

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, 2026-07-06

Object of the declaration: **Korsolex Endo-Disinfectant**

Korsolex Endo-Disinfectant		
Pack size	Article number BODE	Article number HARTMANN
5 l	972030	980121
5 l	982224	982224

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:

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

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

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



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Person Responsible for Regulatory Compliance	Head of Quality
Signiert von: <i>Marina Smit</i>  Name des Unterzeichners: Marina Smit Signiergrund: Ich genehmige dieses Dokument Signierzeit: July 6, 2026 08:01 MESZ 27BF23530C1744ACBFE5F624BB7F96C4	Signiert von: <i>R. Böhner</i>  Name des Unterzeichners: Raphael Böhner Signiergrund: Ich genehmige dieses Dokument Signierzeit: July 6, 2026 10:38 MESZ 0474E537F0F24A87AFE69C10ADBA9DB5

Valid until: 2028-07-05

