

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1843
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	40495001843KZ	
EMDN	Code	Term
	M010202	SYNTHETIC WOOL WADDING
	GMDN	59049
	UMDNS	11-326
		Verbandpolster (dressing pads)

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
932043	Rolta-soft Binde synt. 6cmx3m P6 int
932045	Rolta-soft Binde synt. 10cmx3m P6 int
932047	Rolta-soft Binde synt. 15cmx3m P4 int
932048	Rolta-soft Binde synt. 6cmx3m P50 int
932049	Rolta-soft Binde synt. 10cmx3m P30 int
932050	Rolta-soft Binde synt. 15cmx3m P20 int
932051	Rolta-soft Binde synt. 25cmx3m P10 int

GLN 404 9500 00000 0

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