

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1229
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	40495001229K9	
EMDN	Code	Term
	M030301	ELASTIC FIXING BANDAGES
GMDN	58964	Non-adhesive device retention bandage
UMDNS	15-557	Binde

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

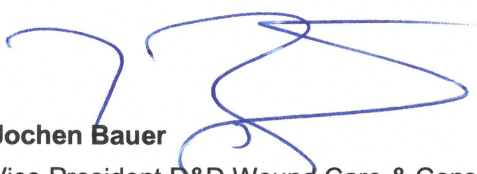
Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info

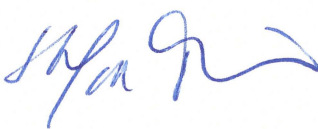


PAUL HARTMANN AG

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Jochen Bauer
Vice President R&D Wound Care & Consumer
Health


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
300010	Peha-Haft Latex Free RU 4cmx20m P1
300012	Peha-Haft Latex Free RU 6cmx20m P1
300013	Peha-Haft Latex Free RU 8cmx20m P1
300014	Peha-Haft Latex Free RU 10cmx20m P1
300018	Peha-Haft Latex Free RU 12cmx20m P1
932483	Peha-haft 4cmx4 m RUS
932484	Peha-haft 6cmx4 m RUS
932485	Peha-haft 8cmx4 m RUS
932486	Peha-haft 10cmx4 m RUS
300026	Peha-Haft Latex Free 10cmx21m DE P1 C24
300027	Peha-Haft Latex Free 12cmx21m DE P1C24
300028	Peha-Haft Latex Free 6cmx21m DE P1 C24
300029	Peha-Haft Latex Free 8cmx21m DE P1 C24
300030	Peha-haft 4cm x 4m P1 LG1
300032	Peha-haft 4cmx4m LPPR (P1) OTC
300033	Peha-haft 6cmx4m LPPR (P1) OTC
300034	Peha-haft 8cmx4m LPPR (P1) OTC
300035	Peha-haft 10cmx4m LPPR (P1) OTC
300036	Peha-haft 12cmx4m LPPR (P1) OTC

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921465	Peha-haft 25mm x 4m- 1's
928001	Peha-haft 6cm x 4m P1 LG1
928002	Peha-haft 6cm x 4m P1 LG5
928003	Peha-haft 6cm x 4m P1 LG6
928004	Peha-haft 8cm x 4m P1 LG1
928005	Peha-haft 8cm x 4m P1 LG5
928006	Peha-haft 8cm x 4m P1 LG6
932437	Peha-haft 6cmx20m (P6)
932438	Peha-haft 8cmx20m (P6)
932439	Peha-haft 10cmx20m (P6)
932441	Peha-haft 4cmx4m(P1) Peha-haft 4cmx4m LPPR (P1)
932442	Peha-haft latex free 6cmx4 m LPPR Peha-haft 6cmx4m(P1)
932443	Peha-haft latex free 8cmx4 m LPPR Peha-haft 8cmx4 m (P1)
932444	Peha-haft 10cmx4 m (P1)
932445	Peha-haft 12cmx4m (P1)
932446	Peha-haft 4cmx20m (P1)
932447	Peha-haft 6cmx20m (P1)
932448	Peha-haft 8cmx20m (P1)
932449	Peha-haft 10cmx20m (P1)
932450	Peha-haft 12cmx20m (P1)
932452	Peha-haft 2,5cmx4m w P8
932476	Peha-haft LFree 6cmx20m (P8)
932477	Peha-haft LFree 8cmx20m (P8)
932478	Peha-haft LFree 10cmx20m (P8)
932710	Peha-haft 6cmx4m EN,ES,PT,IT
932711	Peha-haft 8cmx4m EN,ES,PT,IT
932712	Peha-haft 10cmx4m EN,ES,PT,IT

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