BODE Chemie GmbH
A company of the HARTMANN GROUP
Melanchthonstr. 27
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EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2023-10-11

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

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 1 l	981944	981944
Bacillol 30 Sensitive Foam 750 ml with spray head	981690 981844 981845 981699 981846 981847	981690 981844 981845 981699 981846 981847

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.

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
Certificate No. 0523GB448210329A

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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

Raphael Bohner
Head of Quality

Valid until: 2025-10-11