

## EC-Declaration of Conformity for Medical Device Class IIa

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 (80 T.)	981387	981387
	981808	981808
	981809	981809
Mikrobac Tissues, Flow-Pack (40 XXL T.)	981339	981339
	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 14<sup>th</sup> 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



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This document is valid until: 2023-02-08