

Implementation Status of the Medical Devices Regulation

(December 2019)

A Call to Action



Taking Stock

The legal framework of the Medical Devices Regulation 2017/745 ('the MDR') establishes three ways how medical devices could continue to be placed on the market, and thereby remain available to patients, after 26 May 2020:

- Manufacturers obtain CE certification against the new requirements of the new legal framework, via an MDR-designated Notified Body (only few are available today).
- By 26 May 2020, manufacturers make use of the MDR Grace Period for devices eligible for it, i.e., they obtain CE certification against the existing rules of today's Medical Devices Directives, via one of the existing Notified Bodies (55 of which exist today).
- If neither of the above two ways are possible, manufacturers would need to apply at national level for a time-limited derogation, which the European Commission can render EU-wide in order to keep the device available to patients and doctors across Europe.



*MD: Medical Device

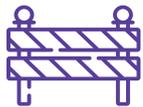


All three legally available ways face significant challenges in practice today and can only be used in a very limited and insufficient way.

This paper outlines the urgency of the matter, highlighting the main challenges that apply to each of these three routes, and proposing solutions for how they might be addressed.

I. Enable certification via MDR-designated Notified Bodies

Manufacturers obtain CE certificates from the Notified Bodies designated to the new Medical Devices Regulation 2017/745.



CHALLENGES

There are several severe challenges today that prevent manufacturers and their devices from being (re-)certified against the new rules of the Medical Device Regulation (MDR):

Severe lack of Notified Body capacity

Low number of designated Notified Bodies: Most of today's 55 Notified Bodies are still awaiting their MDR designation, and thus may not yet start certifying devices to the new Regulation. This is not expected to change for several more months.

'Certification timeline': Even when designated, a Notified Body needs at least 6 months for each single certification, yet fewer than 6 months remain until 26 May 2020.

Workload/tasks: MDR-designated Notified Bodies cannot focus their full capacity on MDR evaluations. They need to divide their time to undertake other critical tasks, e.g., renewing certificates issued under the former Directives, and conducting surveillance of devices currently on the market.

Lack of expert panels

Until these panels are up and running, MDR certification before 26 May 2020 is inaccessible to various devices, e.g., certain innovative implants and medicine-administering devices.

Lack of needed Delegated and Implementing Acts

Some implementation-critical Acts are lacking, making MDR certification inaccessible to certain devices.

Lack of needed EU Guidance

The MDR includes key new obligations which Notified Bodies and manufacturers must understand and apply for the first time. This makes MDR certifications even more complex and time-consuming for Notified Bodies, given that good-quality EU-level guidance on several of these requirements is still pending.

De facto orphaned devices

MDR-designated Notified Bodies are overworked and unable for now to accept files from additional manufacturers e.g., those whose current Notified Bodies will not receive an MDR designation soon. This makes MDR certification inaccessible in practice to very large numbers of devices.

Innovation

In addition to the lack of expert panels, MDR-designated Notified Bodies have no spare capacity to evaluate files for new/innovative products, neither under the MDR nor via the MDR Grace Period. This has created an innovation backlog, which presents the risk that European patients risk losing out versus those in other parts of the world.



As a result, if these challenges remain unaddressed, neither existing nor new devices will be able to go through MDR certification by 26 May 2020.

To remain available to patients, medical devices need instead seek to use one of the two other ways.



PROPOSED SOLUTIONS

Notified Bodies

Designate and notify Notified Bodies to the MDR faster, and enable them to certify manufacturers' quality systems in as timely a manner as possible.

Expert panels

Rapidly establish the panels, so that devices depending on these panels can start going through MDR certification as soon as possible.

Delegated and Implementing Acts

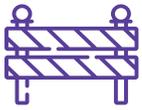
Publish the most needed Acts as soon as possible, including common specifications.

Guidance

Publish good-quality guidance in the most urgent areas – e.g., clinical evidence requirements for existing devices – to make MDR certification faster and more workable for as many devices as possible.

II. Make the MDR Grace Period work in practice

By no later than 26 May 2020, manufacturers renew their CE certificates from the 55 Notified Bodies designated to the former Directives, and keep them valid until 26 May 2024 at the latest.



CHALLENGES

The legally-foreseen transitional provision of MDR Article 120(3), commonly referred to as the 'MDR Grace Period', faces significant practical challenges:

Lack of Notified Body capacity

Although all 55 Notified Bodies that exist today are legally allowed – until 26 May 2020 – to renew or extend the validity of certificates issued under the former Directives, their capacity to do so in practice is extremely limited, putting at risk the continued availability of existing devices. Industry is observing severe delays in Notified Bodies' assessments of files submitted, and even rejection of files for devices that are legally eligible for the MDR Grace Period. Furthermore, it is expected that there will be assessments still unfinished on 26 May 2020, and this means solutions need urgently to be found.

