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.

S. Fischer
Head of Regulatory Affairs

i.A.

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.