BODE Chemie GmbH A company of the HARTMANN GROUP Melanchthonstr 27 22525 Hamburg Germany T. +49 40 54006-0 F. +49 40 54006-200 bode-chemie.com info@bode-chemie.de



EU-Declaration of Conformity for Medical Device Class IIb

Hamburg, 2023-01-30

Object of the declaration:

Dismozon plus

Dismozon plus		
Pack size	Article number BODE	Article number HARTMANN
100 x 16 g sachets	981187	981187
50 x 16 g sachets	981579	981579
50 x 16 g sachets	981257	981257

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 IIb according to classification rule 1 and rule 16 in Annex VIII of Regulation (EU) 2017/745.

The conformity assessment procedure according to Article 52 (4) 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

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

Basic UDI-DI: 40316782759M7 Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

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

Valid until: 2023-11-13



HARTMANN SCIENCE CENTER Research for infection protection.

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Dr. Ralf Meier Head of Quality Assurance

Managing Director: Alexander Schwieger HupoVereinsbank IBAN: DE83 6002 0290 0611 0224 33 BIC: HYVEDEMM473 · VAT-ID: DE118115768