14 July 2022

MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation

Survey data was gathered during 4 – 29 April 2022

MedTech Europe
from diagnosis to cure

Contents

Disclaimer:

This survey has been conducted by MedTech Europe to assess the state of implementation of several key aspects of MDR. The raw results have been aggregated in accordance with applicable laws and regulations. No part of this report may be construed as providing guidance, recommendations, or any type of suggestion as to how individual companies should operate.

Notes on survey responses:

- *The data provided is aggregated*
- *The aggregated information will be used with EU institutions (European Commission, Council and European Parliament) and external stakeholders*
- *Any examples will be anonymised without reference to companies*
- *This survey report will be made available on the MedTech Europe website*

Note on quality of data:

MedTech Europe has aggregated the data received via its survey in order to prepare the present report, however, MedTech Europe cannot be held responsible for the quality and accuracy of the data inputs received from individual respondents which determines the quality and accuracy of the aggregated results as they are presented.

Executive Summary & Key Figures

- The survey represents an estimated **60-70%** market revenue coverage.
- MDR certificates have not been issued yet for **>85%** of the >500,000 devices previously certified under the MDD or AIMDD[1].
- Larger companies are actively filing under MDR. Review is still ongoing for **70%** of submitted industry applications.
- The time-to-certification with MDR-designated Notified Bodies is taking **13-18 months** on average. This is double the time historically needed for certification under the Directives.
- **>50%** of respondents plan portfolio reductions. **33%** of these companies' medical devices are currently planned for discontinuation.
- **All** product categories are impacted by potential device discontinuations.
- At least 15 % and **up to 30%** of Small and Medium Enterprises (SMEs) still have no access to an MDR-designated Notified Body.
- **~50%** of respondents are deprioritising the EU market (or will do so) as the geography of choice for first regulatory approval of their new devices.
- **>20%** of respondents attribute delays in MDR certification to the publication of new or revised MDCG guidance.

[1] AIMDD: Active Implantable Medical Devices Directive 90/385/EEC
MDD: Medical Devices Directive 93/42/EEC

MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the MDR implementation

Introduction

To align with significant developments in technology and healthcare over the last 20 years, the European Union has revised laws governing medical devices (MDs). The MD Directive (MDD) 93/42/EEC and Active Implantable MDD (AIMDD) 90/385/EEC were first published in 1993 and 1990 respectively and have now been replaced by the MD Regulation (MDR) 2017/745 which entered into full application on 26th May 2021 after a transition period of three years, extended in early 2020 for a fourth year due to the COVID-19 crisis. CE marking under the old Directives is not possible anymore, and all new or legacy medical devices must meet the new, modernised and more stringent requirements of the MDR to continue being placed on the market in the future.

Implementation of the MDR is a top priority for the medical devices industry, and ever since its inception, MedTech Europe has welcomed and supported the MDR's goals. Industry has committed significant resources to comply with new requirements and has been investing heavily throughout the transition period to help make a success of the new regulatory system.

Now, more than one year under the MDR regime, despite its earnest efforts to get ready, the sector remains seriously held back by the slow and piecemeal implementation of the new regulatory framework. Continuity of patient access and care are threatened, both in the EU and in the more than 100 countries around the world that rely on European CE marking of medical devices.

Over the years, MedTech Europe has consistently predicted and reported these challenges, which continue to exacerbate over time. With a view to illustrate these challenges with concrete data, MedTech Europe ran a survey within the medical device industry. The survey questions were drafted in part with the help of MedTech Europe members and in part with the help of the Medical Device Coordination Group (MDCG) Task Force on Certification Capacity Monitoring.

We conclude from this data that **solutions are still urgently needed to course-correct the MDR**, and to thereby ensure that all categories of medical devices can remain available to patients.

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

Methodology & Participation

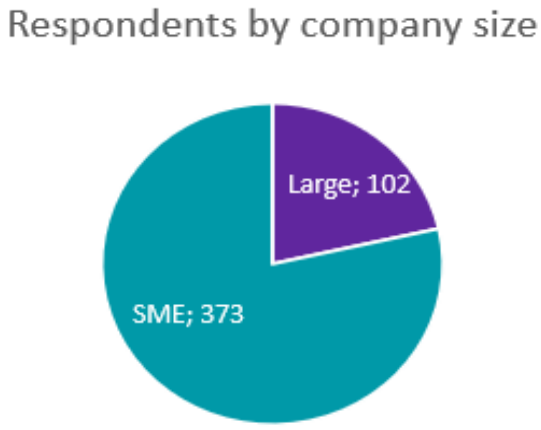
The MDCG task force on certification capacity monitoring (formally part of the Competent Authorities for Medical Devices (CAMD)) commissioned MedTech Europe to run a survey on the MDR market. Between the 4th and 29th of April 2022, the survey was sent to all MD manufacturer members of MedTech Europe. National Associations and certain partner associations outside of Europe were encouraged to invite their own member manufacturers to participate. Only one submission per manufacturer was allowed.

The survey was partly drafted by the MDCG task force on capacity monitoring and partly drafted with the help of MedTech Europe members. It included 30 questions divided in to two core sets of questions:

- Part 1 questions (1 to 14): were mainly aimed at assessing the capacity of Notified Bodies and the certification situation under the MDR
- Part 2 questions (15 to 30): included additional questions drafted by MedTech Europe only.

The participants had the option to answer/skip questions according to their preference. Only questions related to identification of respondents were mandatory.

The numerical results have been aggregated and are being published in conformity with the legal disclaimer. MedTech Europe presented a preliminary high-level summary of key results of the survey at the occasion of the 19 May 2022 MDCG-Stakeholder meeting and subsequently shared an initial report with the MDCG task force on capacity monitoring as well as the European Commission.



