



EU Declaration of Conformity

Heidenheim, 2024-11-20

Product Group Number	1419
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	40495001419KG	
	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

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PAUL HARTMANN AG

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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
450100	Telaprep dissector sponges X-ray detectable, small/size 1, sterile, P30x10
450101	Telaprep dissector sponges X-ray detectable medium/size 2, sterile, P30x10
450103	Telaprep dissector sponges X-ray detectable large/size 3, sterile, P16x10
450200	Telaprep dissector sponges X-ray detectable small/size 1, sterile, P30x20
450201	Telaprep dissector sponges X-ray detectable medium/size 2, sterile, P16x20
450203	Telaprep dissector sponges X-ray detectable large/size 3, sterile, P16x20

GLN 404 9500 00000 0

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