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EC-Declaration of Conformity for Medical Device Class I

Hamburg, 2021-07-08

We herewith declare,

Object of the declaration: **Bodedex forte**

Pack size	Article number BODE	Article number Hartmann
2L	973762	980244
5L	973761 973769	980243 980250

which is first placed on the market by BODE Chemie GmbH, meet the applicable provisions, especially the essential health and safety requirements of the following EC-Directive:

- **Regulation (EU) 2017/745 of the European Parliament and the Council on medical devices**

The Conformity Assessment Procedure according to Article 52 (7) Class I and Annex IX has been performed and the Technical Documentation is kept available.

This EC-Declaration of Conformity is issued under the sole responsibility of the BODE Chemie GmbH.

The product has been identified as a medical device in risk class I according to Rule 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40316783776ME

Single Registration Number: DE-MF-000005851

The object of the declaration is in conformity with the relevant harmonized standards and with the technical specifications in relation to which conformity is declared as defined in the General Safety and Performance Requirements.

BODE Chemie GmbH

Dr. Henning Mallwitz
Director Research & Development

André Maack
Head of Quality Assurance

This document is valid until: 2023-07-08