

EC-Declaration of Conformity for Medical Devices

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Heidenheim, 2018-06-13

EC-Declaration of Conformity for Medical Devices

We herewith declare,

That the below named products, which are first placed on the market by PAUL HARTMANN AG, meet the applicable provisions, especially the essential requirements of the following EC-Directive:

Council Directive 93/42/EEC for medical devices

The required conformity assessment procedure according to Annex VII 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.

Product(s): Coverflex fast

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

UMDNS: 10-291

PAUL HARTMANN AG

ppa.

i.A.

S. Fischer

Head of Regulatory Affairs

Dr. L. Roche

Global Product Marketing Wound Management

Are further regulations requiring an EC-declaration of conformity applicable to the above-mentioned product(s)?

☒ no

☐ yes Regulation/Directive: _____

This document is valid until: 2018-09-30.

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