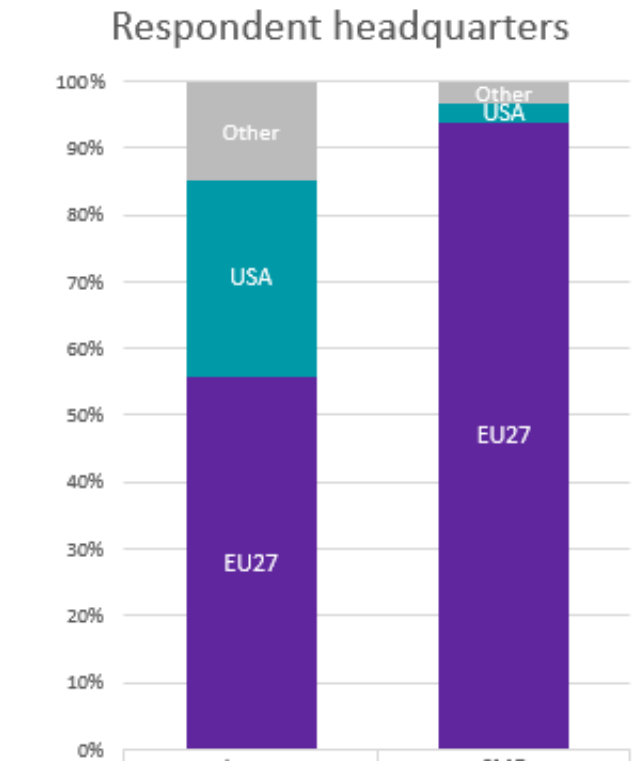
With 475 responses from EU and international companies operating in the EU across large (102) and Small and Medium Enterprises - SMEs [2] (373), representing an estimated 60-70 % market revenue coverage[3], the quality and quantity of data provided by the survey gives sufficient confidence in the conclusions drawn here.

[2] SME – Small and Medium size Enterprise: employ fewer than 250 persons and which have an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro.
[3] MedTech Europe estimation based on the annual turnover indicated by survey respondents compared to the Facts and Figures publication available at: https://www.medtecheurope.org/about-the-industry/facts-figures/

56%, i.e., 57 of the 102 large companies that participated in this survey, have their headquarters in the European Union (EU). The remaining 29% are based in the United States of America (USA). 15% (15 large companies) have their headquarters in other countries.

94%, that is 350 Small and Medium Enterprises (SMEs) out of the 373 that responded to the MedTech Europe survey are EU based. 6% are based in USA or other countries.

This is shown in the graph and a table is included with the numbers of respondents per category.



	Large	SME
Other	15	13
USA	30	10
EU27	57	350

Survey Key Findings

1) The majority of devices on the market is yet to transition to the MDR in less than two years that remain until 26 May 2024.

- The vast majority of medical devices are yet to be certified under the MDR: Certificates have not been issued yet for more than 85% of the > 500,000 devices estimated to be covered by (AI)MDD certificates.

- The time-to-certification with MDR-designated Notified Bodies is slow: it takes 13-18 months on average across all devices and company sizes for an initial certification. At the time of the survey, 70% of submitted applications are still under review.

- Progress to certification is slow. Around 14% of all certificates (Quality Management System – QMS - and Technical File) have been issued so far. For both large companies and Small and Medium Enterprises (SMEs) who have at least some legacy products, on average 83% of their portfolio are ‘legacy’ devices.

2) Over half of all survey respondents plan portfolio reductions.

- Those respondents planning portfolio reductions foresee on average 33% of their devices for discontinuation.

- Respondents highlighted concerns in every specific product category offered in the survey and added further product areas of particular concern. It is difficult to know which categories of medical device would be left unaffected by MDR implementation. This will have a significant impact on healthcare systems.

3) SMEs are more impacted by the MDR than larger companies.

- Up to 30% of SMEs have either no Notified Body (15%) and/or have a Notified Body that is not yet designated to MDR (15%).

- Progress to certification is slower than average: only 7% of MDR certificates have been issued for SMEs compared to 13% on average.

- According to the survey data, while SMEs account for 26% of the total number of devices expected on the market by 26 May 2024, they will require 40% of the total certificates needed.

4) Innovation is leaving Europe.

- Nearly half of the respondents are deprioritising (or will do so) the EU market as the geography of choice for first regulatory approval of new devices.

- MDR has not supported innovation in the EU. A large number of issues has been linked to the MDR as hinderance of innovation and can be consulted in the specific section of this report.

5) MDCG guidance documents and delays in certification

- More than 1 in 5 companies have reported a delay in certification due to a publication of new or revised MDCG guidance. Almost half of all delays led to some level of reworking.

- Large companies seem to be more impacted.

