stagger certification work according to the transitional deadlines while 36 respondents will continue their certification work according to the same schedule before publication of the amendment which established extended transitional periods to IVDR.
- The progressive roll out of the IVDR – and ability to stagger work – has likely prevented a certification bottleneck from appearing in 2022 and should prevent one in 2023.

If your IVDD certificates were not renewed or extended to May 2025, please comment on the reason (select all that apply)

33 – All my IVDD certificates were renewed or extended to May 2025

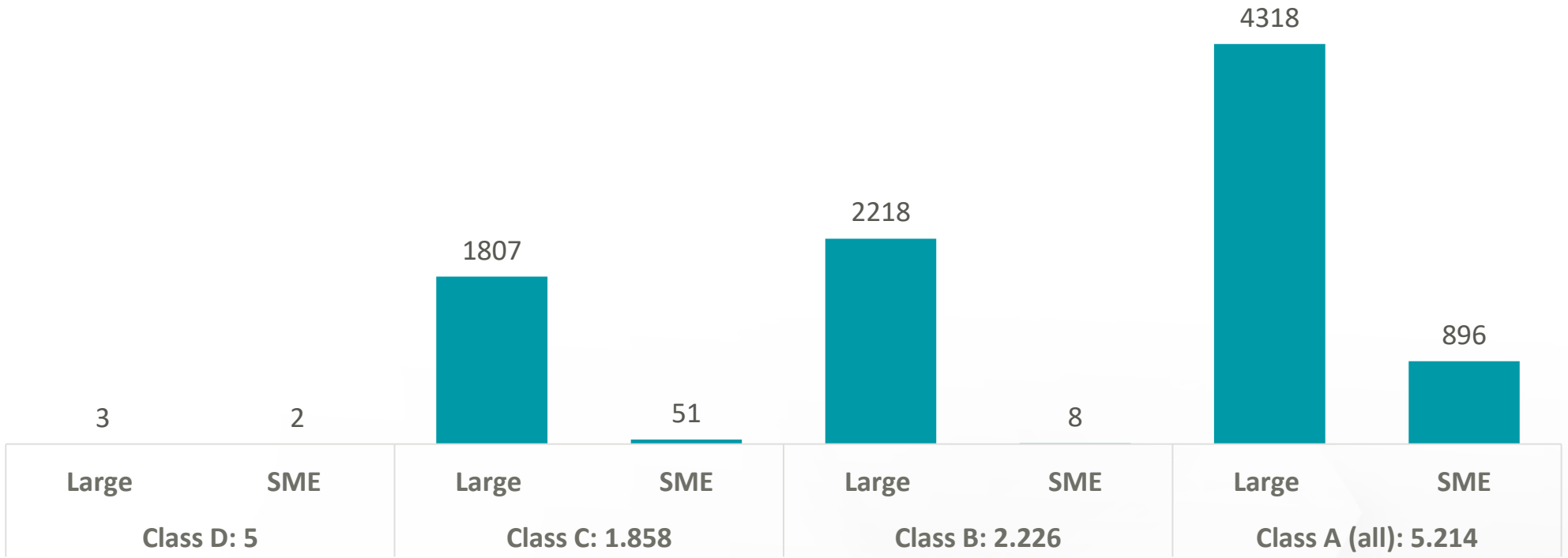
19 – in process of converting the IVDD certificates to IVDR certificates

12 – I decided not to extend/renew the IVDD certificate(s)

5 – NB unable to complete the renewal/extension of my certifications before 26 May 2022

- Of those respondents which did not renew their IVD Directive (IVDD) certificates to May 2025:
  - ❑ Only 5 responses stated that this was due to the NB being unable to complete this work on time
  - ❑ 19 respondents intend to convert their certificates before May 2025
  - ❑ 12 respondents simply said that they will not extend or renew their certificates – which in some but not all cases, may mean discontinuation of the device
- 33 (or less than half) of respondents renewed or extended all their certificates to May 2025

