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EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2023-04-25

Object of the declaration: **Bacillol Zero Tissues**

Bacillol Zero Tissues		
Pack size	Article number BODE	Article number HARTMANN
981713	981713	80 Tissues/Flowpack
981935	981935	100 Tissues/Flowpack
981936	981936	80 Tissues/XL Flowpack
981714	981714	40 Tissues/XXL Flowpack

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 IIa according to classification rule 1 and rule 16 in Annex VIII of Regulation (EU) 2017/745.

The conformity assessment procedure according to Article 52 (6) 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
Certificate No. 0523GB448210329A

(High-Level) Intended Purpose:
Cleaning disinfection of non-invasive medical devices. Cleaning disinfection of invasive medical devices, not as end point of processing.

Basic UDI-DI: 40316783959MQ
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

ppa.

Dr. Henning Mallwitz
Director Research & Development

Anton Seifert
Head of Quality Assurance

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