Medical Device Regulation (MDR)

European Medical Device Regulation

B|BRAUN SHARING EXPERTISE

The MDR will replace the EU's current medical device directives. For manufacturers of medical devices market access in the EU depends on compliance with the MDR.

Why MDR?

The stricter requirements for medical devices are the European answer especially to scandal cases with low-quality and defective medical devices.

Core objectives

- Better protection of public health and patient safety
- Higher transparency and traceability

CLASSIFICATION OF MEDICAL DEVICES ACCORDING TO MDR

CLASS I	CLASS Ir (NEW)	CLASS IIa	CLASS IIb	CLASS III
low risk	low risk	medium risk	medium / high risk	high risk
~205,000		~155,000	~90,000	~50,000

The MDR affects about 500,000 medical devices in the EU. It is estimated that approximately 65 % of the products will be (re)certified according to the new regulation.

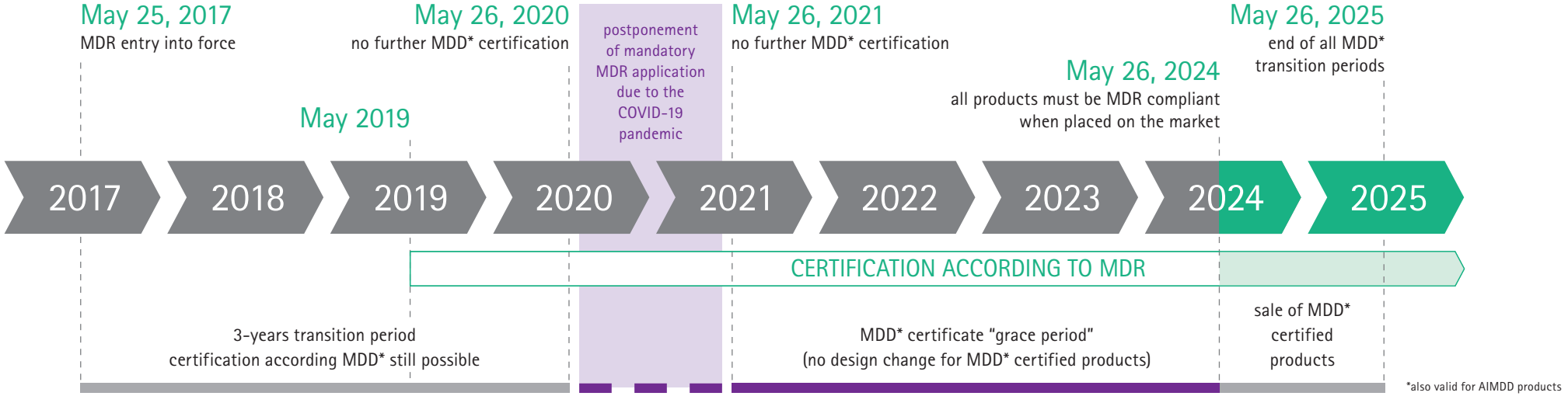
Source: BVMed

MAIN CHANGES

- New regulations regarding product classification
- Increased requirements related to technical documentation
- Increased requirements regarding clinical data
- More extensive reporting obligations for manufacturers (e.g. active market observation)
- Higher approval requirements for high-risk products (Scrutiny)
- More extensive requirements regarding the documentation, provision and traceability of product data and product-related information (UDI and EUDAMED)

Further information available at www.bbraun.com/mdr

MDR Timeline PREVIOUS PLANNING



B. BRAUN
MDR
CONFORMITY & COMPLIANCE
- your reliable partner -

Implementation at B. Braun

Our vision

We protect and improve the health of people around the world.

Yes, we can MDR

- For the MDR transition we are providing resources in multi-digit million range.
- We are transferring our medical devices to the MDR as quickly as possible and on-time.
- **Our quality management systems of B. Braun Melsungen AG, Aesculap AG and B. Braun Avitum AG are certified** by our Notified Bodies **according to the MDR.**
- **Our class I medical devices meet all legal requirements by the mandatory application date of the MDR since May 26, 2021.**
- Medical devices higher than class I will be transferred to MDR successively by the maximum term.

We are committed to security of supply

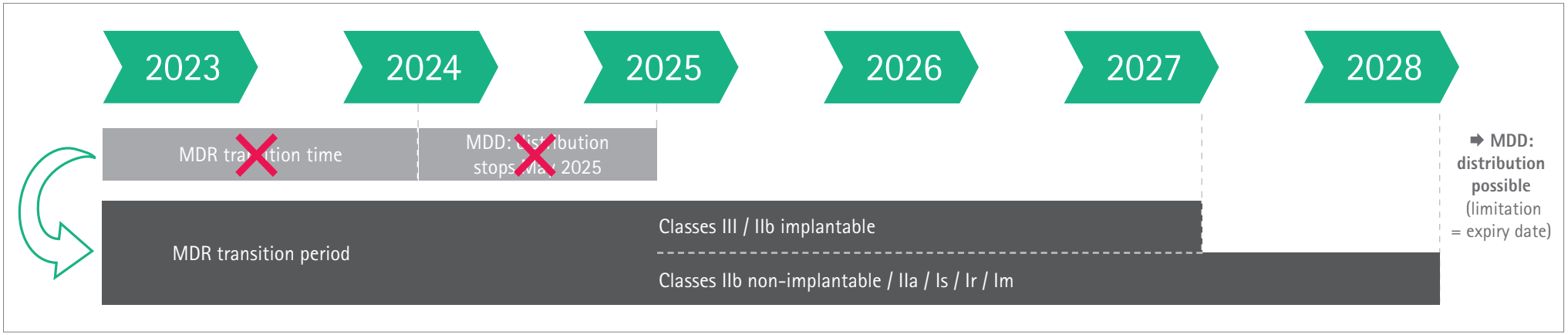
- Our top priority: **Safe and reliable supply of our customers!**
- Our broad product portfolio covers not only mass articles but also many niche products.
- We communicate standard product range adjustments in a timely, open and transparent manner and offer alternatives as far as possible.

Family-owned company

- As a family-owned company with over 180 years of tradition, we think long-term and work closely, fairly and in partnership with our customers and suppliers.

Do you have any **further questions** about the implementation of MDR at B. Braun? Please visit us at **www.bbraun.com/mdr**

Amendment of the MDR transitional provisions



CERTIFICATES

- ✓ MDD EC certificate validity extended automatically (**no new certificates** to be issued)
- ✓ MDD and MDR EC certificates will be **valid in parallel** over the period of the timeline extension
- ✓ Both, MDD and MDR products can be **placed on the market**

Prerequisites

- Devices shall not present any unacceptable risk to health and safety
- QMS shall be already MDR compliant
- MDR application signed by May 2024
- MDR contract with Notified Body shall be signed within September 2024
- No significant changes to MDD products

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