

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	3521
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	40495003521KN	
EMDN	Code	Term
	M040406	POLYURETHANE DRESSINGS
GMDN	58301	Synthetic polymer semi-permeable film dressing, adhesive
UMDNS	17-428	Verband, transparent-adhäsiv (dressings, transparent adhesive)

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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PAUL HARTMANN AG

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Jochen Bauer

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Health

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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
970000	Hydrofilm 6x7cm steril P10
970001	Hydrofilm 6x7cm steril New P100
970002	Hydrofilm 10x12,5cm steril P10
970003	Hydrofilm 10x12,5cm steril P100
970004	Hydrofilm 10x15cm steril P10
970005	Hydrofilm 10x15cm steril P50
970006	Hydrofilm 15x20cm steril P10
970007	Hydrofilm 15x20cm steril P50
970008	Hydrofilm 10x25cm steril P25
970009	Hydrofilm 12x25cm steril New P25 Hydrofilm 12x25cm steril P25
970010	Hydrofilm 20x30cm steril P10

GLN 404 9500 00000 0

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