B BRAUN
SHARING EXPERTISE

**EU Medical Device Regulation (MDR)**
**Implementation at B. Braun Medical, Inc.**

Dear Sir or Madam,

The European Union Medical Device Regulation went into effect on May 25, 2017. During the subsequent three-year transition period, either the previous Medical Devices Directive (MDD) or the new MDR may be used. For Manufacturers, implementing the MDR means expanding their responsibilities significantly; among other things, manufacturers are obliged to adapt to the following challenges:

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

B. Braun Medical, Inc. has initiated comprehensive measures and provided resources to ensure the implementation of the EU MDR. The implementation of EU MDR with the above-mentioned applicable new clinical requirements, additional documentation, and reporting obligations involves considerable work and coordination effort as well as high costs for us as manufacturer.

During this ongoing process we have extended our EC Certifications under the allowable four year time frame for compliance to EU MDR of our CE marked products until May 2024. Although we have extended our EC Certifications, we are pursuing the scheduling of our EU MDR site audit with our Notified Body and working diligently to transition our Quality Management System and CE marked products to the new requirements.

We assure you that we evaluate all measures for the implementation of EU MDR with a sense of responsibility and the greatest possible care. With our extensive portfolio and know-how, we will continue to support our customers and contribute to process improvement and workflow optimization. We supplement this approach with individual system solutions to optimize the economic relationship between costs and revenues.

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 want to work together with our customers in a trusting relationship over many years. Partnership and fairness are decisive for us.

If you have any further questions we will be happy to answer them, please do not hesitate to contact us.

Kind Regards,

Christian Kelly, Corporate Vice President – Quality

Rebecca Stolarick, Corporate Vice President – Regulatory Affairs