

EU Declaration of Conformity

Heidenheim, 2025-11-20

Product Group Number	3786
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
	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: H02010106 - METAL SURGICAL STAPLE REMOVERS, SINGLE-USE	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003786LU	

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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Germany

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Helps. Cares. Protects.

Product Group Number	3786	
	Code	Term
EMDN	H02010106	METAL SURGICAL STAPLE REMOVERS, SINGLE-USE
GMDN	47192	Surgical staple remover, single-use
UMDNS	16-787	Staple Removers

PAUL HARTMANN AG

ppa.

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:

3786

REF	Name - Description
471001	MediSet Staple remover

GLN 404 9500 00000 0

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