

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
www.hartmann.info



Helps. Cares. Protects.

PAUL HARTMANN AG, P.O. Box 1420, 89504 Heidenheim, Germany

EU Declaration of Conformity Class I

Heidenheim, 2024-09-02

We herewith declare under our sole responsibility that the Class I medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (7) have been performed and the Technical Documentation is kept available.

Intended Purpose		No active, non-implantable device for wound and skin care	
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Peha-haft	4086	1	40495004086KY
Peha-haft (bulk)	4089	1	40495004089L6
DermaPlast Cofix	4106	1	40495004106KD

PAUL HARTMANN AG

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François Georgelin
Member of the Management Board

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2025-06-30

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Oliver Neubrand
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