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EU-Declaration of Conformity for Medical Device Class I

Hamburg, 2022-12-05

Object(s) 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)	981479	981479

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:
Application aid for reprocessing of invasive and non-invasive medical devices.

Basic UDI-DI: 40316783775MC
Single Registration Number: DE-MF-000005851
Certificate No. 0523GB448210329A

BODE Chemie GmbH

Dr. Henning Mallwitz
Director Research & Development

06. DEZ. 2022 i.V.

Dr. Ralf Meier
Head of Quality Assurance

Valid until: 2024-12-05