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, 2025-10-23

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:

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

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

(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

Thekla Bredthauer
Person Responsible for Regulatory Compliance

Raphael Bohner
Head of Quality

Valid until: 2027-10-23