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EU-Declaration of Conformity for Medical Device Class Ila

Hamburg, 2023-02-07

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
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 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: 40316783778MJ Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

ppa.

Dr. Henning Mallwitz **Director Research & Development**

Valid until: 2025-02-07



HARTMANN SCIENCE CENTER Research for infection protection.

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Head of Quality Assurance