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

Hamburg, 2024-09-13

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

Bacillol 30 Sensitive Tissues		
Pack size	Article number BODE	Article number HARTMANN
Flow-Pack (80 Tissues)	981693	981693
Flow-Pack (80 Tissues)	981848	981848
Flow-Pack (80 Tissues)	981849	981849
Flow-Pack (80 Tissues)	981700	981700
Flow-Pack (80 Tissues)	981851	981851
Flow-Pack (40 XXL Tissues)	981865	981865
Flow-Pack (24 Tissues)	981866	981866
Flow-Pack (120 Tissues)	981943	981943
Flow-Pack (120 Tissues)	981987	981987
Flow-Pack (160 Tissues)	981983	981983

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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(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 Assurance

Valid until: 2025-11-13