BODE Chemie GmbH
A company of the HARTMANN GROUP
Melanchthonstr. 27
22525 Hamburg
Germany
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EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2025-11-13

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

Bacillol Oxy Tissues		
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.

HARTMANN SCIENCE CENTER
Research for
infection protection.

BODE Chemie GmbH
Commercial Register Hamburg
HRB 108924

Managing Director:
Arne-John Roettger

HypoVereinsbank
IBAN: DE83 6002 0290 0611 0224 33
BIC: HYVEDEMM473 · VAT-ID: DE118115768

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Basic UDI-DI: 40316784007KX
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Thekla Bredthauer
Person Responsible for Regulatory Compliance

Raphael Bohner
Head of Quality

Valid until: 2027-11-13

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