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| **Medical Devices Regulation (MDR) implementation –** **MedTech Europe Survey** |

Introduction

Since 26 May 2021, the Medical Devices Regulation (MDR) has come into full application. Within the framework of new MDR advocacy efforts, MedTech Europe and its members have identified priority areas that lead to an unpredictable and innovation unfriendly regulatory system. These include e.g. challenges when transitioning Directive certificates, lack of Notified Body capacity, fragmented MDR implementation across Europe, implementation of guidelines, innovation, etc.

MedTech Europe now needs concrete evidence / data to illustrate these points. We are therefore reaching out to our members (corporate members as well as national associations and their members) with a request to fill in a survey by 25 April 2022 (EOB).

The survey, which was partly drafted by regulatory Authorities and partly drafted with the help of members, includes two core sets of questions

* Part 1: aimed at assessing the capacity of Notified Bodies; these are questions from Authorities, i.e., the Medical Device Coordination Group (MDCG) Task Force on certification capacity monitoring
* Part 2: additional questions drafted by MedTech Europe.

**MedTech Europe strongly encourages all members to reply to the survey. Our aim is to provide regulatory Authorities with a realistic picture of the state of the MDR implementation and your feedback is therefore of utmost importance.**

Acting in full compliance with EU competition law, and within its limits, MedTech Europe will keep any company specific information (raw data) collected strictly confidential and under no circumstances will disclose individualized company level information. We will share aggregated, company anonymous survey outcomes with responders of the survey and third parties, including but not limited to Regulators, legislators, and relevant stakeholders (e.g., Notified Bodies).

National associations may get access to individualized company data, if companies request a copy of their replies in the survey – MedTech Europe will then share a pdf version of the company replies (which can then be forwarded to the respective national association directly by the company).

Survey practical information:

* Deadline for reply: Monday 25 April 2022 (EOB)
* Access the survey here: [**https://www.surveymonkey.com/r/MDR\_implementation**](https://www.surveymonkey.com/r/MDR_implementation)
* Kindly provide only ONE answer per company.
* We have distributed a word document of the survey questions to help you compile data from several of your company divisions. It is important to note that answers submitted through means other than Survey Monkey (e.g., submissions in WORD or PDF format) will not be accepted.

If you have any questions or enquiries, please contact Jana Russo at regulatory@medtecheurope.org.

This exercise is of crucial importance in our future advocacy efforts, and we need your help! Thanks very much in advance for all the time and effort you’ll invest in this survey.

Acronyms and definitions:

* MDR: [Regulation (EU) 2017/745](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
* MDD: [COUNCIL DIRECTIVE 93/42/EEC](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3a31993L0042&msclkid=c7a3d508b0ef11ecabed034653fb6ea0) of 14 June 1993 concerning medical devices
* AIMDD: COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385 /EEC)
* Legacy devices: should be understood as devices, which, in accordance with Article 120(3) MDR and Article 110(3) IVDR, are placed on the market after MDR or IVDR dates of application respectively and until 26 May 2024, or until the relevant certificate becomes void, if certain conditions are fulfilled ([MDCG 2021-13 rev.1](https://ec.europa.eu/health/system/files/2021-07/md_mdcg_2021-13_q-a-actor_registr_eudamed_en_0.pdf))
* NB - Notified body
* Class Ir – class I reusable surgical instrument
* Class Im – class I with measuring function
* Class Is – class I sterile
* 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.

***Please note: For the purpose of this survey one medical device should be understood and counted per: individual catalogue number, model number or a reference number.***

**MDR implementation – state of play**

Company information and contact details

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1. What is the size of your company?

Large medical device manufacturer

Small or medium-sized manufacturer (SME)

Please provide your approximate annual European medical device revenue turnover (in EUR for 2019). MedTech Europe will aggregate the figures for all responders to understand the representativeness of the survey data. Your company specific information will not be disclosed.

2. Where is your company's headquarters located?

EU-27

USA

Other (please specify)



3. Is your company a member of MedTech Europe, AdvaMed, and/or of a National Association?

MedTech Europe

 AdvaMed

National Association member of MedTech Europe (please specify country and name)



None of the above

4. Please provide us with your contact details

We value your privacy. This information will be used to take into account and/or delete any double submissions from the same company and/or subsidiaries. We may contact you in case we have any questions about your submission. We will not share your personal details - they will be deleted as soon as they are no longer needed to process the results.

