

EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2025-03-05

Object(s) of the declaration: **Korsolex Endo-Cleaner**

Korsolex Endo-Cleaner		
Pack size	Article number BODE	Article number HARTMANN
5 L	972020	980117

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 I according to classification rule 1 in Annex VIII of Regulation (EU) 2017/745. The conformity assessment procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

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

Basic UDI-DI: 40316783776ME
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH



Thekla Bredthauer
Person Responsible for Regulatory Compliance



Raphael Bohner
Head of Quality

Valid until: 2027-03-05