

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	2502
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 IIa	Rule 4 main paragraph + 4th indent
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: H900102 - BANDAGES FOR SUTURES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002502KB	
EMDN	Code	Term
	H900102	BANDAGES FOR SUTURES
GMDN	32207	Skin-closure adhesive strip
UMDNS	10-288	Verbandmaterial, selbstklebend (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

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 Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
540010	Omnistrip 6x38mm st 1x6ST DE,FR,IT,NL P2
540020	Omnistrip 6x76mm st 1x3St DE,FR,IT,NL P2
540030	Omnistrip 6x38mm st 1x6St EN,ES,PT,GR P2
540040	Omnistrip 6x76mm st 1x3St EN,ES,PT,GR P2
540681	Omnistrip 3x76mm st, 1x5St, P50
540682	Omnistrip 6x38mm st, 1x6St, P50
540683	Omnistrip 6x76mm st, 1x3St, P50
540684	Omnistrip 6x101mm st, 2x5St, P50
540685	Omnistrip 12x101mm st, 2x3St, P50
540686	Omnistrip 25x127mm st, 2x2St, P50

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