BODE Chemie GmbH
A company of the HARTMANN GROUP
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EC-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2021-06-29

We herewith declare,

Object of the declaration: **Bacillol 30 Sensitive**

Bacillol 30 Sensitive Tissues		
Pack size	Article number BODE	Article number HARTMANN
Bacillol 30 Sensitive Tissues Flow-Pack (80 T.)	981693 981848 981849 981864 981700 981850 981851	981693 981848 981849 981864 981700 981850 981851
Bacillol 30 Sensitive Tissues Flow-Pack (40 XXL T.)	981865 981852 981853 981701 981854 981855	981865 981852 981853 981701 981854 981855
Bacillol 30 Sensitive Tissues Flow-Pack (24 T.)	981866 981856 981857 981858 981702 981859 981860	981866 981856 981857 981858 981702 981859 981860
Bacillol 30 Sensitive Foam		
Pack size	Article number BODE	Article number HARTMANN
Bacillol 30 Sensitive Foam 5 l	981861 981839 981840 981841 981842 981843	981861 981839 981840 981841 981842 981843
Bacillol 30 Sensitive Foam 750 ml with spray head	981690 981844 981845 981699 981846 981847	981690 981844 981845 981699 981846 981847

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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: 40316783833LZ

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