

EC-Declaration of Conformity for Medical Device Class IIb

Hamburg, 2019-12-02

We herewith declare, that

Object of the declaration: **Dismozon plus**

| Pack size | Article number BODE | Article number Hartmann |
|-------------------|---------------------|-------------------------|
| 100 x 16 g sachet | 981187 | 981187 |
| | 981608 | 981608 |
| 50 x 16g sachet | 981257 | 981257 |

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 IIb 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