PAUL HARTMANN AG
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89522 Heidenheim

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Germany

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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-05-06

Product Group Number	1372
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: M020199 - COTTON GAUZES - OTHER	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001372KF	
	Code	Term
EMDN	M020199	COTTON GAUZES - OTHER
GMDN	48134	Woven gauze pad
UMDNS	13-705	Sponges, X-ray Detectable

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

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List of products falling under the respective Product Group Number:

REF	Name - Description
356173	Telaprep, small/No.1, 24 threads, 10 pcs Dissector sponges X-ray detectable
356183	Telaprep, small/No.1, 24 threads, 20 pcs Dissector sponges X-ray detectable
356193	Telaprep, medium/No.2, 24 threads, 10 pcs Dissector sponges X-ray detectable
356213	Telaprep, medium/No.2, 24 threads, 20 pcs Dissector sponges X-ray detectable
356223	Telaprep, large/No.3, 24 threads, 10 pcs Dissector sponges X-ray detectable
356233	Telaprep, large/No.3, 24 threads, 20 pcs Dissector sponges X-ray detectable
489000	Telaprep, small/No.1, 24 threads, 4x 1000 pcs Dissector sponges X-ray detectable
489001	Telaprep, medium/No.2, 24 threads, 4x 1000 pcs Dissector sponges X-ray detectable
489002	Telaprep, large/No.3, 24 threads, 4x 1000 pcs Dissector sponges X-ray detectable
489291	Telaprep, medium/No.2, 24 threads, 1000 pcs Dissector sponges X-ray detectable
489293	Telaprep, large/No.3, 24 threads, 1000 pcs Dissector sponges X-ray detectable

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Oliver Neubrand
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