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EU-Declaration of Conformity for Medical Device Class Ila

Hamburg, 2023-11-07

Object of the declaration:

Kohrsolin FF

Kohrsolin FF		
Pack size	Article number BODE	Article number HARTMANN
125 x 40 ml Sachet	975382	980428
5 L	975386	980431
200 L	975387	980432

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

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

Basic UDI-DI: 40316782723LJ Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Britta Glogau

Director Research & Development

Valid until: 2025-11-07



HARTMANN SCIENCE CENTER Research for infection protection. BODE Chemie GmbH Commercial Benister Hamburg HRB 108924

& amo

Raphael Bohner Head of Quality

> Managing Director: Alexander Schwieger

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