

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	4042
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	40495004042KC	
EMDN	Code	Term
	M030401	ELASTIC COMPRESSION BANDAGES
GMDN	61223	Pressure bandage, non-latex, non-sterile, reusable
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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Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

List of products falling under the respective Product Group Number:

REF	Name - Description
332010	Idealflex Bandage (596) 6cmx5m P10
332022	Idealflex Bandage (596) 8cmx5m P10
332033	Idealflex Bandage (596) 10cmx5m P10
332035	Idealflex Bandage (596) 12cmx5m P10
332036	Idealflex Bandage (596) 15cmx5m P10
332037	Idealflex Bandage (596) 20cmx5m P10
332038	Idealflex Bandage (596) 6cmx5m cel 10xP1
332039	Idealflex Bandage (596) 8cmx5m cel 10xP1
332049	Idealflex Bandage(596) 10cmx5m cel 10xP1
332050	Idealflex Bandage(596) 12cmx5m cel 10xP1
332051	Idealflex Bandage(596) 15cmx5m cel 10xP1
332052	Idealflex Bandage(596) 20cmx5m cel 10xP1

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