

## EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2025-10-16

**Object of the declaration:**

**Bacillol 30 Sensitive Foam**

<b>Bacillol 30 Sensitive Foam</b>		
Pack size	Article number BODE	Article number HARTMANN
Bacillol 30 Sensitive Foam 5 l	981861	981861
Bacillol 30 Sensitive Foam 1 l	981944	981944
Bacillol 30 Sensitive Foam 750 ml with spray head	981690 981844 981845 981847 981699	981690 981844 981845 981847 981699

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:

**DNV MEDCERT GmbH**  
Pilatuspool 2  
20355 Hamburg  
Germany  
Identification No. 0482  
Certificate No. 0523GB448210329A/0523GB448251013

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**Intended Purpose:**  
Cleaning disinfection of non-invasive Medical Devices.

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

BODE Chemie GmbH

Thekla Bredthauer  
Person Responsible for Regulatory Compliance

Raphael Bohner  
Head of Quality

Valid until: 2027-10-16

