

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

Hamburg, 2019-12-02

We herewith declare, that

**Object of the declaration:** **Kohrsolin FF**

Pack size	Article number BODE	Article number Hartmann
125 x 40 ml sachet	975382	980428
5 l canister	975383	980429
	975386	980431
200 l drum	975387	980432

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, Deutschland**

**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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Director Research & Development



André Maack  
Head of Quality Assurance

This document is valid until: 2021-12-02