

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1193
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 4 main paragraph + 1st indent
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001193KD	
EMDN	Code	Term
	M020201	NON-WOVEN FOLDED GAUZES
GMDN	48131	Non-woven gauze pad,
UMDNS	15-216	Verband, sonstige (dressings, other)

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
515990	Med.TEST VL-Kompr ust 10x20 4f S30 P100
411831	Medicomp VL-Kpr ust 5x5 4F S30 P100 K50
411833	Medicomp VL-Kpr ust 7,5x7,5 4F S30 P100
411834	Medicomp VL-Kpr ust 7,5x10 4F S30 P100
411835	Medicomp VI-Kpr ust 10x10 4f S30 P100 Medicomp VL-Kpr ust 10x10 4F S30 P100
411841	Medicomp VL-Kpr ust 5x5 4F S40 P100
411843	Medicomp VL-Kpr ust 7,5x7,5 4F S40 P100
411844	Medicomp VL-Kpr ust 7,5x10 4F S40 P100
411845	Medicomp VL-Kpr ust 10x10 4F S40 P100
421821	Medicomp VL-Kpr ust 5x5 4F S30 P100 K24
421823	Medicomp VL-Kpr ust 7,5x7,5 4F S30 P100
421825	Medicomp VL-Kpr ust 10x10 4F S30 P100
421827	Medicomp VL-Kpr ust 10x20 4F S30 P100

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