

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	4086
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	40495004086KY	
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

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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 until: 2030-10-31

List of products falling under the respective Product Group Number:

REF	Name - Description
300037	Peha-haft 2,5cmx4m P8
300038	Peha-haft 4cmx4m P1
300039	Peha-haft 6cmx4m P1
300040	Peha-haft 8cmx4m P1
300041	Peha-haft 10cmx4m P1
300042	Peha-haft 12cmx4m P1
300043	Peha-haft 4cmx20m P1
300044	Peha-haft 6cmx20m P1
300045	Peha-haft 8cmx20m P1
300046	Peha-haft 12cmx20m P1
300047	Peha-haft 6cmx20m P6
300048	Peha-haft 8cmx20m P6
300049	Peha-haft 10cmx20m P6
300050	Peha-haft LFree 6cm x 20m P8
300051	Peha-haft LFree 8cm x 20m P8
300052	Peha-haft LFree 10cm x 20m P8
300053	Peha-haft 4cmx4m LPPR (P1) OTC
300054	Peha-haft 6cmx4m LPPR (P1) OTC
300055	Peha-haft 8cmx4m LPPR (P1) OTC

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300056	Peha-haft 10cmx4m LPPR (P1) OTC
300057	Peha-haft 12cmx4m LPPR (P1) OTC
300058	Peha-haft 6cmx4m P1 EN,ES,PT,IT
300059	Peha-haft 8cmx4m P1 EN,ES,PT,IT
300060	Peha-haft 10cmx4m P1 EN,ES,PT,IT
300061	Peha-haft 4cm x 4m P1 DE, FR, NL, IT
300062	Peha-haft 6cm x 4m P1 DE, FR, NL, IT
300063	Peha-haft 8cm x 4m P1 DE, FR, NL, IT
300064	Peha-haft 6cm x 4m P1 EN, PL, HR, SI
300065	Peha-haft 8cm x 4m P1 EN, PL, HR, SI
300066	Peha-haft 6cm x 4m P1 EN, GR, BG, RO
300067	Peha-haft 8cm x 4m P1 EN, GR, BG, RO
300068	Peha-haft 10cm x 21m DE P1 (C24)
300069	Peha-haft 12cm x 21m DE P1 (C24)
300070	Peha-haft 6cm x 21m DE P1 (C24)
300071	Peha-haft 8cm x 21m DE P1 (C24)
300083	Peha-haft 10cmx20m P1

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