



Helps. Cares. Protects.

P.O. Box 1420
 89504 Heidenheim
 Germany

EU Declaration of Conformity

Heidenheim, 2024-11-20

Product Group Number	1267
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: M020199 - COTTON GAUZES - OTHER	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001267KH	
	Code	Term
EMDN	M020199	COTTON GAUZES - OTHER
GMDN	48134	Woven gauze pad
UMDNS	13-705	Sponges, X-ray Detectable

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.

i.V.



Martin Walther
Senior Vice President
Risk Prevention



Andreas Hartmann
Director Quality
Risk Prevention

Valid until: 2025-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
451103	Telasling twisted gauze sponges X-ray detectable, walnut/size 2, sterile, P30x10
451104	Telasling twisted gauze sponges X-ray detectable, plum/size 3, sterile, P20x10
451105	Telasling twisted gauze sponges X-ray detectable, fist/size 6, sterile, P7x10
451106	Telasling twisted gauze sponges X-ray detectable, extra large/size 5, sterile, P10x10
451109	Telasling twisted gauze sponges X-ray detectable, egg/size 4, sterile, P18x10
451204	Telasling twisted gauze sponges X-ray detectable, plum/size 3, sterile, P12x20
451206	Telasling twisted gauze sponges X-ray detectable, extra large/size 5, sterile, P6x20
451209	Telasling twisted gauze sponges X-ray detectable, egg/size 4, sterile, P10x20
451309	Telasling twisted gauze sponges X-ray detectable, egg/size 4, sterile, P15x30

GLN 404 9500 00000 0

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