

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, 2025-05-05

Product Group Number	1633
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	Single-use, non-active, non-implantable instruments for medical interventions to be used in sterile condition.	
Classification	Risk Class	Rule
	Class IIa	Rule 6
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04 Device Group: Z121290 – VARIOUS OPHTHALMOLOGY INSTRUMENTS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001633KL	
	Code	Term
EMDN	Z121290	VARIOUS OPHTHALMOLOGY INSTRUMENTS
GMDN	62556	Iris scissors, single-use
UMDNS	13-488	Scissors, Eye, Iris

PAUL HARTMANN AG

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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ppa.

Martin Walther
Senior Vice President
Risk Prevention

i.V.

Christiana Hofmann
Head of Regulatory Affairs
Risk Prevention

Valid from: 2025-05-06
Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
991086	Peha-instrument Iris scissors straight 11.5 cm

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