Summary of Results

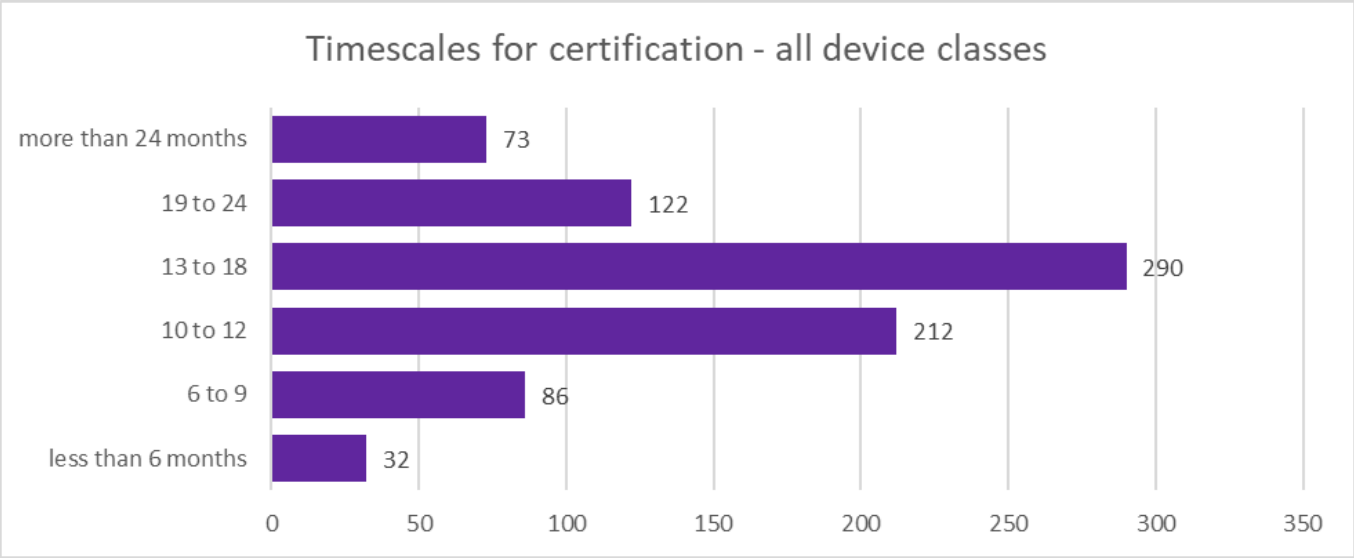
Certification and Applications under MDR

It takes a significant amount of time to have a device MDR certified: 13-18 months on average and the timescale indications do not differ based on the company size.

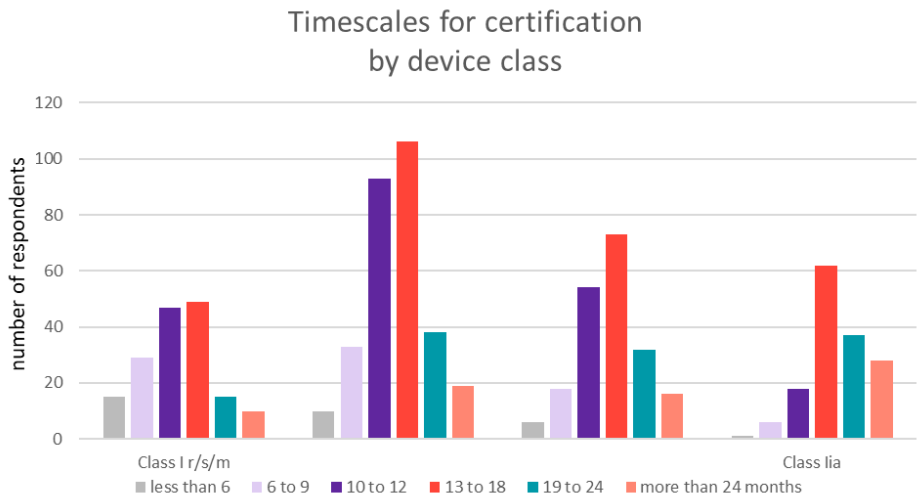
70% of submitted applications are currently under Notified Body review.

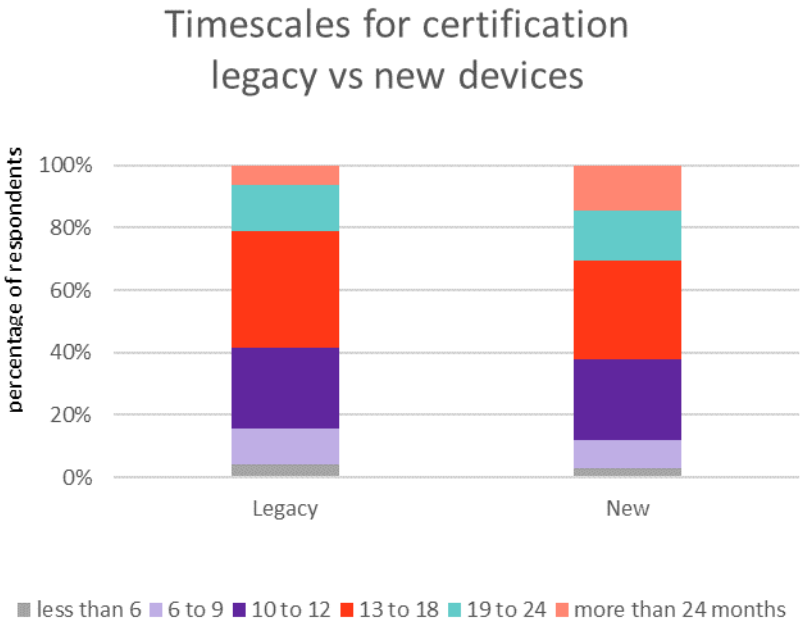
Timescales

Data collected on this subject demonstrate that although timescales to certification (product and QMS certification) can be rapid (less than 6 months) this is far from the 'most likely' timescale with only 32 respondents having experienced this. The timescale most often quoted for Notified Body certification is 13 to 18 months by 290 respondents. This is double the time historically needed for certification under the Directives. 73 respondents experienced certification timelines greater than 24 months.



