BODE Chemie GmbH

A company of the HARTMANN GROUP

HARTMANN

Melanchthonstr. 27 22525 Hamburg Germany

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EU-Declaration of Conformity for Medical Device Class Ila

Hamburg, 2023-11-14

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

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 Certificate No. 0523GB448210329A

(High-Level) Intended Purpose: Disinfection of non-invasive medical devices.

Basic UDI-DI: 40316783833LZ

Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Britta Glogati

Director Research & Development

Valid until: 2025-11-13

Raphael Bohner Head of Quality