

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1700
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	40495001700KA	
EMDN	Code	Term
	M030301	ELASTIC FIXING BANDAGES
GMDN	58964	Non-adhesive device retention bandage
UMDNS	15-557	Binde (Binders)

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

Vice President R&D Wound Care & Consumer
Health

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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
303010	Peha-crepp E Binde 4cmx4m, cel, P1
303055	Peha-fix RUS 4cmx4m cel 50x(P1)
303056	Peha-fix RUS 6cmx4m cel 60x(P1)
303057	Peha-fix RUS 8cmx4m cel 50x(P1)
303058	Peha-fix RUS 10cmx4m cel 50x(P1)
303059	Peha-fix RUS 12cmx4m cel 50x(P1)
303070	Peha-fix Binde 4cmx4m cel (P1)
303071	Peha-fix Binde 6cmx4m, cel (P1)
303072	Peha-fix Binde 8cmx4m, cel (P1)
303073	Peha-fix Binde 10cmx4m, cel (P1)
303074	Peha-fix Binde 12cmx4m, cel (P1)
303075	Peha-fix Binde 4cmx4m na (P20)
303076	Peha-fix Binde 6cmx4m na (P20)
303077	Peha-fix Binde 8cmx4m na (P20)
303078	Peha-fix Binde 10cmx4m na (P20)
303079	Peha-fix Binde 12cmx4m na (P20)
303081	Peha-fix Binde 6cmx4m, na (P100)
303082	Peha-fix Binde 8cmx4m, na (P100)
303083	Peha-fix Binde 10cmx4m, na (P100)

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303085	Peha-fix Binde Ost 4cmx4m,cel (P1)
303086	Peha-fix Binde Ost 6cmx4m,cel (P1)
303087	Peha-fix BindeOst8cmx4m,cel (P1)
303088	Peha-fix BindeOst10cmx4m,cel (P1)
303089	Peha-fix BindeOst 12cmx4m,cel (P1)
303090	Peha-fix Binde Ost 4cmx4m na (P20)
303091	Peha-fix Binde Ost 6cmx4m na (P20)
303092	Peha-fix Binde Ost 8cmx4m na (P20)
303093	Peha-fix Binde Ost 10cmx4m na (P20)
303094	Peha-fix Binde Ost 12cmx4m na (P20)
303096	Peha-fix Binde Ost 6cmx4m na (P100)
303097	Peha-fix Binde Ost 8cmx4m na (P100)
303098	Peha-fix Binde Ost 10cmx4m na (P100)
303099	Peha-fix Binde Ost 12cmx4m na (P100)

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