

EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2023-10-11

Object(s) of the declaration: **Korsolex PAA Test**

Korsolex PAA Test		
Pack size	Article number BODE	Article number HARTMANN
1 pc. = 100 test sticks	975233	980409

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.

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

Basic UDI-DI: 40316784073LC
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH


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Valid until: 2025-10-11