BODE Chemie GmbH
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EC-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2019-12-02

We herewith declare, that

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

Pack size	Article number BODE	Article number Hartmann
Bacillol AF Tissues, Flow-Pack (80 T.)	981311 981440	981311 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 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, Deutschland
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

This document is valid until: 2021-12-02