

PAUL HARTMANN AG
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Going further
for health

Heidenheim, 2017-01-12

EC-Declaration of Conformity for medical Devices

We herewith declare,

That the below named products, which are manufactured and/or 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 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 process is under the supervision of the Notified Body: TÜV SÜD Product Service GmbH, DE-80339 München, Ridlerstr. 65, Identification No. 0123.

Product(s): **M-Plast wound dressings**

Medical device class: **Class I acc. to rule 4(1)**

(acc. to Annex IX of the directive)

UMDNS: **10-288**

PAUL HARTMANN AG

ppa.

Dr. W. Neumann
Chief Medical Officer

Dr. A. Eckle
Head of Regulatory Affairs

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

☒ no

☐ yes Regulation/Directive: _____

IILN 040 9500 00000 0

Vorstand/ Management Board: Andreas Joehle
(Vorstandsvorsitzender/ CEO). Dr. Raymund Heinen.
Michel Kuehn. Dr. Wolfgang Neumann. 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