Name:

Company:

Email Address:

Phone Number:

5. Would you like to receive a copy of your answers via email? (do not forget to indicate an email address above)

Yes

No

**Part 1: Questions from Authorities, i.e. the Medical Device Coordination Group (MDCG) Task Force on certification capacity monitoring**

MDR estimates (all devices - legacy and new)

6. How many MDR devices\* in total (Class I, Ir, Is, Im, IIa, IIb, III) do you **expect** to have on the market by 26 May 2024?

\*This refers to the catalogue number (not individual units of the catalogue number).



7. How many MDR devices\* and corresponding QMS certificates and technical files per Class do you **expect** to have by 26 May 2024?
Please fill in per class according to your portfolio and enter"0" for the Classes that are not applicable.

\* This refers to the catalogue number (not individual units of the catalogue number).

Number of MDR **Class I devices\* :**

Number of MDR **Class Is/m/r devices\* :**

Number of MDR **Class Is/m/r** corresponding **QMS certificates:**

Number of MDR **Class IIa devices\* :**

Number of MDR **Class IIa** corresponding **QMS certificates:**

Number of MDR **Class IIb devices\* :**

Number of MDR **Class IIb** corresponding **QMS certificates:**

Number of MDR **Class IIb implantable technical file certificates:**

Number of MDR**Class III devices\*:**

Number of MDR**Class III** corresponding **QMS certificates:**

Number of MDR **Class III** **technical file certificates:**

8. Do you have a Notified Body?

Yes

No

9. Has your current Notified Body already been designated under the MDR?

Yes, it has been designated under the MDR.

No, it has not been designated under the MDR.

No, but I plan to change to a Notified Body already designated under MDR.

MDR implementation

10. How many applications in total have you **submitted** under the MDR to your NB(s)? If you have not submitted any applications, please enter "0".

QMS applications:

Technical file (Class III & Class IIb implantable):

11. How many MDR applications (QMS and Technical file) **accepted** by your NB(s) **are still ongoing/under review**?  Please also indicate the number of devices\* covered by these ongoing applications. If you have not submitted any applications, please enter "0".

\* This refers to catalogue number (not individual units of catalogue number).

QMS applications: 

Technical file (Class III & Class IIb implantable): 

Number of devices\* covered by ongoing applications: 

12. How many certificates have already been**issued** under the MDR for your portfolio? If no certificates have been issued, please enter "0".

QMS applications: 

Technical file: 

13. How many devices (catalogue number) are covered by certificates that have already been**issued** under the MDR? Please provide a total number as well as a breakdown per class.

Total:  

Class Ir/s/m 

Class IIa 

Class IIb 

Class III 

MDCG Task Force on certification capacity monitoring questions: AIMDD/MDD

14. Please indicate the following according to your company portfolio:

#### \* This refers to the catalogue number (not individual units of the catalogue number).

Total number of AIMDD/MDD devices\* placed on the market (Class I, Class Is/ Im, Class IIa, Class IIb, Class III):

Total number of devices\* with AIMDD/MDD certificates (Class I, Class Is/ Im, Class IIa, Class IIb, Class III):

Total number of AIMDD/MDD certificates:

Number of AIMDD/MDD devices you plan to transition to MDR:

Number of Class I AIMDD/MDD devices that will be up-classified under MDR and will need NB intervention for the first time:

**Part 2: MedTech Europe questions *(note: these were not discussed with MDCG Task Force on certification capacity monitoring)***

Transition to MDR

15. Does your company have medical devices for which you are concerned that they will not be certified under MDR on time? If yes, please indicate in which application area/product group these devices would fall into?

No

Capital goods (e.g., hospital and nursing home beds, large and small sterilizers, imaging equipment, etc.)

Circulatory system, cardiology

Dentistry

Endocrinology and diabetes

Gastroenterology and hepatology

Medical software/apps.

Medical aids (e.g., respiratory home therapy, visual or hearing aids, medical care aids, etc.)

