

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1245
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	40495001245K7	
EMDN	Code	Term
	M030502	BANDAGES AND SPLINTS
	GMDN	33056
	UMDNS	10-665
		Cast construction material
		Cast material

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
332730	Safix plus Gipsbinde 6cmx2m P2 K28
332731	Safix plus Gipsbinde 8cmx2,7m P2 K15
332732	Safix plus Gipsbinde 10cmx2,7m P2 K12
332733	Safix plus Gipsbinde 12cmx2,7m P2 K10
332734	Safix plus Gipsbinde 15cmx2,7m P2 K8
332735	Safix plus Gipsbinde 20cmx2,7m P2 K6
332739	Safix plus Gipsbinde 5cmx3m P2 K24
332740	Safix plus Gipsbinde 8cmx3m P2 K15
332741	Safix plus Gipsbinde 10cmx3m P2 K12
332742	Safix plus Gipsbinde 12cmx3m P2 K10
332743	Safix plus Gipsbinde 14cmx3m P2 K10
332744	Safix plus Gipsbinde 15cmx3m P2 K8
332745	Safix plus Gipsbinde 20cmx3m P2 K6

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