

EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2022-01-03

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 (80 T.)	981693	981693
	981848	981848
	981849	981849
	981864	981864
	981700	981700
	981850	981850
	981851	981851
Bacillol 30 Sensitive Tissues Flow-Pack (40 XXL T.)	981865	981865
	981852	981852
	981853	981853
	981701	981701
	981854	981854
Bacillol 30 Sensitive Tissues Flow-Pack (24 T.)	981855	981855
	981866	981866
	981856	981856
	981857	981857
	981858	981858
	981702	981702
	981859	981859
981860	981860	

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.

BODE Chemie GmbH · P. O. Box 54 07 09 · 22507 Hamburg

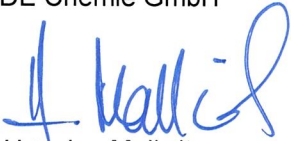
The conformity assessment procedure is under the supervision of the Notified Body:

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2
20355 Hamburg
Germany
Identification No. 0482

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



André Maack
Head of Quality Assurance

This document is valid until: 2024-01-03