Nephrology and urology

Neurology

Neurosurgery

Obstetrics and gynecology, including reproductive medicine

Ophthalmology

Orthopedics, traumatology, rehabilitation, rheumatology

Paediatrics

Paediatric surgery

Pneumology and sleep medicine, anesthesia, intensive care medicine

Surgical instruments

Thoracic surgery

Trauma surgery

Vascular surgery

Visceral surgery

Other application area



16. What is the percentage of your total portfolio that you do not intend to transition to MDR?

\_\_\_\_\_\_%

17. Are there any MDR specific issues that are leading to end of life / product discontinuation decisions within your company?  If yes, please choose all that apply:

No

Documented clinical evidence for legacy devices with an established post market safety history is not available

Substantially increased costs to recertify under MDR

Sustaining costs under MDR

Capacity issues at manufacturer - increased requirements versus available resources

Capacity issue at NB

Choosing innovation over recertifying legacy devices

Other (please specify):

MDR conformity assessment procedure

18. What percentage of your product portfolio which you plan to transition to MDR has already received an MDR certificate?

\_\_\_\_\_\_\_\_\_\_\_\_%

19. What percentage of your product portfolio currently CE Marked under MDR is considered ‘’directive/legacy devices’’?

\_\_\_\_\_\_\_\_\_\_\_\_%

20. How many new devices (excluding MDR transitioned legacy devices) have you already certified under the MDR?

Number of new devices (catalogue number):

Please specify the product category:

21. How long does it take to obtain MDR certification (product and QMS certification) starting from pre-application until a certificate is received?
Please indicate the average time for both legacy devices being transferred to MDR and for new products.  Please enter "N/A" if certain Class(es) of devices are not covered in your portfolio.

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| Classes: | Legacy devices being transferred to MDR: | New products: |
| Class Ir/s/m |  |  |
| Class IIa |  |  |
| Class IIb |  |  |
| Class III |  |  |

22. What are, if any, the main challenges you encounter with your Notified Body(ies)?

No challenges

Fragmented/ non-harmonized interpretations of the same requirements of the MDR

Fragmented/ non-harmonized interpretations of MDCG guidelines

No acceptance / recognition of certificates from other notified bodies covering the same requirement (e.g. 13485)

Lack of predictability, e.g. no binding conformity assessment timelines from the notified body

Unpredictable certification time resulting in longer cycles longer waiting time than the remaining validity of our certificate(s) and planned launch dates

Lack of responsiveness

We cannot find a notified body

The NB terminated our contract

Diverging decisions from different experts of the same NB on the same issue

Please give some examples:

Guidance documents (e.g. MDCG guidelines)

23. Have you experienced any unexpected delays in the completion of a conformity assessment due to issuance of a new or revised, MDCG Guidance Document, considered by your Notified Body to be applicable (immediately) or to represent the State of the Art?

No, I have not experienced a delay.

Yes, a delay of less than 1 month.

Yes, a delay of between 1 and 3 months.

Yes, a delay of more than 3 months.

24.  If yes, was a rework of the file, resubmission or reapplication of the file required?

Yes, re-work of parts of the file.

Yes, re-work of parts of the file and re-submission of a revised file (multiple parts).

Yes, re-work of parts of the file, re-submission of a revised file (multiple parts) and re-application of the file (back in queue).

Yes, re-work of parts of the file, re-submission of a revised file (multiple parts), re-application of the file (back in queue) and we had to generate new or additional evidence.

Not applicable

25. Please indicate the guidance document(s) which caused delay or challenges in the conformity assessment procedure. (Please consult the list of guidance documents [here on the European Commission’s website](https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en))

None

 Please indicate the MDCG guidance name and reference:

MDR’s impact on innovation

26. Because of MDR, have you deprioritized the European Union (or are planning to deprioritize) as a first regulatory approval geography for innovative medical devices? Yes

No

27. What geography would you prioritize (or have you prioritized) for a first regulatory approval since the MDR Date of Application- 26 May 2021?

Australia/New Zealand

Canada

China

European Union

Japan

United States of America

Other (please specify)



28. How many new products have you launched in geographies outside of the European Union since 26 May 2021 (instead of the EU)?

Number of new devices (catalogue number):

Please specify the product categories:

29. What impact does the MDR have on your innovation activities? Please indicate all that apply.

MDR has enhanced our innovation activities.

No impact.

Our innovation projects are currently on hold.

We are no longer making any changes/optimizations to our medical devices.

We are working on selected innovations, but plan to approve them in other markets first.

Our R&D budget will be reduced.

Our R&D department will be relocated abroad in the medium to long term.

Inability to engage early with NB to explain new technologies.

Inability to consult expert panels (MDR Art.61.2).

We expect a delay for the introduction of innovative medical products of our company in Europe.

Too costly to continue developing and bringing innovation to the European market.

Other (please specify)

30. Do you have any other comments you would like to share?Bottom of Form

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