**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



BODE Chemie GmbH · P. O. Box 54 07 09 · 22507 Hamburg

**EU-Declaration of Conformity for Medical Device Class Ila** 

Hamburg, 2022-01-03

**Object of the declaration:** 

**Bomix plus** 

Bomix plus		
Pack size	Article number BODE	Article number HARTMANN
2L	974602	980320
5L	974609	980321

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:

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH **Pilatuspool 2** 20355 Hamburg Germany **Identification No. 0482** 

Intended Purpose: Disinfection of invasive and non-invasive medical devices.

Basic UDI-DI: 40316782718LR Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

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

This document is valid until: 2024-01-03

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André Maack Head of Quality Assurance



HARTMANN SCIENCE CENTER Research for infection protection.

**BODE Chemie GmbH** Commercial Register Hamburg HRB 108924

Managing Director: Alexander Schwieger HupoVereinsbank Page 1 of 1 IBAN: DE83 6002 0290 0611 0224 33 BIC: HYVEDEMM473 · VAT-ID: DE118115768