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Regulation (EU) 2020/561 of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions

Reading Grid

APRIL 2020

Context

To ensure that the medtech industry and all stakeholders focus their efforts on the fight against the Covid-19 outbreak and the associated public health crisis, the European Commission issued a proposal, dated 3 April 2020 (COM/2020/144 final), to defer the application of certain provisions of the Medical Devices Regulation (EU) 2017/745 ("MDR").

The Commission proposal followed a fast-track legislative procedure: The European Parliament adopted its position of 17 April 2020, the decision of the Council of the European Union was issued on 22 April 2020 and, on 24 April 2020, the Publications Office of the European Union published a Regulation (EU) 2020/561 of 23 April 2020 amending the MDR as regards the dates of application of certain of its provisions (the "Regulation")

This Regulation clarifies that:

- Medical devices, such as medical gloves, surgical masks, equipment for intensive care and other medical equipment, **play a crucial role in the context of the Covid-19 outbreak**; they ensure the health and safety of EU citizens and enable Member States to give the necessary medical treatment to patients in urgent need of such treatment.
- The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as an increased availability of vitally important medical devices, **that could not reasonably have been anticipated at the time of adoption of the MDR**.
- Given the unprecedented magnitude of the current challenges, and taking into account the complexity of the MDR, it is very likely that Member States, health institutions, economic operators and other relevant parties **will not be in a position to ensure the proper implementation and application of the MDR from 26 May 2020**.
- In light of the overriding need to immediately address the public health crisis associated with the Covid-19 outbreak, **the Regulation should enter into force as a matter of urgency**.

This is not the first time the MDR has been amended since its publication, in May 2017. The MDR was corrected by two Corrigenda published in **May 2019** and **December 2019**. Notably, the latest Corrigendum to the MDR provided for an extension of the so-called 'grace period' for a number of medical devices (please see **this page** for further details).

The Regulation has entered into force on 24 April 2020. It is binding in its entirety and directly applicable in all Member States.

Content of the Regulation

The Regulation (i) defers the application of certain provisions that would otherwise start to apply from 26 May 2020 and (ii) adapts certain MDR transitional periods that would otherwise no longer apply as from 26 May 2020.

Areas affected by the Regulation include:

- The possibility to grant '**national derogations**' and '**Union-wide derogations**' from running conformity assessment procedures (i) in accordance with the MDD[1] or the AIMD[2] (until 26 May 2021) or (ii) in accordance with the MDR
- The possibility for the Commission to **extend national derogations** granted under the MDD or the AIMD until May 2021 and the possibility or the obligation (depending on the case) for competent authorities to notify national derogations to the Commission
- The depletion of stocks of MDD or AIMD devices after the MDR application date ('**sell-off period**')
- National laws laying down provisions on **penalties** for breaches of the MDR
- The '**grace period**' mechanism by which certain class I medical devices complying with the MDD may be placed on the market or put into service until 26 May 2024
- The functionality and obligations related to **EUDAMED**, the European database on medical devices
- **Clinical investigations** started in accordance with the MDD or the AIMD
- Common specifications ("CS") for **Annex XVI products** (List of groups of products without an intended medical purpose)
- The requirement to place **Unique Device Identifier** ("UDI") carriers on the label or on the device itself and on all higher levels of device packaging
- European Commission guidance on **expert panels' scientific opinion** for certain class IIb and class III devices
- **Early MDR compliance** (ie compliance with the MDR before the application date)
- The placing on the market of devices manufactured, utilising **derivatives of tissues or cells of human origin** which are non-viable or are rendered non-viable
- The designation and notification of **notified bodies** under the MDR, the issuance of certificates by notified bodies and their obligations under the MDR
- Conditions of **reprocessing of single-use devices** and reprocessing of single-use devices within health institutions.

For each area described above, the Reading Grid clarifies the new timelines and requirements set out in the Regulation in alphabetic order.

[1] Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended.

[2] Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical, as amended.

