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Extensive EU Medtech Regulatory Survey Reveals Scale Of MDR Hurdles And Where Problems Lie

by Amanda Maxwell

MedTech Europe says solutions are still urgently needed to ensure the MDR is on course and warns that 50% of companies are deprioritizing the EU as launch market, potentially denying EU citizens vital health care.

Medical Device Regulation certificates have not been issued yet for over 85% of the more than 500,000 devices previously certified under the Medical Devices Directive or the Active Implantable Medical Devices Directive. Only 69,239 devices have been certified to the MDR in the past three years.

That is the shocking figure just released by MedTech Europe, the EU's largest medtech industry association, in a *survey* entitled MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation. It is the most extensive survey of its kind to date.

Worrying, but not surprisingly, the 21-page survey report also claims that the MDR "is currently a disincentive against launching medical device innovation in the EU."

Indeed, approximately 50% of respondents, MedTech Europe says, were found to be deprioritizing the EU market (or will do so) as the geography of choice for first regulatory approval of their new devices.

Devices Needing Audits By Risk Class

The expected number of legacy devices needing auditing under the MDR by the 26 May 2024 cut-off, or sooner if the certificates themselves are due to expire earlier, are as follows, according to the risk class of the products (with class I representing the lowest risk class and class III the

highest):

Expected number of devices under MDR	Large companies	SMEs	Total
Class I	83,850	76,457	160,307
Class I sterile, class I measuring function, and class I reusable surgical devices	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 expected to need a certificate (excludes class I)	**394,380**	**87,399**	**481,779**

Varying Certification Timelines And Notified Body Fragmentation

Data collected showed that although timescales to notified body certification for medtech products can be rapid (less than six months), 73 respondents experienced certification timelines greater than 24 months:

Time To MDR Certification	No. of Devices Within Timescale
Over 24 months	73
19-24 months	122
13-18 months	290
10-12 months	212
6-9 months	86
Less than 6 months	32

New devices and class III devices were more likely to experience longer certification timescales.

MedTech Europe Warning

MedTech Europe warns that "this survey clearly indicates an urgent need for immediate action" by decision-makers to help keep needed medical devices available in Europe.

If the situation highlighted by this data is not urgently steered back towards a manageable course, the association predicts that legacy devices across all categories will disappear from the market between now and May 2024. It also warns that if action is not swiftly taken that the clinical benefits of new and improved device designs will become preferentially available to

patients in third countries first, requiring EU patients to wait until the MDR system is ready.

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.

How Notified Bodies Contribute To Company Challenges

The survey also highlighted the top five challenges with notified bodies:

1. Unpredictable certification time resulting in longer cycles, longer waiting time impacting device availability (e.g., directive certificates expiring 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 from notified bodies.

4. Fragmented/non-harmonized interpretations of the same requirements of the MDR, not only among notified bodies as a group but also within them individually.

5. Fragmented/non-harmonized interpretations of Medical Device Coordination Group (MDCG) guidelines.

More Worrying Facts And Figures

Among other headline facts and figures that emerged from the survey's findings are the following:

- The time-to-certification with MDR-designated notified bodies is 13-18 months on average. This is double the time historically needed for certification under the directives.

- 70% of submitted applications are still under review.

  Over 50% of respondents plan portfolio reductions. In all, 33% of these companies' medical devices are currently planned for discontinuation.

- All product categories are impacted by potential device discontinuations.

- For both large companies and small and medium-sized enterprises (SMEs) who have at least some legacy products, on average 83% of their portfolio are "legacy" devices.

- Between 15% and 30% of SMEs still have no access to an MDR-designated notified body. Even when they have, their time to certification is slower than average.

- 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.

- Over 20% of respondents attribute delays in MDR certification to the publication of new or revised MDCG guidance, and large companies seem to be more impacted.

The Survey And MDCG's Involvement

Notably, the review was commissioned by Medical Device Coordination Group (MDCG), the European Commission body tasked with supporting the implementation of the MDR and IVDR.

Controversially, the MDCG recently blamed industry for delays in compliance with the new regulations. But the general view among industry, notified bodies and consultants is that the root of the delay for industry's lack of preparedness is the insufficient notified body availability and capacity - in the main due to the slow designation of notified bodies.

The survey questions were drafted in part with the help of MedTech Europe members and in part with the help of the MDCG Task Force on Certification Capacity Monitoring.

The survey data is recent. It was gathered between 4 and 29 April and MedTech Europe says there should be confidence in the conclusions as there were 475 respondents across large (102) and SME (373) companies and it represents an estimated 60-70 % of EU market revenue coverage.