

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1474
Manufacturer	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim GERMANY

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

Applied legislative act

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Single use, non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 4 main paragraph + 1st indent
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001474KQ	
EMDN	Code	Term
	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
	GMDN	44990 Skin-cover adhesive strip
	UMDNS	10-288 Bandages, Self-Adherent

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

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Helps. Cares. Protects.

PAUL HARTMANN AG

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

List of products falling under the respective Product Group Number:

REF	Name - Description
535351	DERMAPLAST soft 4cmx5m P1 int.
535353	DermaPlast soft injec. 1,6x4cm P250 (RU)
535361	DermaPlast SOFT 6cmx5m P1 int.
535371	DermaPlast SOFT 8cmx5m P1 int.
535381	DermaPlast SOFT Inj. 16x40mm P250
535382	DermaPlast SOFT 22mm P200
535384	DermaPlast Soft Inj. white 16x40mm,P250

GLN 404 9500 00000 0

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