

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1473
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	40495001473KN	
EMDN	Code	Term
	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
	GMDN	44990
	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
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ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

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List of products falling under the respective Product Group Number:

REF	Name - Description
500303	DermaPlast SOFT bulk 19x72mm P5000
524020	DermaPlast Sensitive CH w 6x10cm P10
524030	DermaPlast Sensitive CH w 8x10cm P10
524070	DermaPlast Sensitive CH w 4cmx5m P1
524080	DermaPlast Sensitive CH w 6cmx5m P1
524090	DermaPlast Sensitive CH w 8cmx5m P1
524310	DermaPlast SENSIT. Centro CH 3x4cm P100
524320	DermaPlast SENSIT. Centro CH 4x6cm P100
524610	DermaPlast SENSITIVE CH 4cmx10cm P10
524620	DermaPlast SENSITIVE CH 6cmx10cm P10
524630	DermaPlast SENSITIVE CH 8cmx10cm P10
524670	DermaPlast SENSITIVE CH 4cmx5m P1
524680	DermaPlast SENSITIVE CH 6cmx5m P1
524690	DermaPlast SENSITIVE CH 8cmx5m P1
524740	DermaPlast SENSITIVE Spots CH 22mm P20
524850	DermaPlast SENSITIVE Expr CH 19x72mm P15
524860	DermaPlast SENSITIVE Family CH 3Gr P32
535320	DermaPlast soft 19x72mm,P20 (ME,DX)
535326	DermaPlast soft 22mm, P20 (ME,DX)
535341	DermaPlast MDR SOFT West 6x10cm P10
535342	DermaPlast MDR SOFT West 19x72mm P20
535347	DermaPlast soft 6x10cm, P10 (PPay)
535360	DermaPlast MDR Soft East2 6cmx1m P1

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