

## EU Declaration of Conformity

Heidenheim, 2024-11-12

<b>Product Group Number</b>	2548
<b>Manufacturer</b>	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
	Class Is	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. 04, Device Group: T0202 – SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002548L3	
	Code	Term
EMDN	T0202	SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
GMDN	47783	Patient surgical drape, single-use
UMDNS	15-646	Drapes, Surgical, Disposable

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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PAUL HARTMANN AG

ppa.

**Martin Walther**  
Senior Vice President  
Risk Prevention

i.V.

**Andreas Hartmann**  
Director Quality  
Risk Prevention

Valid until: 2025-11-29

List of products falling under the respective Product Group Number:

REF	Name - Description
279211	Foliodrape Protect Delivery set IV
936727	Foliodrape Protect TVT / Perineal Set I, crepe
936786	Foliodrape Protect Gynecology / Perineal set II, crepe
936791	Foliodrape Protect Gynaecology / Perineal set IV
936795	Foliodrape Protect Delivery set III
936796	Foliodrape Protect Delivery set II
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 Gynecology / 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

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