PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

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Germany

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www.hartmann.info

HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-11-20

Product Group Number	**2548**
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	40495002548L3	

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Product Group Number	**2548**	
	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

ppa.

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
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: **2548**

REF	Name - Description
279211	Foliodrape Protect Obstretics set with fluid collection bag
936787	Foliodrape Protect Gynecology / Perineal set V, crepe
936727	Foliodrape Protect TVT/Perineal set I, crepe
936796	Foliodrape Protect Delivery set II
936786	Foliodrape Protect Gynecology / Perineal set II, crepe
936791	Foliodrape Protect Gynaecology / Perineal set IV
936795	Foliodrape Protect Delivery set III
936811	Foliodrape Protect Delivery set I
938711	Foliodrape Protect Caesarean section set IV, leggings
938720	Foliodrape Protect Caesarean section set III
938725	Foliodrape Protect Perineal set II
938727	Foliodrape Protect Perineal set III
938745	Foliodrape Protect Gynaecology/Perineal set I
938903	Foliodrape Protect Gynaecology/Perineal set III, crepe
938904	Foliodrape Protect Caesarean section set I, crepe
938916	Foliodrape Protect Perineal set I, crepe
938918	Foliodrape Protect Caesarean section set II, crepe

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück
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