

EU Declaration of Conformity

Heidenheim, 2025-03-18

Product Group Number	2008
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
	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. 05, Device Group: T0202 – SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002008JW	
	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

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Martin Walther
Senior Vice President
Risk Prevention

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Thomas Haeni
Vice President R&D and HAI program
Risk Prevention

Valid until: 2025-11-29

List of products falling under the respective Product Group Number:

REF	Name - Description
938751	Foliodrape Protect Ophthalmology set
938935	Foliodrape Protect Ophthalmology set II
938936	Foliodrape Protect Ophthalmology set III
938937	Foliodrape Protect Ophthalmology set I

GLN 404 9500 00000 0

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