



EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1681
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	Non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001681KX	
EMDN	Code	Term
	M050101	PLASTERS ON SPOOLS (ROLLS)
GMDN	16866	Basic adhesive tape
UMDNS	10-028	Adhesive Strips, Hypoallergenic

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
900132	Omnoplast PP 2,5x5 West BE/F/NL/AL
900440	Omnoplast 1,25cm x 5m P1 Omnoplast 1,25cm x 5m P1 c300
900441	Omnoplast 2,5cm x 5m P1 Omnoplast 2,5cm x 5m P1 c240
900442	Omnoplast 5cm x 5m P1 Omnoplast RUS 5cm x 5m P1
900466	Omnoplast RO, HU, BU, GR 2,5cmx5m P1
900467	Omnoplast DE, PL, SL, HR 2,5cmx5m P1
900504	Omnoplast 1,25cm x 5m RU P1
900537	Omnoplast 2,5cmx5m R,B,SL,CR P1
900538	Omnoplast 2,5cmx5m RU P1
900573	Omnoplast 1,25cm x 9,2m P1
900574	Omnoplast 2,5cm x 9,2m P1 Omnoplast RUS 2.5cm x 9.2m P1 C80 STO
900575	Omnoplast 5cm x 9,2m P1
900663	Omnoplast 5cm x 5m R,B,SL,CR P1
900664	Omnoplast 5cm x 5m RU P1

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