Reading Grid

Topic	Before 24 April 2020	After 24 April 2020 (Regulation 2020/561)	Reference
Annex XVI products	Necessary CS for Annex XVI products should be adopted by 26 May 2020. They will apply as from six months after the date of their entry into force or from 26 May 2020, whichever is the latest.	Necessary CS for Annex XVI products should be adopted by **26 May 2021**. They will apply as from six months after the date of their entry into force or **from 26 May 2021**, whichever is the latest.	Article 1(2)
Application date	26 May 2020.	**26 May 2021**.	Article 123(2)
Clinical investigations	Clinical investigations which have started to be conducted in accordance with the MDD or the AIMD prior to 26 May 2020: ● may continue to be conducted, but ● are subject to the MDR requirements concerning the reporting of (a) serious adverse events and (b) device deficiencies, from 26 May 2020.	Clinical investigations which have started to be conducted in accordance with the MDD or the AIMD **prior to 26 May 2021**: ● may continue to be conducted, but ● are subject to the MDR requirements concerning the reporting of (a) serious adverse events and (b) device deficiencies, **from 26 May 2021**.	Article 120(11)
Devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable	Devices manufactured utilising derivatives of tissues or cells of human origin, which are non-viable or are rendered non-viable, if they have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2020, may continue to be placed on the market and put into service in the Member States concerned.	Devices manufactured utilising derivatives of tissues or cells of human origin, which are non-viable or are rendered non-viable, if they have been legally placed on the market or put into service in accordance with the rules in force in the Member States **prior to 26 May 2021**, may continue to be placed on the market and put into service in the Member States concerned.	
Early MDR compliance	By way of derogation from the MDD and the AIMD, devices which comply with the MDR may be placed on the market prior to 26 May 2020.	By way of derogation from the MDD and the AIMD, devices which comply with the MDR may be placed on the market **prior to 26 May 2021**.	Article 120(5)
EUDAMED – Functionality	Publication in the Official Journal of the European Union of the Commission notice confirming that EUDAMED has achieved full functionality and meets the **functional specifications**, should take place by 25 March 2020.	Publication in the Official Journal of the European Union of the Commission notice confirming that EUDAMED has achieved full functionality and meets the **functional specifications**, should take place **by 25 March 2021**. Note that **the Commission announced** in December 2019 that the 'launch' of EUDAMED would take place **in May 2022.**	Article 34(1)
EUDAMED – Related obligations and requirements	If Eudamed is not fully functional on 26 May 2020, the obligations and requirements that relate to Eudamed (as listed in Article 123(3), d) apply six months after the publication of the Commission notice.	If Eudamed is not fully functional **on 26 May 2021**, the obligations and requirements that relate to Eudamed (as listed in Article 123(3), d) apply six months after the publication of the Commission notice. Note that **the Commission announced** in December 2019 that the 'launch' of EUDAMED would take place **in May 2022**.	Article 123(3), d)

