

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

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

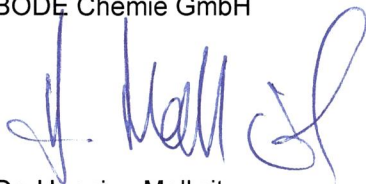
The product has been identified as a medical device in risk class IIa according to Rule 16 in Annex VIII of Regulation (EU) 2017/745.

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