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EC-Declaration of Conformity for Medical Device Class I

Hamburg, 2021-07-08

We herewith declare,

Object of the declaration: **Bode X-Wipes**

Pack size	Article number BODE	Article number Hartmann
90 wipes per roll (in a Safety Pack, i.e. stand up pouch with bucket lid, closing lid and tear off inset)	981479	981479

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: 40316783775MC

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