

P. J. Dahlhausen & Co. GmbH · Postfach 56 01 32 · 50986 Köln

To whom it may concern

Cologne, June 10, 2024

MDR transitional period

Dear Customer,

We refer to the Regulation (EU) 2017/745 and the regulations (EU) 2023/607.

As known, the Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 regarding the transitional provisions for certain medical devices has been published on the European Union Official Journal on the 20 March 2023 and entered into force since the same day. The Regulation (EU) 2023/607 provides for the extension of the transitional period by extending the validity of certificates issued in the scope of the Medical Devices Directives (93/42/EEC).

With regard to this we would like to advise you that we signed a MDR framework agreement with our notified body, the TÜV Product Service GmbH (0123,) in February 2022 and have made a formal application in accordance with the section 4.3, first paragraph of Annex VII MDR for a conformity assessment. These carried out processes enables us to issue the enclosed Manufacturer's Declaration where we confirm all relevant aspects. According to the laid down transitional period our present certificates issued in accordance with the Medical Device Directive 93/42/EEC and our Declaration of Conformities are valid until 31 December 2028. During the transitional period the notified body cannot issue new MDD certificates.

If you have further questions, please do not hesitate to contact us.

Best regard,

P. J. Dahlhausen & Co. GmbH



Petra Hardt
Manager QM/RA

Enclosure

Manufacture's Declaration