

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1686
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	40495001686L9	
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

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



PAUL HARTMANN AG

ppa.

Jochen Bäuer

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
900418	Omnisilk 1,25cm x 9,2m P1
900419	Omnisilk 2,5cm x 9,2m P1
900420	Omnisilk 5cm x 9,2m P1
900430	Omnisilk 1,25cm x 5m P1
900431	Omnisilk 2,5cm x 5m P1 Omnisilk RUS 2,5cm x 5m P1
900432	Omnisilk 5cm x 5m P1
900483	Omnisilk 2,5cmx5m R,B,SL,CR P1
900484	Omnisilk 2,5cm x 5m Ru P1
900494	Omnisilk 1,25cm x 5m RU P1
900554	Omnisilk 5cm x 5m Ru P1

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