PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
hartmann.info

HARTMANN
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: (acc. to Annex IX of the directive)	**Class I acc. to rule 4(1)**
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:_____