New devices and class III devices were more likely to lead to longer certification timescales, as shown in the two following graphs:



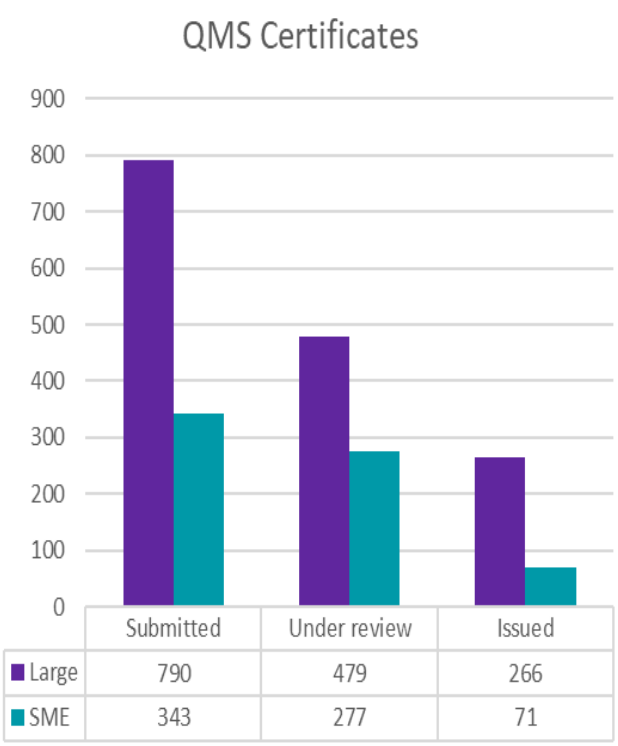


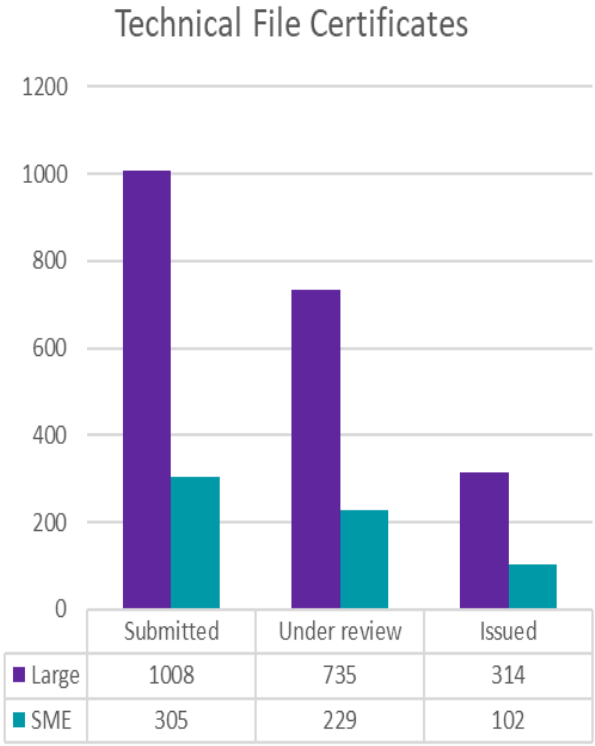
In addition, the top 5 indicated challenges with Notified Bodies are the following:

1. Unpredictable certification time resulting in longer cycles, longer waiting time; this has consequences on availability of devices (e.g., Directives certificates expire before being transitioned to MDR) and/or planned product launch dates
2. Lack of predictability, e.g., no binding conformity assessment timelines from the Notified Body
3. Lack of responsiveness
4. Fragmented/ non-harmonised interpretations of the same requirements of the MDR among Notified Bodies and within Notified Bodies
5. Fragmented/ non-harmonised interpretations of MDCG guidelines

Applications

70% (1,720 out of 2,446 total) of submitted applications for Quality Management System (QMS) and Technical File (TF) certificates are still under review by the Notified Bodies. 31% or 753 out of the 2,446 total of submitted applications have resulted in the issuance of a certificate. The absolute number of applications is higher for large companies however, the proportions are remarkably similar for the applications made by SMEs.[4]





[4] Please note that there are small discrepancies regarding the numbers of technical file certificates for SMEs and large companies as well as for QMS for SMEs (i.e., the totals of submitted applications are lower than the sum of 'issued' + 'under review'). In our view, this could be potentially attributed to or explained by:

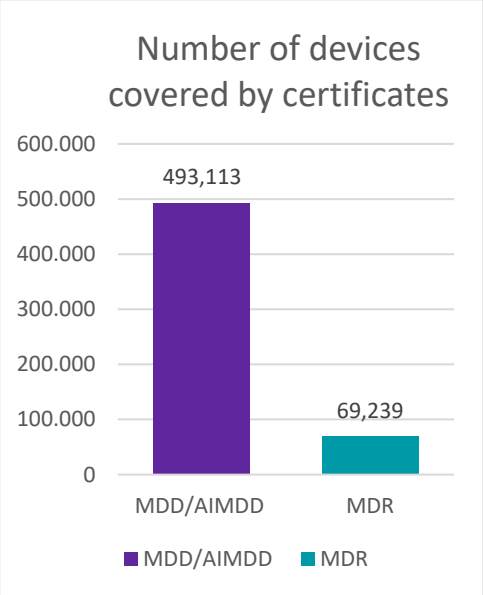
- For QMS certificates: inconsistencies in the manufacturers' submissions of data and/or misunderstanding of the question.
- For the Technical files: only for Class III and Implantable Class IIb there is a systematic review of all dossiers (and therefore an application), while for other Class IIb the decision to review the file is taken by the Notified Body on an ad hoc basis.

In general, additional targeted feedback requested from some companies revealed that the actual "submission of a dossier" could have been interpreted differently, e.g., the fact that a dossier has been submitted may not necessarily mean that an evaluation/review started at Notified Body level.

Numbers of Directive and MDR devices covered by certificates: current and expected

The number of devices covered by certificates: Directives versus Regulation.

According to the survey, since the first MDR certificates were issued in 2019, only 69,239 devices have been certified to MDR in the past three years.