Topic	Before 24 April 2020	After 24 April 2020 (Regulation 2020/561)	Reference
Expert panels	Guidance on the criteria which scientific experts should consider when choosing whether or not to provide a scientific opinion for certain class III and class IIb devices, will be provided by the Commission before 26 May 2020 after consultation with the Member States.	Guidance on the criteria which scientific experts should consider when choosing whether or not to provide a scientific opinion for certain class III and class IIb devices, will be provided by the Commission **before 26 May 2021** after consultation with the Member States.	Annex IX, point 5.1, h)
Grace period	The following class I MDD devices may be placed on the market or put into service **until 26 May 2024**: ● those for which the declaration of conformity was drawn up **prior to 26 May 2020** and for which the conformity assessment procedure pursuant to the MDR requires the involvement of a notified body, ● those which have a certificate that was issued in accordance with the AIMD or the MDD and that is valid by virtue of Article 120(2) of the MDR. To benefit from the 'grace period' mechanism, such devices should: ● **from 26 May 2020**, continue to comply with the AIMD or the MDD as applicable; ● not undergo significant changes in the design and intended purpose; ● be subject to the MDR requirements relating to post-market surveillance (PMS), market surveillance, vigilance, registration of economic operators and of devices (which will apply in place of the corresponding requirements in the AIMD or MDD).	The following class I MDD devices may be placed on the market or put into service **until 26 May 2024**: ● those for which the declaration of conformity was drawn up **prior to 26 May 2021** and for which the conformity assessment procedure pursuant to the MDR requires the involvement of a notified body, ● those which have a certificate that was issued in accordance with the AIMD or the MDD and that is valid by virtue of Article 120(2) of the MDR. To benefit from the 'grace period' mechanism, such devices should: ● from 26 May 2021, continue to comply with the AIMD or the MDD as applicable; ● not undergo significant changes in the design and intended purpose; ● be subject to the MDR requirements relating to post-market surveillance (PMS), market surveillance, vigilance, registration of economic operators and of devices (which will apply in place of the corresponding requirements in the AIMD or MDD).	
National derogations from conformity assessment procedures – Conditions	Competent authorities may authorise the placing on the market or putting into service within the territory of their Member State, of a specific device, even if the applicable conformity assessment procedures of the MDR have not been carried out. Such national derogations may only be granted upon duly justified request and provided that the use of the specific device is in the interest of public health or patient safety or health.	From 24 April 2020, competent authorities may authorise the placing on the market or putting into service within the territory of their Member State, of a specific device, even if: ● the applicable **conformity assessment procedures of the MDR** have not been carried out; or ● the applicable **conformity assessment procedures of the MDD or the AIMD** have not been carried out, from 24 April 2020 **until 25 May 2021**. Such national derogations may only be granted upon duly justified request and provided that the use of the specific device is in the interest of public health or patient safety or health.	Articles 59(1) and 123(3), j)

Topic	Before 24 April 2020	After 24 April 2020 (Regulation 2020/561)	Reference
National derogations from conformity assessment procedures – Notification requirements	Notification of national derogations from conformity assessment procedures by a concerned Member State to the Commission and the other Member States is mandatory when such derogations are granted in accordance with the MDR, for use other than for a single patient.	From 24 April 2020, notification of national derogations from conformity assessment procedures by a concerned Member State to the Commission and the other Member States is: • still mandatory when such derogations are **granted in accordance with the MDR** (as amended by the Regulation), for use other than for a single patient; and • optional when such derogations are **granted in accordance with the MDD or the AIMD**.	Articles 59(2) and 123(3), j)
National derogations from conformity assessment procedures – Repeal of MDD and AIMD procedures	Member States may no longer grant national derogations from conformity assessment procedures in accordance with the MDD and the AIMD from 26 May 2020.	Member States may no longer grant national derogations from conformity assessment procedures in accordance with the MDD and the AIMD **from 26 May 2021**.	Article 122
Notified bodies – Designation and notification	Any publication of a notification in respect of a notified body in accordance with the MDD and the AIMD shall become void from 26 May 2020. By way of derogation from the MDD and the AIMD, notified bodies complying with the MDR may be designated and notified prior to 26 May 2020.	Any publication of a notification in respect of a notified body in accordance with the MDD and the AIMD shall become void **from 26 May 2021**. By way of derogation from the MDD and the AIMD, notified bodies complying with the MDR may be designated and notified **prior to 26 May 2021.**	Article 120(1) and 120(6)
Notified bodies – Issuance of certificates	Notified bodies which are designated and notified in accordance with the MDR may carry out conformity assessment procedures and issue certificates under the MDR prior to 26 May 2020.	Notified bodies which are designated and notified in accordance with the MDR may carry out conformity assessment procedures and issue certificates under the MDR **prior to 26 May 2021**.	Article 120(6)
Notified bodies – Obligations	Until 26 May 2020, the MDR obligations placed upon notified bodies only apply to those bodies which submit an application for designation under the MDR.	**Until 26 May 2021**, the MDR obligations placed upon notified bodies only apply to those bodies which submit an application for designation under the MDR.	Article 123(3), a)
Penalties	Member States have until 25 February 2020 to notify national laws laying down the rules on penalties applicable for MDR infringement to the Commission. They are also required to notify, without delay, any subsequent amendment affecting those rules.	Member States have **until 25 February 2021** to notify national laws laying down the rules on penalties applicable for MDR infringement to the Commission. They are also required to notify, without delay, any subsequent amendment affecting those rules.	Article 113
Repeal of the MDD and AIMD	The MDD and the AIMD are repealed from 26 May 2020, subject to a number of conditions (eg the MDR 'grace period' mechanism and the MDR 'sell-off' period for MDD or AIMD devices) and exceptions listed in Article 122.	The MDD and the AIMD are repealed **from 26 May 2021**, subject to a number of conditions (eg the MDR 'grace period' mechanism and the MDR 'sell-off' period for MDD or AIMD devices) and exceptions listed in Article 122.	Article 122

