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schlanke Prozesse

Transition Timelines MDR 2017/745

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1. Objective and Purpose

On April 23, 2020, the EU Parliament adopted a regulation (Amending Regulation (EU) 2017/745)[1], which postpones the date of application of the Medical Devices Regulation (MDR) by one year to May 26, 2021. With the publication of this regulation in the Official Journal of the European Union, the MDR postponement is now officially valid.

This document should help you to easily keep track of the most important dates and deadlines of MDR.

2. Use Cases

In the illustration of the MDR transition periods, we assume use cases such as we frequently encounter in our daily practice with manufacturers and other economic operators.
The abbreviations we use in the tables are based primarily on practical experience and only secondarily on the regulatory definitions from the directives. These abbreviations are explained here.

Designation of Use Case	Explanation
Existing products	Medical devices that already have CE approval for the European market (i.e. conformity assessment) - also called "legacy products". This does not necessarily mean that these products must be physically located in a warehouse.
➢ With conformity assessment according to MDD	Placing on the market of medical devices for which a conformity assessment according to the old Directives 93/42/EEC[2] or 90/385/EEC[3] is given. - excl. special case "type examination"
➢ Selling-off according to MDD	Making available on the market or putting into service of products already placed on the market in accordance with the MDD. These are finished products, which are e.g. in the warehouse of the distributor.
➢ Conformity assessment according to MDR	Placing on the market of medical devices for which a conformity assessment according to annex IX of the new Regulation (EU) 2017/745 MDR[4] is sought.
New products	Medical devices that do not yet have CE approval for the European market (i.e. no conformity assessment).
➢ Conformity assessment according to MDD	Medical devices for which conformity assessment and placing on the market is sought under the old Directives 93/42/EEC or 90/385/EEC. - excl. special case "type examination"
➢ Conformity assessment according to MDR	Medical devices for which a conformity assessment and placing on the market according to Annex IX of the new regulation (EU) 2017/745 MDR is sought.
Special case: higher classification	Extended transition periods apply to class I products that are newly assigned to a higher class according to the MDR. These are explained in section 4.2.

3. Medical Device Classes

Medical device class	Execution of the conformity assessment procedure according to annex IX, (EU) MDR 2017/745
I	By the manufacturer → self-declaration
I m Class I medical devices with measuring function	With involvement of a notified body
I r Reusable surgical instruments	
I s Class I sterile medical devices	
IIa	
IIb	
III	

4. Transition Periods according to Medical Device Classes

4.1 Class I (without Ir, Is, Im)

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD			✘	✘	✘	✘	✘	✘	Possible until May 26, 2021, no extension for class I products
➢ Selling-off acc. to MDD							✘	✘	Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021
New product									
➢ Conformity assessment acc. to MDD			✘	✘	✘	✘	✘	✘	Possible until May 26, 2021
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021

4.2 Special Case «Higher Classification of Class I»

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product (=MDD Class I)									
➢ With conformity assessment acc. to MDD	■	■	■	■	■	✘	✘	✘	• Relevant is the expiry date of the existing declaration of conformity. To take advantage of the maximum transition period until May 26, 2024, the manufacturer's declaration of conformity must be renewed by May 26, 2021 at the latest • No significant changes[5] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD	■	■	■	■	■	■	✘	✘	Possible until May 26, 2025
➢ Conformity assessment acc. to MDR	-	-	-	-	-	-		-	See regulation for the new, higher class according to MDR
New product (=MDR > Class I)									
➢ Conformity assessment acc. to MDD	■	■	✘	✘	✘	✘	✘	✘	Possible until May 26, 2021 as class I acc. to MDD
➢ Conformity assessment acc. to MDR	-	-	-	-	-	-	-	-	See regulation for the new, higher class according to MDR

4.3 Class Ir

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD	-	-	-	-	-	-	-	-	
➢ Selling-off acc. to MDD	-	-	-	-	-	-	-	-	This is a new class of medical devices in the MDR. → For details see descriptions under par. 4.2
➢ Conformity assessment acc. to MDR	-	-	-	-	-	-	-	-	
New product									
➢ Conformity assessment acc. to MDD									
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021

4.4 Class Is, Im

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD						✘	✘	✘	• Relevant is the expiry date of the existing EC certificate. To take advantage of the maximum transition period until May 26, 2024, the conformity assessment with the involvement of the notified body may have to be renewed until May 26, 2021 at the latest. • No significant changes[5] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD							✘	✘	Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2024
New product									
➢ Conformity assessment acc. to MDD			✘	✘	✘	✘	✘	✘	Theoretically possible until May 26, 2021, depending on the notified body, chances rather low
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021

4.5 Class IIa and IIb

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD						✘	✘	✘	• Relevant is the expiry date of the existing EC certificate. To take advantage of the maximum transition period until May 26, 2024, the conformity assessment with the involvement of the notified body may have to be renewed until May 26, 2021 at the latest. • No significant changes[5] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD							✘	✘	Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2024
New product									
➢ Conformity assessment acc. to MDD			✘	✘	✘	✘	✘	✘	Theoretically possible until May 26, 2021, depending on the notified body, chances rather low
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021

4.6 Class III

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD						✘	✘	✘	• Relevant is the expiry date of the existing EC certificate. To take advantage of the maximum transition period until May 26, 2024, the conformity assessment with the involvement of the notified body may have to be renewed until May 26, 2021 at the latest. • No significant changes[5] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD							✘	✘	Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2024
New product									
➢ Conformity assessment acc. to MDD			✘	✘	✘	✘	✘	✘	Theoretically possible until May 26, 2021, depending on the notified body, chances rather low
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021

5. Bibliography / References

No. in the present document	Literature	Hyperlink
1	Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 **amending Regulation (EU) 2017/745** on medical devices, as regards the dates of application of certain of its provisions	Link
2	Council Directives **93/42/EEC** of 14 June 1993 concerning medical devices Last modification 21.09.2007	Link
3	Council Directives **90/385/EEC** of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices Last modification 21.9.2007	Link
4	**Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices Last modification 27.12.2019	Link
5	**MDCG 2019-3** Interpretation of article 54(2)b rev. 1 Medical Device Coordination Group about Significant changes	Link

6. Our Experience - Your Benefit

We at inmedis are the experts for quality management and regulatory affairs in medical technology. With our well-founded know-how and the neutral view of the external consultant we guarantee a successful project completion. I look forward to hearing from you.

Kind regards

inmedis GmbH

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