BODE Chemie GmbH
A company of the HARTMANN GROUP
Melanchthonstr. 27
22525 Hamburg
Germany
T. +49 40 54006-0
F. +49 40 54006-200
bode-chemie.com
info@bode-chemie.de

EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2023-02-07

Object of the declaration: **Mikrobac Tissues**

Mikrobac Tissues		
Pack size	Article number BODE	Article number HARTMANN
Flowpack (80 Tissues)	981387	981387
Flowpack (40 XXL Tissues)	981339	981339
Flowpack (80 Tissues)	981808	981808
Flowpack (80 Tissues)	981809	981809
Flowpack (40 XXL Tissues)	981688	981688

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

Intended Purpose:
Disinfection of non-invasive medical devices

Basic UDI-DI: 40316783778MJ
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

ppa. 07/02/2023

Dr. Henning Mallwitz
Director Research & Development

Dr. Ralf Meier
Head of Quality Assurance

Valid until: 2025-02-07