Topic	Before 24 April 2020	After 24 April 2020 (Regulation 2020/561)	Reference
Reprocessing of single-use devices – Conditions	Only single-use devices that have been placed on the market (i) in accordance with the MDR, or (ii) prior to 26 May 2020 in accordance with the MDD, may be reprocessed.	Only single-use devices that have been placed on the market (i) in accordance with the MDR, or (ii) **prior to 26 May 2021** in accordance with the MDD, may be reprocessed.	Article 17(6)
Reprocessing of single-use devices – Within health institutions	Necessary CS for the reprocessing of single-use devices within health institutions shall be adopted by 26 May 2020. If those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with the applicable harmonised standards and national provisions.	Necessary CS for the reprocessing of single-use devices within health institutions shall be adopted **by 26 May 2021**. If those CS are not adopted **by 26 May 2021**, reprocessing shall be performed in accordance with the applicable harmonised standards and national provisions.	Article 17(5)
Sell-off period for MDD and AIMD devices	Devices lawfully placed on the market, pursuant to the MDD and the AIMD prior to 26 May 2020, and devices placed on the market from 26 May 2020 in accordance with the MDR 'grace period' mechanism, may continue to be made available on the market or put into service until 26 May 2025.	Devices lawfully placed on the market, pursuant to the MDD and the AIMD **prior to 26 May 2021**, and devices placed on the market **from 26 May 2021** in accordance with the MDR 'grace period' mechanism, may continue to be made available on the market or put into service until 26 May 2025.	Article 120(4)
UDI carriers – Placing on the device itself and higher levels of packaging (reusable devices)	For reusable devices that must bear the UDI carrier on the device itself and on all higher levels of device packaging, the following timelines apply: ● for implantable devices and for class III devices **from 26 May 2023**; ● for class IIa and class IIb devices, **from 26 May 2025**; and ● for class I devices, **from 26 May 2027**.	No change.	Article 123(3), g)
UDI carriers – Placing on the label and higher levels of packaging	UDI carriers must be placed on the label of the device and on all higher levels of packaging as follows: ● for implantable devices and for class III devices **from 26 May 2021**; ● for class IIa and class IIb devices, **from 26 May 2023**; and ● for class I devices, **from 26 May 2025**.	No change.	Article 123(3), f)
Union-wide derogations from conformity assessment procedures	In exceptional cases relating to public health or patient safety or health, the Commission may adopt implementing acts ('Union-wide derogations') extending, for a limited period of time, the validity of a national derogation granted under the MDR.	From 24 April 2020, in exceptional cases relating to public health or patient safety or health, the Commission may adopt implementing acts ('Union-wide derogations') extending, for a limited period of time, the validity of a national derogation: ● granted **in accordance with the MDR** (as amended by the Regulation); or ● granted **in accordance with the MDD or the AIMD**, in which case the national derogation should have been granted before the entry into force of the Regulation.	Articles 59 (3) and 123(3), j)

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