New medical device regulation: Understanding the transition period

Fact sheet on the transition period for the new medical device regulation (2017/745 - MDR)

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What is the "transition period"?

In order to avoid any major rupture in the supply of medical devices in Europe after the date of application of the new Medical Device Regulation (MDR, applicable from 26 May, 2021*), the new regulation includes a **"transition period**" during which medical devices that are compliant with the current regulatory regime (Directive 93/42/CEE - MDD) will be still allowed on the European market.

In short, the MDR transition period allows some medical devices to remain legally on the European market until their full compliance with MDR has been declared.

What is the practical impact with regard to ResMed product certificates?

ResMed has worked intensively for more than two years to update its quality management system (QMS) and product portfolio documentation to align with the new MDR requirements. This means that for products placed on the EU market:

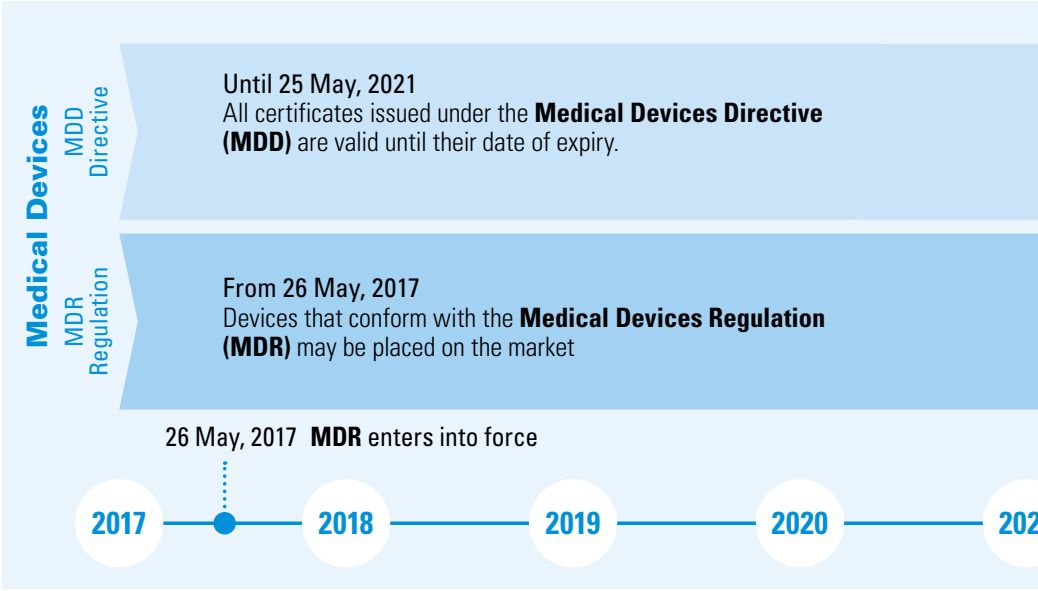
1. **All Class I ResMed devices** (e.g. batteries, Narval MRD, tubing) will be compliant with the new MDR requirements on 26 May, 2021.
2. **All other ResMed medical devices will continue to be sold under MDD certification**, as allowed by the provisions of the MDR transition period. The transition to MDR certification will be managed gradually, starting in 2021 and concluding no later than 25 May, 2024.

You will be informed of any relevant changes as soon as they occur.

What does the Medical Device Regulation state

All medical devices marked CE under the current regulatory regime (except Class I medical devices), called **"legacy" medical devices**, can be manufactured and sold on the European market until 25 May, 2024, as long as their CE declaration of conformity and related CE certificate remain valid.

From 26 May, 2024, remaining stock can be put into service but only until 27 May, 2025. From that date onwards, any remaining **unused** "legacy" product can no longer be put into service.



