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EC-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2021-06-29

We herewith declare,

Object of the declaration: **Bomix plus**

Pack size	Article number BODE	Article number HARTMANN
2L	974602	980320
5L	974609 981785	980321 981785

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-regulation:

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

The Conformity Assessment Procedure according to Article 52 (6) Class IIa 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 conformity assessment procedure is under the supervision of the Notified Body:

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2
20355 Hamburg
Germany

Identification No. 0482

The product has been identified as a medical device in risk class IIa according to Rule 16 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40316782718LR
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: 2023-06-29