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 Ilb

Hamburg, 2022-01-03

Object of the declaration:

...

Korsolex Endo-Disinfectant

Korsolex Endo-Disinfectant		
Pack size	Article number BODE	Article number HARTMANN
5L	972030	980121

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 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

Intended Purpose: Disinfection of invasive medical devices.

Basic UDI-DI: 40316783777MG Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Dr. Henning Mallwitz Director Research & Development

This document is valid until: 2024-01-03

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
 HypoVereinsbank
 Page 1 of 1

 IBAN: DE83 6002 0290 0611 0224 33
 BIC: HYVEDEMM473 · VAT-ID: DE118115768