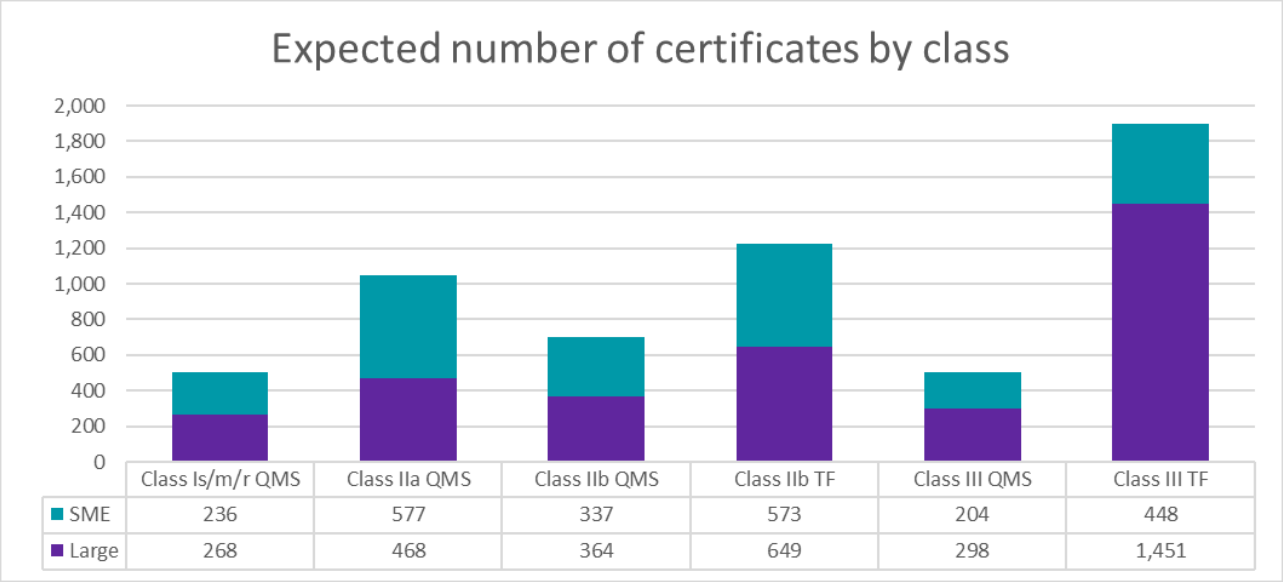
These numbers confirm the slow progress to MDR certification and raise concerns on the feasibility of transferring the almost 500,000 devices currently with MDD/AIMDD certificates to MDR in the less than 24 months remaining before May 2024.

Expected number of devices under MDR	Large companies	SMEs	Total
Class I	83,850	76,457	160,307
Class Is/Im/Ir	58,769	38,230	96,999
Class IIa	119,435	17,818	137,253
Class IIb	130,710	16,428	147,138
Class III	85,466	14,923	100,389
Total number of expected devices needing a certificate [5]	**394,380**	**87,399**	**481,779**

In the transition to MDR, respondents expect a drop of around 5% in the number of devices expected to be covered by a certificate. However, given the slow progress of certification until this point and the long

[5] This total excludes class I

timelines for getting an MDR certification, it seems unlikely that the expected number of devices will in fact be available in 2024.



Class Is/Im/Ir devices will make up around 1/3rd of all class I devices and almost 20% of all certified devices.

It is also important to note that 54,820 Class I devices will be up-classified under the MDR, this represents 8% of total AIMDD/MDD devices placed on the market. These devices did not have an AIMDD/MDD certificate and will need a certificate for the first time under MDR.

	Large companies	**SMEs**	**Total**
Class I up-classified	42,970	11,850	**54,820**
Class I up-classified as percentage of total AIMDD/MDD devices placed on the market	7.8%	10.4%	**8.3%**

Based on data collected on devices that are expected under MDR by May 2024 and the number of applications for certification submitted up until this point, the following conclusions can be drawn (shown in the table below):

- Industry is actively filing applications for MDR certification
- Large companies have so far submitted applications for 57% of the QMS certificates expected in May 2024 and for 48% in case of Technical File applications.
- However, for SMEs these figures are much lower: they have so far submitted applications for only 25% of the QMS certificates which are expected in May 2024 and for 30% in case of Technical File

applications. These lower numbers could be attributed to the difficulties SMEs are facing with MDR implementation, such as insufficient access to Notified Bodies.

Total Needed for expected devices	Large companies	SMEs	Total
QMS	1,398	1,354	**2,752**
TF	2,100	1,021	**3,121**

Total Submitted for expected devices	Large companies	SMEs	Total
QMS	790	343	**1,133**
Technical Files	1,008	305	**1,313**

