

PAUL HARTMANN AG
 Paul-Hartmann-Strasse 12
 89522 Heidenheim
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 89504 Heidenheim
 Germany

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



EU Declaration of Conformity

Heidenheim, 2025-06-24

Product Group Number	2140
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 Quality Management System Certificate (MDR) No. G21 011858 0069 Rev. 05, Device Group: T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002140JX	

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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Product Group Number	2140	
	Code	Term
EMDN	T0399	PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER
GMDN	47783	Patient surgical drape, single-use, sterile
UMDNS	15-646	Drapes, Surgical, Disposable

PAUL HARTMANN AG

ppa.

Martin Walther
Senior Vice President
Risk Prevention

i.V

Thomas Haeni
Vice President R&D, PRRC
Risk Prevention

Valid from: 2025-03-13

Valid until: 2025-11-29

GLN 404 9500 00000 0
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Helps. Cares. Protects.

List of products falling under the respective Product Group Number:

2140

REF	Name - Description
277500	Foliodrape Protect Surgical drape
277501	Foliodrape Protect Surgical drape
277502	Foliodrape Protect Surgical drape
277504	Foliodrape Protect Surgical drape
277536	Foliodrape Protect Drape sheet
277505	Foliodrape Protect Surgical drape
277506	Foliodrape Protect Surgical drape
277516	Foliodrape Protect Surgical drape
277547	Foliodrape Protect Surgical drape
277548	Foliodrape Protect Surgical drape
936152	Foliodrape Protect Surgical drape
936155	Foliodrape Protect Surgical drape
936252	Foliodrape Protect Patient underlay with 2 bags
936652	Foliodrape Protect Patient underlay with bag
938810	Foliodrape Protect Surgical drape

GLN 404 9500 00000 0

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