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EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2022-12-05

Object(s) of the declaration: **Bodedex forte**

Bodedex forte		
Pack size	Article number BODE	Article number HARTMANN
2 l	973762	980244
5 l	973761 973769	980243 980250

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by BODE Chemie GmbH, comply with the applicable provisions, in particular, the

- General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The objects of the declaration have been identified as medical devices in risk class I according to classification rule 1 in Annex VIII of Regulation (EU) 2017/745. The conformity assessment procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

Intended Purpose:
Cleaning of invasive and non-invasive medical devices.

Basic UDI-DI: 40316783776ME
Single Registration Number: DE-MF-000005851
Certificate No. 0523GB448210329A

BODE Chemie GmbH

Dr. Henning Mallwitz
Director Research & Development

06. DEZ. 2022

Dr. Ralf Meier
Head of Quality Assurance

Valid until: 2024-12-05