



## EU Declaration of Conformity

Heidenheim, 2025-11-20

<b>Product Group Number</b>	<b>3794</b>
<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>
	I s	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 Production Quality Assurance Certificate No. G26 011858 0077 Rev. 00 Device Group: Z129080 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - HARDWARE ACCESSORIES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003794LT	

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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P.O. Box 1420  
89504 Heidenheim  
Germany



Helps. Cares. Protects.

<b>Product Group Number</b>	<b>3794</b>	
	<b>Code</b>	<b>Term</b>
EMDN	Z129080	VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - HARDWARE ACCESSORIES
GMDN	62489	Dressing/utility forceps, tweezers-like, single-use
UMDNS	11-774	Forceps

PAUL HARTMANN AG

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**Martin Walther**  
Senior Vice President  
Risk Prevention

i.V

**Christiana Hofmann**  
Head of Regulatory Affairs, PRRC  
Risk Prevention

**Valid from:** 2025-11-30

**Valid until:** 2030-11-29

GLN 404 9500 00000 0

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List of products falling under the respective Product Group Number:

**3794**

REF	Name - Description
712056	MediSet Dressing forceps 12.5 cm, green

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