The following figure explains key terminology from the MDR which is essential to the understanding of the transition period. These notions apply to each device (unit) individually:

Device **placed on the market**

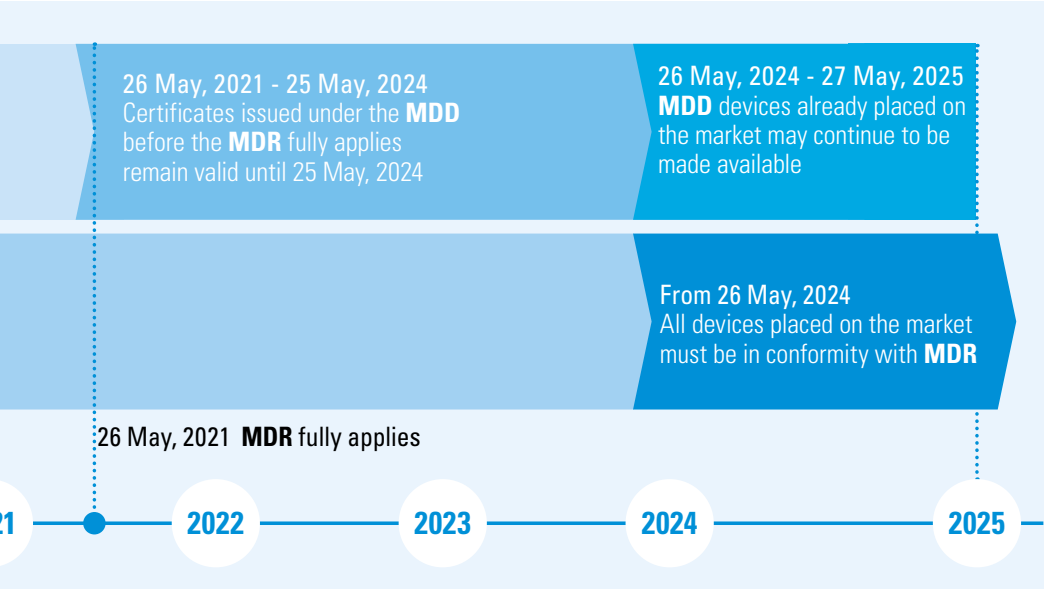
First time the device is made available in the EU (i.e. product released from manufacturing to be sold in the EU)

[1] *https://ec.europa.eu/growth/sectors/medical-devices/getting-ready-new-regulations/manufacturers-md_en*

about the transition period (Art 120)?

It must be noted that, after the transition period, "legacy" devices that are already being used by end-users (e.g. patients and healthcare professionals) can remain on the market.

This is summarised in the EU Commission infographic[1] below.



Device **made available**

Further supply of a device for distribution or use on the EU market

Device **put into service**

Device made available to the final user as being ready for use

Does the transition period apply to all MDR requirements?

No, the **transition measures apply only to medical device certification.**

The transition period is intended to allow full continuity of device availability, taking into account the additional workload generated by the new MDR certification for Notified Bodies (NB), regulators and manufacturers.

The new medical device regulation also includes other requirements applicable to economic operators such as manufacturers, authorised representatives, importers and distributors. **In particular, the MDR enforces new requirements for importers and distributors *(please see the ResMed guide on MDR Distributor requirements)*. These new requirements will apply from 26 May, 2021 onwards.**

For example, from 26 May, 2021, a distributor will not be allowed to perform relabelling / repackaging[2] without complying with the new MDR requirements and being certified by a notified body. Similarly, distributors and importers will need to have implemented product controls and registries to record and follow up complaints and non-conforming products and field safety corrective actions.

How can I verify quickly if a medical device is certified under MDD or MDR?

The only source of information that should be relied upon is the **product's CE declaration of conformity**, which is provided upon request by the manufacturer.

Note: **spare parts** (usually provided and used as part of product maintenance) **are not affected** by the new medical device regulation.

[2] Relabelling: any modification, translation, addition or removal of regulatory information written on the product and/or its packaging (e.g. user manual or labels).
Repackaging: any modification made to the product's packaging system.

The information contained in this booklet is for guidance only. Readers should seek independent legal advice. ResMed accepts no liability in relation to the accuracy, reliability, or completeness of any material contained in this booklet.

*The date of application of the new Medical Device Regulation has been postponed to 26 May, 2021 as per Regulation (EU) 2020/561 of April 2020.

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