BODE Chemie GmbH
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BODE Chemie GmbH · P. O. Box 54 07 09 · 22507 Hamburg

EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2022-01-03

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

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

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by BODE Chemie GmbH, comply with the applicable provisions, in particular, the

- General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The objects of the declaration have been identified as medical devices in risk class IIa according to classification rule 16 in Annex VIII of Regulation (EU) 2017/745.

The conformity assessment procedure according to Article 52 (6) and Annex IX has been performed and the Technical Documentation is kept available.

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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

Intended Purpose:
Disinfection of non-invasive medical devices.

Basic UDI-DI: 40316783833LZ
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Dr. Henning Mallwitz
Director Research & Development

André Maack
Head of Quality Assurance

This document is valid until: 2024-01-03