Lack of EU guidance on 'significant changes'

Certificates renewed under the current Directives may only remain valid for devices which undergo no significant changes to their design or intended purpose after 26 May 2020. However, there is no EU guidance yet on what a 'significant change' is and what it is not.

Therefore, while many devices may be eligible for the MDR Grace Period in theory, the lack of needed guidance presents the risk that renewed certificates may quickly lose their validity after 26 May 2020, e.g., due to changes which are outside the manufacturers' control.

Mixing certification requirements of the current Directives and the future Regulation

Whilst devices eligible for the MDR Grace Period should until 26 May 2020 be re-certified in accordance with the existing Directives, practice shows that Notified Bodies are already imposing several new 'MDR-like' requirements as part of the certificate renewal process.

This needlessly eats up Notified Body capacity, and it jeopardises the purpose of the MDR Grace Period, which is to facilitate the transition to the new Regulation without risking patients' continued access to devices, including those on the market for many years.



As a result, the MDR transitional measure called the 'Grace Period' is currently extremely difficult to apply in practice.

Unless the above challenges are urgently resolved, a very significant number of devices may only remain available to patients via EU-wide derogations.



PROPOSED SOLUTIONS

Notified Body capacity

Up until 26 May 2020 inclusive, enable Notified Bodies to:

- (1) continue accepting files for renewal,
- (2) review them faster and
- (3) issue CE certificates for all submissions made.

For certificate renewal requests already filed: if there is evidence that the Notified Body lacks the capacity needed to issue the renewed certificate on-time, make the devices automatically eligible for EU-wide derogations (see next page), or provide equivalent solutions that seamlessly ensure the devices' continued availability to patients and doctors.

EU guidance on 'significant changes'

Urgently publish EU-level guidance, to interpret the term 'significant' in a manner that ensures that the MDR Grace Period remains usable in practice until 26 May 2024.

Mixing certification requirements of the current Directives and the future Regulation

Urgently publish an EU-level statement to clarify that renewal of certificates issued under the former Directives shall happen only according to the requirements of those Directives and not those of the MDR.

For MDR requirements applicable to these products after 26 May 2020 – e.g., in the area of post-market surveillance – defer Notified Body evaluation to the surveillance phase.

Unfinished or refused assessment of files

Urgently provide guidance and clarity for cases where Notified Bodies have turned down files submitted under the MDR Grace Period, or where they are still assessing them in May 2020. Ensure that the concerned devices - many of which are already widely used today - can remain seamlessly available to patients and doctors.

III. Make EU-wide derogations work

Member States and the European Commission grant EU-wide derogations referred to in MDR Article 59(3), allowing needed devices remain available to patients.

This route should only be seen as a last resort if the first two ways cannot be successfully implemented.



CHALLENGES

The MDR introduces, in Article 59(3), the new instrument of EU-wide derogations, as a novel measure to keep needed devices available to patients. This instrument faces significant challenges:

Scope

EU-wide derogations are typically only intended to address 'exceptional' public health situations, and thus risk to be considered for very specific individual devices only, leaving many other devices ineligible for the derogations.

Process

The concept of EU-wide derogations is new under the MDR. The current Directives had only foreseen national derogations, for which manufacturers would need to apply 28 times (i.e., 'country by country') in order to keep a device available to patients. Before issuing EU-wide derogations, the new MDR still requires a national derogation first, and this process is currently very fragmented amongst Member States, with significant administrative hurdles.

Timing

Derogations are usually meant to be time limited, and in some cases they have been granted for only a few weeks. The new MDR regulatory system for medical devices will likely need many more months to get ready.

International Dimension

In order to keep devices available to patients outside the EU, it must be possible to keep the CE marking affixed when receiving an EU-wide derogation.



PROPOSED SOLUTIONS

Scope

Make EU derogations a systemic solution that ensures adequate supply, by making multiple device categories from multiple manufacturers eligible for derogations.

Process

Rapidly develop and proactively publish harmonized procedures (including application forms), so that applications for EU-wide derogations can be submitted, reviewed and granted as quickly as possible, with minimal administrative burden for all parties involved.

Timing

Allow EU-wide derogations to remain valid for as long as needed, i.e., until the Notified Body system is ready to certify the devices.

International Dimension

Confirm unequivocally that the CE marking may be affixed to devices receiving EU-wide derogations.



To implement the above proposed solutions would require a significant rethink of the derogation process.

As this seems to be very difficult to be achieved in the remaining time before 26 May 2020, it is critical to make the two other ways to (re-)certify existing and innovative products work, so that devices do not need derogations in the first place.



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