

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

Hamburg, 2022-12-06

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

<b>Bacillol 30 Sensitive Tissues</b>		
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
Bacillol 30 Sensitive Tissues Flow-Pack (40 XXL T.)	981851	981851
	981865	981865
	981852	981852
	981853	981853
	981854	981854
	981855	981855
Bacillol 30 Sensitive Tissues Flow-Pack (24 T.)	981701	981701
	981866	981866
	981856	981856
	981857	981857
	981858	981858
	981859	981859
	981860	981860
	981702	981702

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.

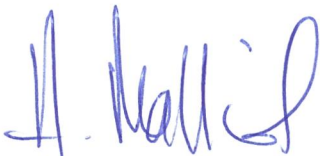
The conformity assessment procedure is under the supervision of the Notified Body:

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2**  
**20355 Hamburg**  
**Germany**  
**Identification No. 0482**  
**Certificate No. 0523GB448210329A**

(High-Level) 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

06. DEZ. 2022



Dr. Ralf Meier  
Head of Quality Assurance

Valid until: 2024-12-06