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EU-Declaration of Conformity for Medical Device Class IIb

Hamburg, 2022-01-03

Object of the declaration: **Korsolex extra**

Korsolex extra		
Pack size	Article number BODE	Article number HARTMANN
2L	973802	980254
5L	973809	980256

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 and non-invasive medical devices.

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

BODE Chemie GmbH

Dr. Henning Mallwitz
Director Research & Development

André Maack
Head of Quality Assurance

This document is valid until: 2024-01-03