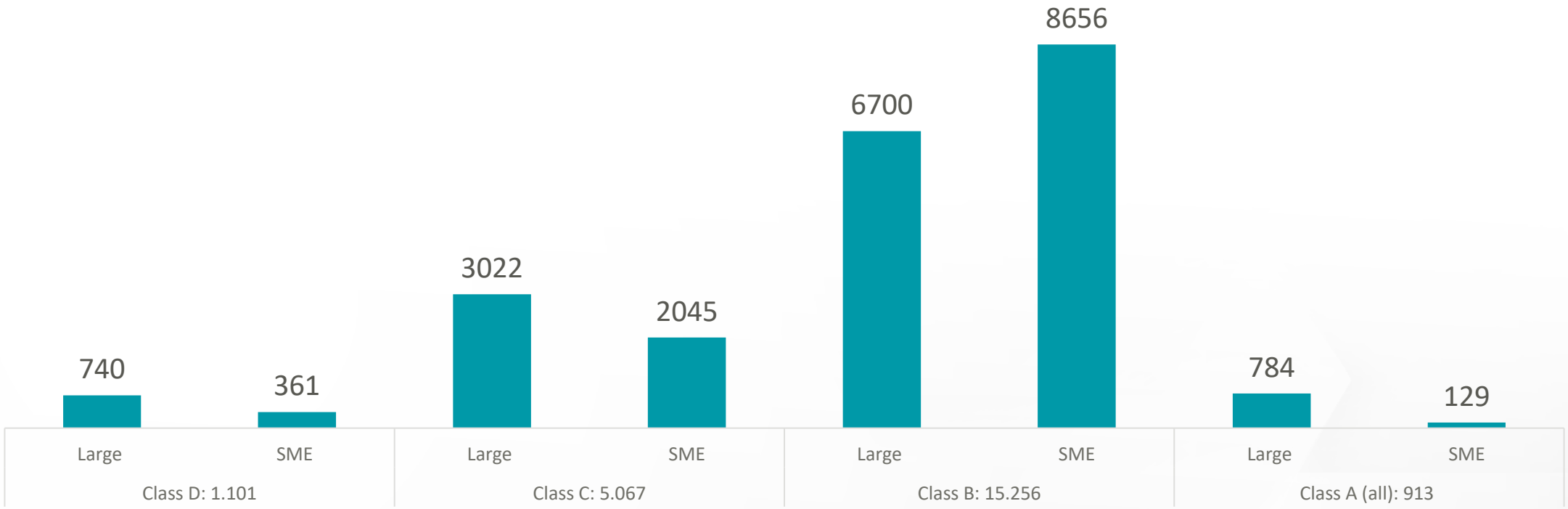
Progress to CE-mark under IVDR



Total 9.303

- Since Class A devices (except sterile) were given no extended transitional period, it is no surprise that Class A represents the risk class with the largest number of devices already CE-marked under IVDR
- Especially larger companies are making progress in CE-marking of Class C and Class B devices. ~27% of Class C and ~12% of Class B devices are already CE-marked when considering the total devices which are CE-marked and under the transitional periods (these percentages will likely be higher as they do not consider device discontinuations)

Overview of legacy devices on the market under the extended transitional periods



Total 22.437

A considerable workload is required leading up to each transitional period which is different for each risk class. The workload per risk class must be started well in advance of each transition deadline, meaning that the workloads must overlap

- ❑ Class D requires individual EU TDA certification alongside EU QMS as well as other conformity assessment procedures
- ❑ While most Class C need only EU QMS with sampling, ~19% will also need EU TDA
- ❑ Class B mostly needs EU QMS with sampling only, but easily represents the largest number of devices

Transition status – Class D devices

Class D (IVDD+IVDR 1.106)	already CE-marked under IVDR?	on the market according to the extended transition	planned significant change	planned new/innovative devices
total	**5**	**1.101**	**60**	**87**
Large	3	740	10	65
SME	2	361	50	22

**European Commission survey of applications and certifications (Oct 2022) – 186 applications were accepted for EU QMS + EU TDA*

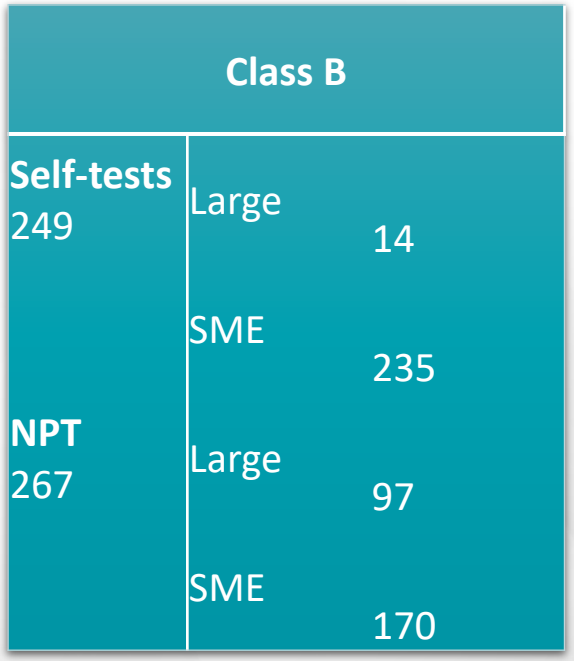
Transition status – Class C devices

Class C (IVDD+IVDR 6925)	already CE-marked under IVDR?	on the market according to the extended transition	planned significant change	new/innovative devices
total	**1.858**	**5.067**	**82**	**209**
Large	1.807	3.022	35	135
SME	51	2.045	48	74

Class C		
Self-tests 597	Large	497
	SME	100
NPT 689	Large	658
	SME	31
CDx 52	Large	25
	SME	27

Transition status – Class B devices

Class B	already CE-marked under IVDR?	on the market according to the extended transition	planned significant change	new/innovative devices
total	**2.226**	**15.356**	**246**	**226**
Large	2.218	6.700	69	72
SME	8	8.656	177	154



Transition status – Class A devices

Class A	already CE-marked under IVDR?	on the market according to the extended transition	planned significant change	new/innovative devices
total	**5.214**	**913**	**102**	**102**
Large	4.318	784	101	64
SME	896	129	1	38

Thank you!

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