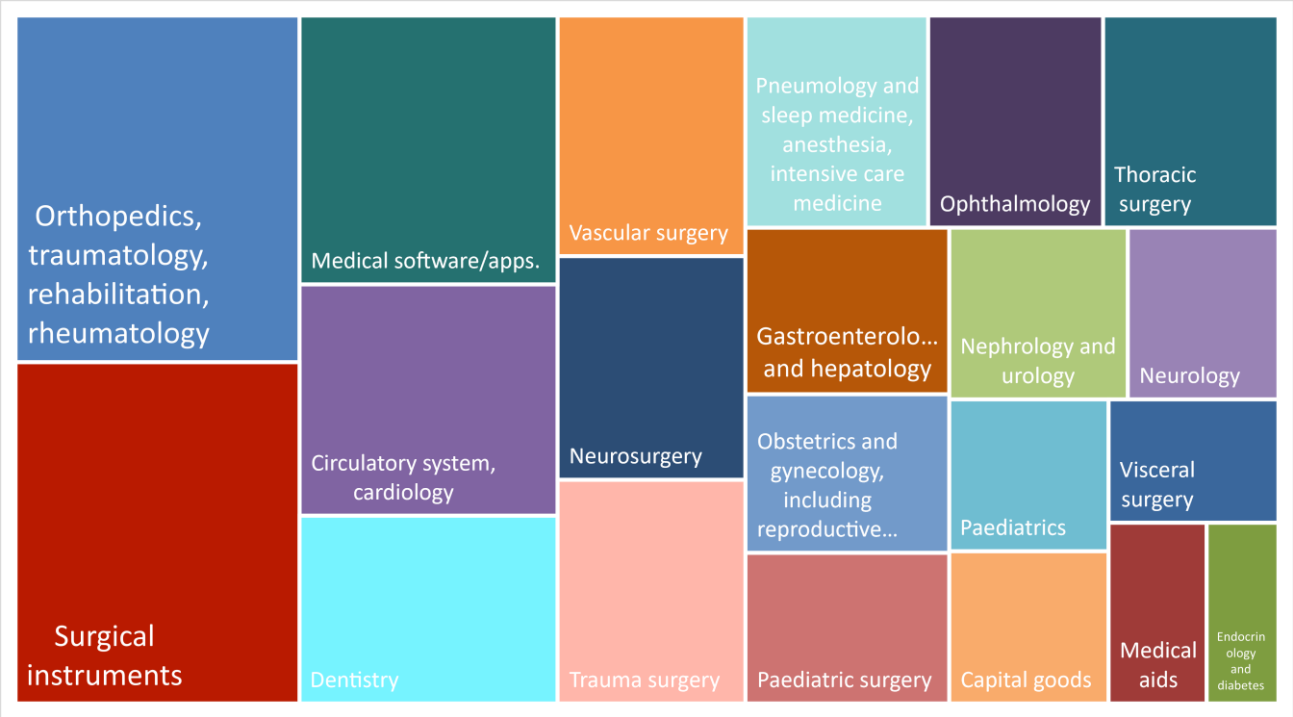
Submitted out of Total needed	Large companies	SMEs	Total
QMS	57%	25%	**41%**
TF	48%	30%	**42%**

Foreseen product portfolio reductions as a consequence of MDR implementation

Respondents highlighted concerns for all categories offered in the survey that their devices will not be MDR certified on time and added further product areas of particular concern (as shown below).

54% of respondents said that they do not intend to transition some of their portfolio to MDR. Overall, manufacturers' portfolios will be reduced by an average of 20%, which is significant

The "tree map" below lists the categories of devices which respondents listed as the most likely to be impacted by portfolio reductions (the size of the square is in proportion to the number of answers received).



The survey respondents highlighted MDR specific issues that are leading to decisions regarding end of life or discontinuation of the device. These issues included mostly substantial increase of costs to recertify under MDR (and general MDR sustaining costs), difficulties linked to clinical evidence for legacy devices, as well as capacity issues at Notified Body level and manufacturer level – due to the unavailable resources as opposed to increased requirements.

Specific comments on this topic also mentioned for instance difficulties linked to up-classification of medical devices.

The impact of the MDR on SMEs

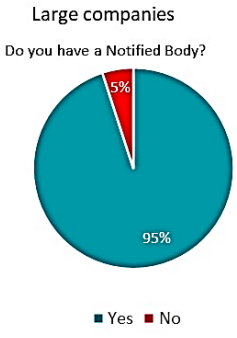
Small and Medium Enterprises face more challenges in MDR implementation than larger companies.

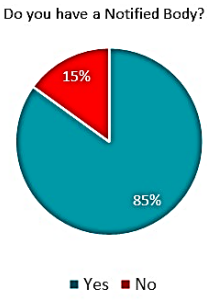
Progress to certification is slower than the average for SMEs: only 6% of their devices planned to be transitioned to MDR have been certified under the new regulation, compared to 16% of MDR certified devices planned to be transitioned by large companies. Furthermore, only 7% of SMEs certificates (TF and QMS) have been issued under MDR, compared to an overall average of 13%.

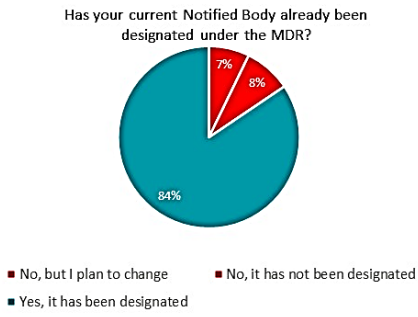
According to the survey data, while SMEs account for 26% of the total number of devices expected on the market by 26 May 2024 (or 18% of devices requiring a certificate, i.e., those in Class Ir/Is/Im/IIa/IIb/III), SMEs will require 40% of the total certificates needed. In addition, as discussed in the previous section, SMEs lag behind larger companies in terms of submitted applications for MDR certification.

At least 15 % and up to 30% of SMEs report having no access to an MDR-designated Notified Body yet.

96 large companies and 316 SMEs have a Notified Body, while 5 large companies and 56 SMEs (that is **15%** of the SMEs responding to this survey) currently do not have one. In addition, **15%** (54 out of 347) of the responding SMEs are with Notified Bodies who are not yet designated.







