BODE Chemie GmbH
A company of the HARTMANN GROUP
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EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2025-10-21

Object of the declaration: **Mikrobac forte**

Mikrobac forte		
Pack size	Article number BODE	Article number HARTMANN
250 x 20 mL Sachet	975392	980434
5 L	975395	980435
5 L	973219	980185
200 L	975397	980437
640 L	975398	980438

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 Medizin GmbH
Pilatuspool 2
20355 Hamburg
Germany
Identification No. 0482
Certificate No. 0523GB448210329A/0523GB448251013

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(High-Level) Intended Purpose:
Disinfection of non-invasive medical devices

Basic UDI-DI: 40316783778MJ
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

i.V.

Thekla Bredthauer
Person Responsible for Regulatory Compliance

Raphael Bohner
Head of Quality

Valid until: 2027-10-21