

## EU Declaration of Conformity

Heidenheim, 2025-05-05

<b>Product Group Number</b>	1655
<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	Single-use, non-active, non-implantable instruments for medical interventions to be used in sterile condition.	
Classification	<b>Risk Class</b>	<b>Rule</b>
	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	40495001655KW	
	<b>Code</b>	<b>Term</b>
EMDN	Z120190	VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
GMDN	47568	Needle Holders, single-use
UMDNS	12-726	Needle Holders

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
991030	Peha-instrument Mayo-Hegar needle holder 14 cm
991031	Peha-instrument Mayo-Hegar needle holder 12 cm
991034	Peha-instrument Mayo-Hegar needle holder 16 cm

GLN 404 9500 00000 0

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