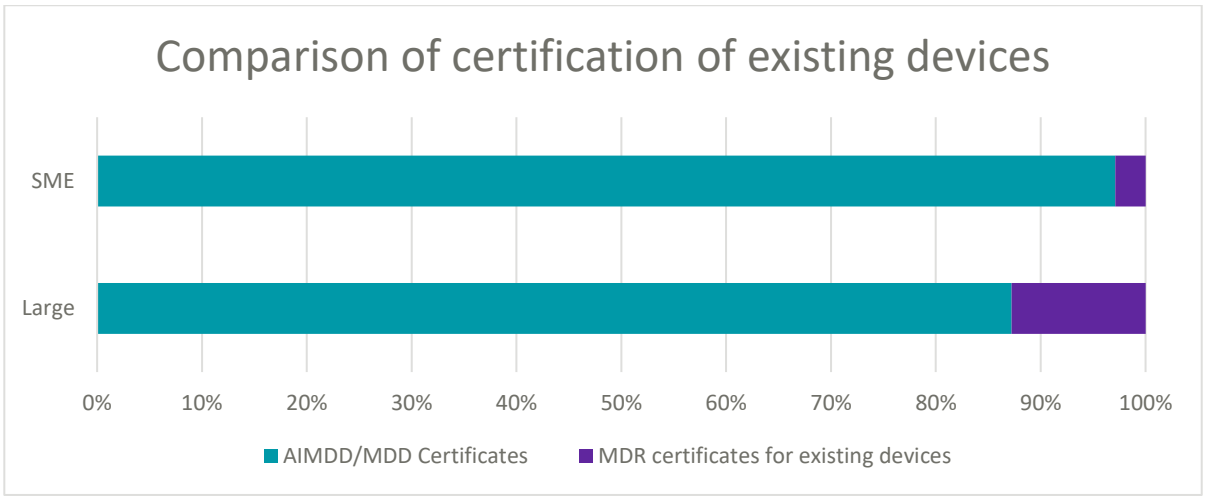
All current Notified Bodies used by the large company respondents are MDR-designated.

	Large companies	SMEs
No, but I plan to change	0	25
No, it has not been designated	0	29
Yes, it has been designated	96	293

Number of existing devices covered by certificates – comparison between SMEs and large companies:

	Large companies	SMEs
Directives	413,334	79,779
Regulations	65,162	4,077

16% (65,162/413,334) of existing devices (i.e., excluding 'new'/innovation devices) made by large companies have been transitioned to MDR certificates. 5% (4,077/79,779) of existing devices made by SMEs have been transitioned to MDR certificates. These figures show that the rate of transition to the MDR is lower for SMEs than for larger companies. The qualitative data gathered through comments points to explanations such as: costs of recertification, time, and resources for MDR are becoming too high for many small companies to absorb.



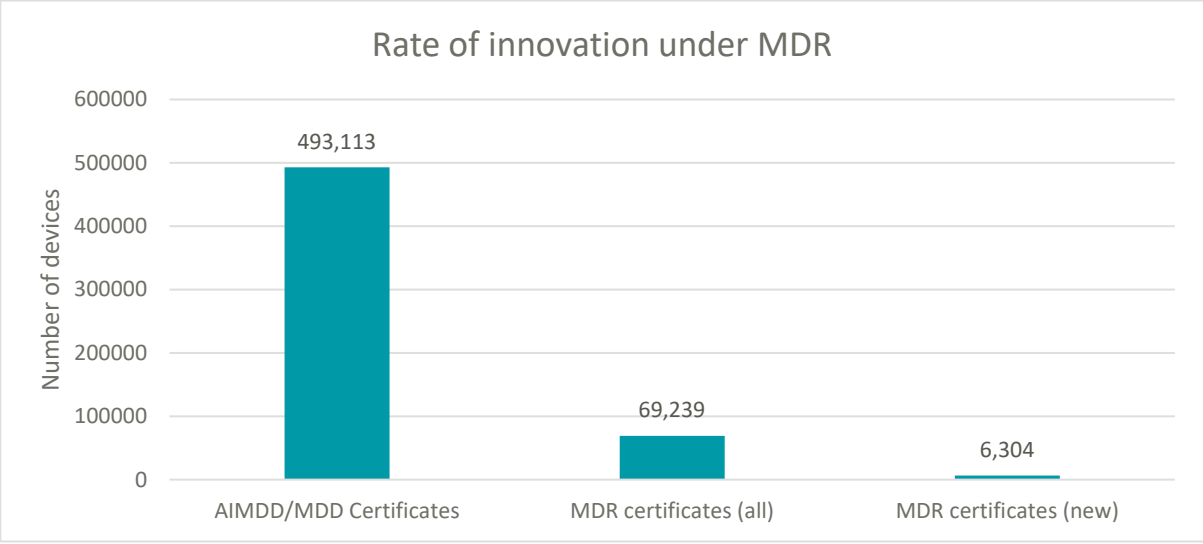
Innovation is leaving the EU

MDR is currently a disincentive against launching medical device innovation in the EU.

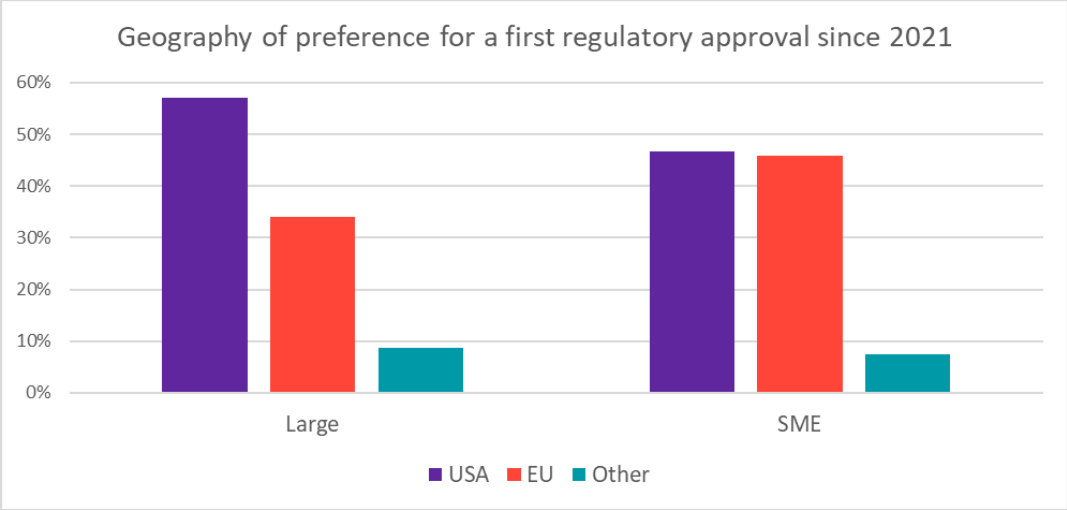
Almost 500,000 devices were covered by an MDD/AIMDD certificate. Less than 70,000 have successfully switched to a MDR certificate. As of now, just over 6,000 'new' devices are covered by MDR certificates. 45% (206/457) of all companies who responded said that they had deprioritised the EU as a market for first regulatory approval.

