

EU Declaration of Conformity

Heidenheim, 2026-02-03

Product Group Number	1208
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 legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

Applied legislative acts

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Single-use, non-active, non-implantable devices for wound and skin care	
Classification	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-No. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04 Device Group: M020102 - COTTON GAUZES - FOLDED	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001208JZ	
	Code	Term
EMDN	M0201020202	Cotton gauzes, folded, with X-ray detectable thread, non-sterile
GMDN	48134	Woven gauze pad
UMDNS	10-966	Compresses, Gauze

PAUL HARTMANN AG
ppa.



Martin Walther
Senior Vice President
Risk Prevention

i.V.



Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid from: 2026-02-03
Valid until: 2030-05-05

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

List of products falling under the respective Product Group Number: 1208

REF	Name - Description
232070	Telacomp, 5cm x 5cm, 17 threads, 12 plies, 30x 100 pcs
232092	Telacomp, 7.5cm x 7.5cm, 17 threads, 8 plies, 100 pcs
302014	Telacomp, 5cm x 5cm, 17 threads, 16 plies, counted 10
302015	Telacomp, 10cm x 10cm, 17 threads, 8 plies, counted 10
302016	Telacomp, 10cm x 12.5cm, 17 threads, 12 plies, counted 10
302017	Telacomp, 10cm x 10cm, 20 threads, 32 plies, counted 10
302018	Telacomp, 7.5cm x 7.5 cm, 17 threads, 12 plies, counted 10
302019	Telacomp, 7.5cm x 7.5cm, 17 threads, 16 plies, counted 10
302020	Telacomp, 10cm x 10cm, 17 threads, 12 plies, counted 10
302021	Telacomp, 10cm x 10cm, 17 threads, 16 plies, counted 10
302022	Telacomp, 10cm x 20cm, 17 threads, 12 plies, counted 10
302023	Telacomp, 10cm x 20cm, 17 threads, 16 plies, counted 10
400513	Telacomp, 10cm x 10cm, 20 threads, 32 plies, 50 pcs
401920	Telacomp, 10cm x 20cm, 17 threads, 24 plies, 50 pcs
401923	Telacomp, 10cm x 10cm, 17 threads, 8 plies, 10x 100 pcs
401925	Telacomp, 10cm x 10cm, 17 threads, 8 plies, 100 pcs
401930	Telacomp, 7.5cm x 7.5cm, 17 threads, 12 plies, 10x 100 pcs
401931	Telacomp, 10cm x 12.5cm, 17 threads, 12 plies, 10x 100 pcs
401932	Telacomp, 10cm x 20cm, 17 threads, 12 plies, 10x 100 pcs
401934	Telacomp, 5cm x 5cm, 17 threads, 16 plies, 20x 100 pcs
401937	Telacomp, 10cm x 20cm, 17 threads, 12 plies, 100 pcs
401938	Telacomp, 7.5cm x 7.5cm, 17 threads, 16 plies, 10x 100 pcs
401939	Telacomp, 10cm x 10cm, 17 threads, 16 plies, 10x 100 pcs
401940	Telacomp, 10cm x 10cm, 20 threads, 32 plies, 10x 50 pcs
401941	Telacomp, 5cm x 5cm, 17 threads, 16 plies, 100 pcs
401942	Telacomp, 10cm x 10cm, 17 threads, 12 plies, 10x 100 pcs
401943	Telacomp, 7.5cm x 7.5cm, 17 threads, 16 plies, 100 pcs
401945	Telacomp, 10cm x 10cm, 17 threads, 16 plies, 100 pcs
992041	Telacomp, 5cm x 5cm, 17 threads, 16 plies, counted 5
992051	Telacomp, 10cm x 10cm, 17 threads, 8 plies, counted 5
992061	Telacomp, 10cm x 12.5cm, 17 threads, 12 plies, counted 5
992156	Telacomp, 10cm x 10cm, 20 threads, 32 plies, counted 5
992161	Telacomp, 10cm x 20cm, 17 threads, 16 plies, counted 5

GLN 404 9500 00000 0

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Helps. Cares. Protects.

992281	Telacomp, 7.5cm x 7.5cm, 17 threads, 12 plies, counted 5
992291	Telacomp, 7.5cm x 7.5cm, 17 threads, 16 plies, counted 5
992351	Telacomp, 10cm x 10cm, 17 threads, 12 plies, counted 5
992361	Telacomp, 10cm x 10cm, 17 threads, 16 plies, counted 5
992381	Telacomp, 10cm x 20cm, 17 threads, 12 plies, counted 5

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