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HARTMANN
Going further for health

PAUL HARTMANN AG, P.O. Box 1420, 89522 Heidenheim, Germany

EC-Declaration of Conformity for Medical Device Class I sterile

Heidenheim, 2018-09-17

We herewith declare,

Object of the declaration: **Cosmopor Entry**

which is first placed on the market by PAUL HARTMANN AG, meet the applicable provisions, especially the essential requirements of the following EC-regulation:

- **Council Directive 93/42/EEC for medical devices**

The required conformity assessment procedure according to Annex VII in connection with Annex V has been performed and the technical documentation is kept available.

This EC-Declaration of Conformity is issued under the sole responsibility of the PAUL HARTMANN AG.

The sterilization processes are under the supervision of the Notified Body:
TÜV SÜD Product Service GmbH, DE-80339 München, Ridlerstr. 65, Identification No. 0123.

Medical Device Class: (acc. to Annex IX of the directive)	**Class I sterile acc. to rule 4 (1.)**
UMDNS:	**10-288**

PAUL HARTMANN AG

ppa.

Stefan Fischer
Head of Regulatory Affairs

i. A.

Dr Laurent Roche
Head of Product Marketing
Wound Management

This document is valid until: 2019-09-30

IILN 040 9500 00000 0

Vorstand/ Management Board: Andreas Joehle (Vorstandsvorsitzender/ CEO). Dr. Raymund Heinen. Michel Kuehn. Stephan Schulz.
Aufsichtsratsvorsitzender/ Chairman of the Supervisory Board: Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090

Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB 661090