

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

Hamburg, 2021-11-16

We herewith declare, that

**Object of the declaration: BacilloI AF Tissues**

| Pack size                                 | Article number BODE | Article number HARTMANN |
|---|---------------------|-------------------------|
| BacilloI AF Tissues, Flow-Pack<br>(80 T.) | 981311<br>981440    | 981311<br>981440        |

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.

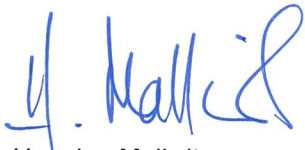
This EC-Declaration of Conformity is issued under the sole responsibility of the BODE Chemie GmbH.

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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André Maack  
Head of Quality Assurance

This document is valid until: 2023-02-08