Since 26 May 2021, 101 companies participating in the survey have already chosen to launch 4,306 new devices outside of the European Union (instead of the EU).

This graph illustrates the vast gap that exists between the devices currently certified to MDD/AIMDD – almost 500,000 as opposed to the nearly 70,000 currently certified to the MDR, out of which only 6,000 are 'innovation' devices. Based on the graph and other indications from the survey, the focus seems to be on recertification of existing devices. Also, for companies that are transferring their devices to MDR, on average 83% of their portfolio already CE marked under MDR are existing devices (not new/innovation devices).



The following graph shows that the geography of preference for a first regulatory approval since 2021 is the USA. Large companies are now more likely to prioritise USA over EU for new approvals. Although 94% of SME respondents in the survey are EU based, EU and USA are now prioritised equally for new products. This means that half of the EU based innovation will benefit patients in the USA first - not in the EU.



	Large companies	SMEs
Australia	0	1
Canada	1	3
China	0	3
EU	31	141
Japan	3	2
Other	4	14
USA	52	144

As indicated above, innovative devices form only a very small part of the new certificates. Apart from the focus on transition of legacy devices from the Directives to the Regulation rather than innovation, the numbers also indicate a strong trend in launching innovative products elsewhere, which may account for the low certification numbers for new products in the EU. In addition, some companies have provided comments indicating that they have had to choose between innovation and recertification - they cannot presently do both in the EU.

A word on MDCG guidance documents

There have been many discussions about guidance documents in general in the recent years. Questions in the MedTech Europe survey also focused on this topic. Data on this subject confirm that MDCG guidance documents can slow down the certification process and lead to rework of the submitted applications, i.e., more than 1 in 5 companies have reported a delay in certification due to a publication of new or revised MDCG guidance. Almost half of all delays led to some level of reworking.

	Large companies	SMEs	total
No answer	11	66	77
No, I have not experienced a delay.	50	243	293
Yes, a delay of less than 1 month.	4	9	13
Yes, a delay of between 1 and 3 months.	15	23	38
Yes, a delay of more than 3 months.	22	32	54
Rework needed	38	53	91
% Reporting a delay	**40%**	**17%**	**22%**
% Reporting a delay of more than 3 months	**22%**	**9%**	**11%**
% Of delays needing rework	**48%**	**45%**	**46%**

Large companies are more affected by changes and related delays due to guidance documents (as they cover a larger portfolio and therefore fall into scope of a wider range of guidance documents).

45 different guidance documents have been associated with some level of delay but three in particular were often named by respondents:

- MDCG 2021-24 Guidance on classification of medical devices[6]
- MDCG 2020-5 Clinical evaluation – Equivalence: A guide for manufacturers and notified bodies[7]
- MDCG 2020-6 Guidance on sufficient clinical evidence for legacy devices[8]

Furthermore, qualitative data collected via comment fields mention the following issues with MDR implementation regarding guidance: delayed or missing (such as PSUR), guidance is treated “as a law” (sometimes in opposition to the MDR legal text) or guidance does not provide the needed clarity.

[6] MDCG 2021-24 Guidance on classification of medical devices (October 2021)
[7] MDCG 2020-5 Clinical evaluation – Equivalence: A guide for manufacturers and notified bodies
[8] MDCG 2020-6 Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC

Conclusions

The implementation of MDR in the EU is having a serious effect on the EU medical device market. This will be felt by EU patients and health systems.

This survey identifies and quantified various challenges linked to MDR implementation, including:

- The transitioning of AIMDD/MDD certificates to the MDR,
- Progress of Notified Bodies in treating applications submitted for MDR certification,
- Notified Body capacity limitations and assessment timelines,
- Impact on availability of medical device innovation in the EU,
- Impact of guidelines.

The data also reveal the differing impacts of the present MDR situation on larger versus and smaller (SME) companies, showing clearly that the latter companies are worse off. This survey represents an estimated 60-70 % of EU market revenue coverage, and with 475 respondents across large and SME companies there should be confidence in the conclusions drawn here.

With less than two years remaining until 26 May 2024, few devices have so far successfully transitioned to the MDR, and timescales for medical device certification are now at an all-time high.

If the situation elucidated by this data is not urgently course corrected, MedTech Europe predicts that legacy devices across all categories will disappear from the market between now and May 2024.

In addition to the disappearance of legacy devices, the survey data clearly shows that innovation is already leaving Europe. This too, MedTech Europe fervently believes, must also be course-corrected, otherwise the clinical benefits of new and improved device designs will become preferentially available to patients in third countries first, requiring patients based in the EU to wait for the MDR system to become ready.

This survey clearly indicates an urgent need for immediate action by decision-makers to help keep needed medical devices available in Europe.

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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