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

Hamburg, 2021-01-29

We herewith declare,

## Object of the declaration:

## **Bode X-Wipes**

Pack size	Article number BODE	Article number Hartmann
90 wipes per roll	981479	981479
(in a Safety Pack, i.e. stand up pouch with bucket lid, closing lid and tear off inset)		

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:

## 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. Medical Device: Class I acc. to rule 1 (acc. to Annex IX of the directive)

**BODE Chemie GmbH** 

Dr. Henning Mallwitz

Director Research & Development

Head of Quality Assurance

This document is valid until: 2021-05-25