



EU Declaration of Conformity

Heidenheim, 2025-05-06

Product Group Number	1420
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	40495001420JZ	
	Code	Term
EMDN	M0201020201	COTTON GAUZES, FOLDED, WITH X-RAY DETECTABLE THREAD, STERILE
GMDN	48134	Woven gauze pad
UMDNS	10-966	Compresses, Gauze

PAUL HARTMANN AG

ppa.

Martin Walther
Senior Vice President
Risk Prevention

i.V.

Hofmann Christiana
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid from: 2025-05-06

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:

REF	Name - Description
232078	Telacomp E, 5cm x 5cm, 17threads 12plies, sterile, 90x 10pcs Gauze swabs, X-ray detectable
232079	Telacomp E, 5cm x 5cm, 17threads 12plies, sterile, 48x 20pcs Gauze swabs, X-ray detectable
232082	Telacomp E, 7.5cm x 7.5cm, 17threads 12plies, sterile, 150x 5pcs Gauze swabs, X-ray detectable
232083	Telacomp E, 7.5cm x 7.5cm, 17threads 12plies, sterile, 90x 10pcs Gauze swabs, X-ray detectable
232084	Telacomp E, 7.5cm x 7.5cm, 17threads 12plies, sterile, 28x 20pcs Gauze swabs, X-ray detectable
232085	Telacomp E, 7.5cm x 7.5cm, 17threads 12plies, sterile, 7x 40pcs Gauze swabs, X-ray detectable
232088	Telacomp E, 10cm x 10cm, 17threads 12plies, sterile, 45x 10pcs Gauze swabs, X-ray detectable
232089	Telacomp E, 10cm x 10cm, 17threads 12plies, sterile, 18x 20pcs Gauze swabs, X-ray detectable
232090	Telacomp E, 10cm x 10cm, 17threads 12plies, sterile, 6x 40pcs Gauze swabs, X-ray detectable
452151	Telacomp E, 10cm x 10cm, 17threads 12plies, sterile, 15x 10pcs Gauze swabs, X-ray detectable
452152	Telacomp E, 10cm x 10cm, 17threads 16plies, sterile, 12x 10pcs Gauze swabs, X-ray detectable
452153	Telacomp E, 10cm x 10cm, 17threads 32plies, sterile, 12x 10pcs Gauze swabs, X-ray detectable
452154	Telacomp E, 10cm x 20cm, 17threads 16plies, sterile, 12x 10pcs Gauze swabs, X-ray detectable

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