



Helps. Cares. Protects.

P.O. Box 1420
 89504 Heidenheim
 Germany

EU Declaration of Conformity

Heidenheim, 2024-11-20

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	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-No. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 03 Device Group: M020102 - Cotton Gauzes - folded	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001421K3	
	Code	Term
EMDN	M020102	Cotton Gauzes - folded
GMDN	48134	Woven gauze pad
UMDNS	10-966	Compresses, Gauze

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



PAUL HARTMANN AG

ppa.

Martin Walther
Senior Vice President
Risk Prevention

i.V.

Andreas Hartmann
Director Quality
Risk Prevention

Valid until: 2025-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
452133	Telacomp gauze swabs X-ray detectable, 7.5 x 7.5, 12p/17th, sterile, P12x10
452135	Telacomp gauze swabs X-ray detectable, 10 x 10, 12p/17th, sterile, P16x10
452137	Telacomp gauze swabs X-ray detectable, 10 x 20, 12p/17th, sterile, P12x10
452143	Telacomp gauze swabs X-ray detectable, 7.5 x 7.5, 16p/17th, sterile, P10x10
452145	Telacomp gauze swabs X-ray detectable, 10 x 10, 16p/17th, sterile, P14x10
452165	Telacomp gauze swabs X-ray detectable, 10 x 10, 32p/17th, sterile, P10x10
452233	Telacomp gauze swabs X-ray detectable, 7.5 x 7.5, 12p/17th, sterile, P12x20
452235	Telacomp gauze swabs X-ray detectable, 10 x 10, 12p/17th, sterile, P12x20
452237	Telacomp gauze swabs X-ray detectable, 10 x 20, 12p/17th, sterile, P8x20
452243	Telacomp gauze swabs X-ray detectable, 7.5 x 7.5, 16p/17th, sterile, P12x20
452245	Telacomp gauze swabs X-ray detectable, 10 x 10, 16p/17th, sterile P10x20

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