

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

Hamburg, 2025-11-13

**Object of the declaration:** **Bacillol Oxy Tissues**

| <b>Bacillol Oxy Tissues</b> |                     |                         |
|-----------------------------|---------------------|-------------------------|
| Pack size                   | Article number BODE | Article number HARTMANN |
| 100 Tissues                 | 981982              | 981982                  |

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:

**DNV MEDCERT GmbH**  
**Pilatuspool 2**  
**20355 Hamburg**  
**Germany**  
**Identification No. 0482**  
**Certificate No. 0523GB448251013**

(High-Level) Intended Purpose:

Cleaning disinfection of non-invasive Medical Devices.

Cleaning disinfection of invasive medical devices, not as end point of processing.

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Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Thekla Bredthauer  
Person Responsible for Regulatory Compliance

Valid until: 2027-11-13

Raphael Bohner  
Head of Quality

