BODE Chemie GmbH

A company of the HARTMANN GROUP



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EC-Declaration of Conformity for Medical Device Class Ila

Hamburg, 2021-11-16

We herewith declare, that

Object of the declaration:

Mikrobac Tissues

Pack size	Article number BODE	Article number HARTMANN
Mikrobac Tissues, Flow-Pack	981387	981387
(80 T.)	981808	981808
	981809	981809
Mikrobac Tissues, Flow-Pack	981339	981339
(40 XXL T.)	981688	981688

which is manufactured and/or placed on the market by BODE Chemie GmbH, meet the applicable provisions, especially the essential health and safety requirements of the following EC-Directive:

Council Directive 93/42/EEC of 14th June, 1993

The required conformity assessment procedure according to Annex II excluding (4) has been performed and the technical documentation is kept available.

This EC-Declaration of Conformity is issued under the sole responsibility of the BODE Chemie GmbH.

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

Medical Device: Class IIa acc. to rule 15 (acc. to Annex IX of the directive)

BODE Chemie GmbH

Dr. Henning Mallwitz

Director Research & Development

André Maack

Head of Quality Assurance