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

BODE Chemie GmbH · P. O. Box 54 07 09 · 22507 Hamburg

EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2023-09-25

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

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

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

Raphael Bohner
Head of Quality

Valid until: 2025-09-25