

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1192
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	Single-use, non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class IIa	Rule 7 main paragraph
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: M020201 - NON-WOVEN FOLDED GAUZES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001192KB	
EMDN	Code	Term
	M020201	NON-WOVEN FOLDED GAUZES
	GMDN	48131
	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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PAUL HARTMANN AG

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Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
411006	Medicomp st 7,5x7,5cm 4f S30 P1000
411007	Medicomp st 10x10cm 4f S30 P1000
411021	Medicomp st 7,5x7,5 P2x5(PL SL CR)
411022	Medicomp st 10x10 P2x5 (PL SL CR)
411029	Medicomp st 7,5x7,5 P2x5(FR NL DE IT)
411041	Medicomp VL-Kpr st 7,5x7,5 4f S30 P10x2
411042	Medicomp VL-Kpr st 10x10 4f S30 P10x2
411049	Medicomp BI st 7,5x7,5 4f S30 P100x2
411050	Medicomp BI st 10x10 4f S30 P100x2
411051	Medicomp BI st 5x5 4f S30 P40x5
411052	Medicomp BI st 7,5x7,5 4f S30 P40x5
411053	Medicomp BI st 10x10 4f S30 P40x5
411055	Medicomp BI st 7,5x7,5 4f S40 P75x2
411056	Medicomp BI st 10x10 4f S40 P75x2
411058	Medicomp BI st 5x5 4f S40 P30x5
411059	Medicomp BI st 7,5x7,5 4f S40 P30x5
411060	Medicomp BI st 10x10 4f S40 P30x5
411061	Medicomp BI st 7,5x10 4f S40 P30x5
411062	Medicomp st 7,5x7,5 P2x5 (RO HU BU GR)

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Helps. Cares. Protects.

411063	Medicomp st 10 x 10 P2x5 (RO HU BU GR)
411064	Medicomp BI st 10x10 4f S30 P25x2
411072	Medicomp BI st 7,5x7,5 4f S30 P25x2
411073	Medicomp BI st 10x10 4f S40 P15x10
411074	Medicomp BI st 5x5 4f S30 P25x2
411075	Medicomp st 10x20 4f S30 P25x2
411141	Medicomp VL-Kpr st 7,5x7,5 4f S30 P50x2
411142	Medicomp VL-Kpr st 10x10 4f S30 P50x2
411241	Medicomp VL-Kpr st 7,5x7,5 4f S30 P25x2
411242	Medicomp VL-Kpr st 10x10 4f S30 P25x2
411533	Medicomp VL-Kompr st 7,5x7,5 4f S30 P50x5
411634	Medicomp OTC st 10x10 4f P10x2
411635	Medicomp OTC st 10x10 4f P25x2
411636	Medicomp OTC st 10x20 4f P25x2
421725	Medicomp VL-Kompr st 10x10 4f S30 P25x2
421727	Medicomp VL-Kompr st 10x20 4f S30 P25x2

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