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Extended Transition Period - Consultant's Perspective

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MEDCON
CONFERENCE
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Implementation of the MDR

Status April 2023

- 57 Notified Bodies applied under the MDR
- 38 Notified Bodies designated under the MDR
- 22,793 certificates under MDD/AIMDD will expire latest by May 2024

Regulation 2023/607 - Extension of Transition Provisions per MDR Art. 120

- ✓ 2027 Class IIb implantable and III
- ✓ 2028 Class I, IIa and IIb non-implantable
- ✓ Consider **Classification changes** under the MDR

- ✓ **Applicable only to devices...**
 - that do not present any unacceptable risk to health and safety
 - that have **not undergone significant changes** in design or intended purpose
 - for which the manufacturers have already undertaken the necessary steps to launch the certification process under the MDR:
 - **Adaptation of their Quality Management System** to the MDR before May 26, 2024
 - **Application** for Conformity Assessment by a NB before a **May 26, 2024**
 - **Contract** with Notified Body before **September 26, 2024**

MDR Transition Considerations for Manufacturers

- ✓ Finding Notified Body with the relevant codes
- ✓ Planning of the (first) MDR submission to the Notified Body
- ✓ Up-Classification of certain devices
- ✓ Generating more clinical data (if required)
- ✓ Consideration of published Expert Panel opinions

