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EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2026-01-28

Object of the declaration: BODE X-Wipes

BODE X-Wipes		
Pack size	Article number BODE	Article number HARTMANN
90 wipes per roll (in a Safety Pack, i.e. stand up pouch with bucket lid, closing lid and tear off inset)	981945	981945

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: 40316783775MC
 Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

Person Responsible for Regulatory Compliance	Head of Quality
Signiert von:  Name des Unterzeichners: Thekla Bredthauer Signiergrund: Ich genehmige dieses Dokument Signierzeit: January 28, 2026 09:26 MEZ C9203FB08C6B4BC0B694A81D55B833D0	Signiert von:  Name des Unterzeichners: Raphael Bohner Signiergrund: Ich genehmige dieses Dokument Signierzeit: January 28, 2026 09:22 MEZ 0474E537F0F24A87AFE69C10ADBA9DB5

Valid until: 2028-01-28

