

EU Declaration of Conformity

Heidenheim, 2025-11-20

Product Group Number	1684
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	40495001684L5	

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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Germany

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www.hartmann.info



Helps. Cares. Protects.

Product Group Number	1684	
	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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Martin Walther
Senior Vice President
Risk Prevention

i.V

Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid from: 2025-11-30

Valid until: 2030-11-29

GLN 404 9500 00000 0

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List of products falling under the respective Product Group Number:

1684

REF	Name - Description
936744	Foliodrape Protect Plus Extremity set IV, extra reinforced, crepe
936747	Foliodrape Protect Plus Bilateral extremity set, crepe
936758	Foliodrape Protect Plus Extremity set III, extra reinforced, crepe
938740	Foliodrape Protect Plus Extremity split sheet set II, extra reinforced
938923	Foliodrape Protect Plus Extremity split sheet set I, extra reinforced, crepe
938905	Foliodrape Protect Plus Extremity set II, crepe
936736	Foliodrape Protect Plus Extremity set V, extra reinforced
936751	Foliodrape Protect Plus Extremity set II, extra reinforced
936757	Foliodrape Protect Plus Extremity set III, extra reinforced, crepe
938773	Foliodrape Protect Plus Extremity set VI, extra reinforced
938774	Foliodrape Protect Plus Extremity set VII, extra reinforced
938775	Foliodrape Protect Plus Extremity set VIII, extra reinforced
250047	Foliodrape Protect Plus Extremity set VII, extra reinforced

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