

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

Hamburg, 2021-05-21

We herewith declare,

**Object of the declaration:** **Single-use Pump**

Pack size	Article number BODE	Article number Hartmann
200 p.	981600	981600
	981601	981601
	981602	981602
	981603	981603
	981736	981736
20 p.	981813	981813
	981814	981814
	981737	981737

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

- **Regulation (EU) 2017/745 of the European Parliament and the Council on medical devices**

The Conformity Assessment Procedure according to Article 52 (7) Class I and Annex IX 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 product has been identified as a medical device in risk class I according to Rule 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40316783780M5

\*\*\*As soon as available SRN, until then authority company registration code (e.g. DIMDI) \*\*\*

Single Registration Number: -

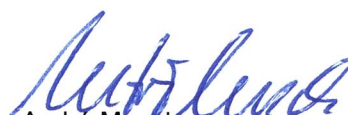
Registration Number: applied for at DIMDI (Registration number DIMDI)

The object of the declaration is in conformity with the relevant harmonized standards and with the technical specifications in relation to which conformity is declared as defined in the General Safety and Performance Requirements.

BODE Chemie GmbH



Dr. Henning Mallwitz  
Director Research & Development



André Maack  
Head of Quality Assurance

This document is valid until: 2023-05-21