BODE Chemie GmbH
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EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2025-10-15

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 (160 T.)	981983	981983
Bacillol 30 Sensitive Tissues Flow-Pack (120 T.)	981943 981987	981943 981987
Bacillol 30 Sensitive Tissues Flow-Pack (80 T.)	981693 981848 981849 981700 981851 982029	981693 981848 981849 981700 981851 982029
Bacillol 30 Sensitive Tissues Flow-Pack (40 XXL T.)	981865	981865
Bacillol 30 Sensitive Tissues Flow-Pack (24 T.)	981866 982036	981866 982036

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:

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

(High-Level) Intended Purpose:
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: 2027-10-15