

EU Declaration of Conformity

Heidenheim, 2025-11-20

Product Group Number	2570
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	General single-use, non-active, non-implantable devices used in health care	
Classification	Risk Class	Rule
	I s	Rule 1
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Production Quality Assurance Certificate No. G26 011858 0077 Rev. 00, Device Group: T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002570KU	

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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89522 Heidenheim

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89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info



Product Group Number	2570	
	Code	Term
EMDN	T0202	SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
GMDN	47783	Patient surgical drape, single-use, sterile
UMDNS	15-646	Drapes, Surgical, Disposable

PAUL HARTMANN AG

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A blue ink signature of Martin Walther.

Martin Walther
Senior Vice President
Risk Prevention

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A blue ink signature of Christiana Hofmann.

Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid from: 2025-11-30

Valid until: 2030-11-29

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Helps. Cares. Protects.

List of products falling under the respective Product Group Number:

2570

REF	Name - Description
938771	Foliodrape Protect Plus Hip set VI, extra reinforced
938772	Foliodrape Protect Plus Hip set VII, extra reinforced
936809	Foliodrape Protect Plus Hip set IV, extra reinforced, crepe
938738	Foliodrape Protect Plus Hip set V
938902	Foliodrape Protect Plus Hip set III, extra reinforced
936737	Foliodrape Protect Plus Hip set I, crepe
936810	Foliodrape Protect Plus Hip set II, extra reinforced, crepe
250058	Foliodrape Protect Plus Hip set VII, extra reinforced

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