

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

Hamburg, 2023-02-07

**Object of the declaration: Bacillol Tissues**

<b>Bacillol Tissues</b>		
Pack size	Article number BODE	Article number HARTMANN
Dispenser (100 Tissues)	975670	980503
Dispenser (100 Tissues)	975680	980505
Refill sachet (100 Tissues)	975673	980504
Refill sachet (100 Tissues)	975683	980506

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 1 and 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.

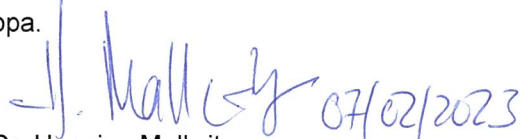
The conformity assessment procedure is under the supervision of the Notified Body:

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

Intended Purpose:  
Disinfection of non-invasive medical devices

Basic UDI-DI: 40316782658LY  
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

ppa.  
  
07/02/2023

Dr. Henning Mallwitz  
Director Research & Development



Dr. Ralf Meier  
Head of Quality Assurance

Valid until: 2025-02-07