PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-05-05

Product Group Number	1650
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 7
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: Z120190 – VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001650KL	
	Code	Term
EMDN	Z120190	VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
GMDN	61478	Surgical soft-tissue manipulation forceps, scissors-like, single-use
UMDNS	11-797	Forceps, Tissue

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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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
991042	Peha-instrument Kocher forceps surgical straight 14 cm
991051	Peha-instrument Kocher forceps surgical straight 16 cm
991053	Peha-instrument Kocher forceps surgical straight 18 cm

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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