

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	980243
	973769	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
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06. DEZ. 2022



Dr. Ralf Meier
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Valid until: 2024-12-05