

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	3522
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 + 3rd 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: M040406 - POLYURETHANE DRESSINGS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003522KQ	
EMDN	Code	Term
	M040406	POLYURETHANE DRESSINGS
GMDN	34865	Adhesive bandage
UMDNS	10-289	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 from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
901050	Cosmopor transparent 5x7,2cm steril P5
901051	Cosmopor transparent 5x7,2cm sterile P50 Cosmopor transparent 5x7,2cm steril P50
901052	Cosmopor transparent 9x10cm steril P5
901053	Cosmopor transparent 9x10cm steril P50
901054	Cosmopor transparent 9x15cm steril P5
901055	Cosmopor transparent 9x15cm steril P25
901056	Cosmopor transparent 10x12cm steril P25
901057	Cosmopor transparent 10x20cm steril P5 Cosmopor transparent 10x20cm steril P5
901058	Cosmopor transparent 10x20cm steril P25
901059	Cosmopor transparent 10x25cm steril P25
901060	Cosmopor transparent 10x30cm steril P25

GLN 404 9500 00000 0

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