Checklist

Requirements for a deadline extension for MDR compliance pursuant to Regulation (EU) 2023/607

The intention of Regulation (EU) 2023/607 is to extend the transitional periods for placing medical devices and IVDs on the market with reference to certificates still issued under the Directives. In addition, time extensions are to be applied to products that were not required to involve a Notified Body in the conformity assessment procedure under the Directives. Basically, four constellations can be distinguished in which a deadline extension is possible.

Case 01

	Yes	No
Certification pursuant to a Directive (MDD / AIMD) from Notified Body		
Certificate issued before 25 May 2017		
Certification on 26 May 2021 still valid		
Certificate was not withdrawn		
Product is still compliant with the Directive		
No significant changes to the product or its intended use		
Product does not pose a safety risk		
QMS implemented pursuant to Article 10(9) MDR by 26 May 2024 at the latest (necessary steps for this already initiated)		
Application of the manufacturer / authorised representative to the Notified Body pursuant to Annex VII, Section 4.3 by 26 May 2024 at the latest		
Written agreement between Notified Body and manufacturer (signed by both parties) pursuant to Annex VII, Section 4.3 MDR by 26 September 2024 at the latest		
If you answer "No" to one of the options, you are not entitled to an extension of the deadline.		
If you answer "Yes" to all options, an extension of the deadline by risk class is conceivable.		

Case 02

	Yes	No
Certification pursuant to a Directive (MDD / AIMD) from Notified Body		
Certificate issued before 25 May 2017		
Certification on 26 May 2021 still valid		
Certificate was not withdrawn		
Certificate expired before Regulation (EU) 2023/607 came into force		
Before expiry: written agreement between Notified Body and manufacturer (signed by both parties) pursuant to Annex VII, Section 4.3 MDR by 26 September 2024 at the latest		

OR: Authority approves exemption from conformity assessment procedure (Article 59 MDR) (special authorisation)		
OR: Authority accepts procedure in accordance with Article 97 MDR		
Product is still compliant with the Directive		
No significant changes to the product or its intended use		
Product does not pose a safety risk		
QMS implemented pursuant to Article 10(9) MDR by 26 May 2024 at the latest (necessary steps for this already initiated)		
If you answer "No" to one of the options, you are not entitled to an extension of the deadline.		
If you answer "Yes" to all options, an extension of the deadline by risk class is conceivable.		

Case 03

	Yes	No
Product for which no involvement of a Notified Body was required under MDD, but is required under MDR		
Declaration of conformity issued before 26 May 2023		
Product is still compliant with the Directive		
No significant changes to the product or its intended use		
Product does not pose a safety risk		
QMS implemented pursuant to Article 10(9) MDR by 26 May 2024 at the latest (necessary steps for this already initiated)		
Application by the manufacturer / authorised representative to the Notified Body pursuant to Annex VII, Section 4.3 by 26 May 2021 at the latest		
Written agreement between Notified Body and manufacturer (signed by both parties) pursuant to Annex VII, Section 4.3 MDR by 26 September 2024 at the latest		
If you answer "No" to one of the options, you are not entitled to an extension of the deadline.		
If you answer "Yes" to all options, an extension of the deadline by risk class is conceivable.		

Case 04

	Yes	No
Implantable custom design		
Product is still compliant with the Directive		
No significant changes to the product or its intended use		
Product does not pose a safety risk		
QMS implemented pursuant to Article 10(9) MDR by 26 May 2024 at the latest (necessary steps for this already initiated)		
Application of the manufacturer / authorised representative to the Notified Body pursuant to Annex VII, Section 4.3 by 26 May 2024 at the latest		
Written agreement between Notified Body and manufacturer (signed by both parties) pursuant to Annex VII, Section 4.3 MDR by 26 September 2024 at the latest		
If you answer "No" to one of the options, you are not entitled to an extension of the deadline.		

If you answer "Yes" to all options, an extension of the deadline by risk class is conceivable.

Deadline extensions depending on risk class

Risk class	Deadline
Class III	31 December 2027
Class IIb implantable	31 December 2027
Class IIb not implantable	31 December 2028
Class Is and Im	31 December 2028
Class III implantable custom device	26 May 2026
Exception: No extensions for Class IIb in the form of sutures, staples, fillings, braces, crowns, screws, wedges, dental or bone plates, wires, pins, clamps, connectors	

No extension of the deadline

The deadline extension primarily takes into account the fact that only relatively few Notified Bodies are accredited in accordance with MDR and IVDR, making it difficult for manufacturers to renew "old" certificates according to the MDR / IVDR requirements. All MDR / IVDR requirements that do not involve cooperation with a Notified Body must already be met.

Contact

If you have any questions about deadline extensions or medical device compliance requirements, feel free to contact me:

Miriam Schuh
Head of Healthcare

Reusch Attorneys at Law
Saarbrücken Office
Stengelstrasse 1
66117 Saarbrücken

P +49 681 859 160 0
E miriam.schuh@reuschlaw.de

www.reuschlaw.de