

EU Declaration of Conformity

Heidenheim, 2025-05-06

Product Group Number	1421
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	40495001421K3	
	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
452000	Telacomp, 10cm x 20cm, 17 threads, 16 plies, sterile, 12x 10 pcs Gauze swabs, X-ray detectable
452001	Telacomp, 10cm x 20cm, 17 threads, 24 plies, sterile, 12x 10 pcs Gauze swabs, X-ray detectable
452002	Telacomp, 5cm x 5cm, 17 threads, 16 plies, sterile, 20x 10 pcs Gauze swabs, X-ray detectable
452133	Telacomp, 7.5cm x 7.5cm, 17 threads, 12 plies, sterile, 12x 10 pcs Gauze swabs, X-ray detectable
452135	Telacomp, 10cm x 10cm, 17 threads, 12 plies, sterile, 16x 10 pcs Gauze swabs, X-ray detectable
452137	Telacomp, 10cm x 20cm, 17 threads, 12 plies, sterile, 12x 10 pcs Gauze swabs, X-ray detectable
452143	Telacomp, 7.5cm x 7.5cm, 17 threads, 16 plies, sterile, 10x 10 pcs Gauze swabs, X-ray detectable
452145	Telacomp, 10cm x 10cm, 17 threads, 16 plies, sterile, 14x 10 pcs Gauze swabs, X-ray detectable
452165	Telacomp, 10cm x 10cm, 17 threads, 32 plies, sterile, 10x 10 pcs Gauze swabs, X-ray detectable
452233	Telacomp, 7.5cm x 7.5cm, 17 threads, 12 plies, sterile 12x 20 pcs Gauze swabs, X-ray detectable
452235	Telacomp, 10cm x 10cm, 17 threads, 12 plies, sterile, 12x 20 pcs Gauze swabs, X-ray detectable
452237	Telacomp, 10cm x 20cm, 17 threads, 12 plies, sterile, 8x 20 pcs Gauze swabs, X-ray detectable
452243	Telacomp, 7.5cm x 7.5cm, 17 threads, 16 plies, sterile, 12x 20 pcs Gauze swabs, X-ray detectable
452245	Telacomp, 10cm x 10cm, 17 threads, 16 plies, sterile, 10x 20 pcs Gauze swabs, X-ray detectable