B|BRAUN
SHARING EXPERTISE

MEDICAL DEVICE REGULATION (MDR)

EUROPEAN MEDICAL DEVICE REGULATION

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

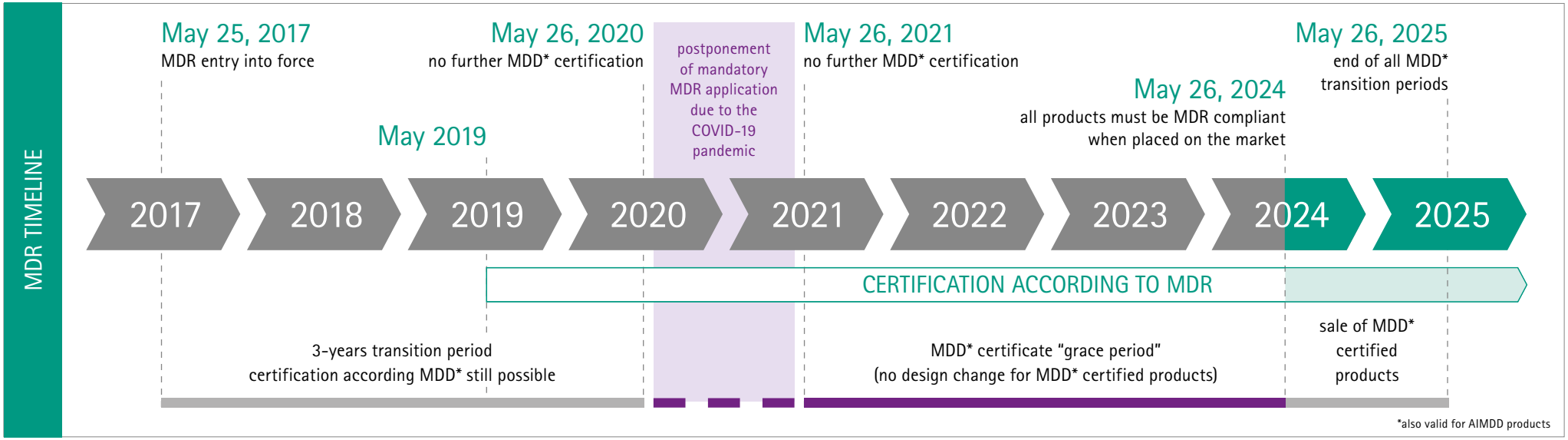
The MDR affects about 500,000 medical devices in the EU. It is estimated that approximately 65 % of the products will be (re)certified according to the new regulation.

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



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

The B. Braun Group has initiated comprehensive measures and provided resources in multi-digit million range in order to **transfer our products to MDR as quickly as possible and on-time.**

WE ARE MDR-READY

With our Notified Bodies we have successfully completed the MDR audit of our quality management systems in almost all locations and **expect the certificates to be issued soon,** if not already done so.

WE GUARANTEE SECURITY OF SUPPLY

Ensuring a reliable supply and delivery has top priority for us. Therefore our class I products will comply with the requirements of the new MDR regulation in the course of 2020. The MDR conversion of our products in the higher classes will take place successively up to the maximum term at the beginning of 2024. With our very broad product portfolio we not only focus on mass products but also **carry many niche products.** Within the scope of standard product range adjustments, **we communicate** this in a **timely, open and transparent** manner and offer alternatives as far as possible.

As the only FAMILY-OWNED COMPANY among the 20 largest manufacturers of medical devices worldwide and with 180 years of tradition, **we think long-term and work closely, in partnership and fairly** 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

B. Braun Melsungen AG | 34209 Melsungen | Germany
Tel. +49 5661 71-0 | Fax +49 5661 71-2732 | www.bbraun.com