



EU Declaration of Conformity

Heidenheim, 2024-03-05

We herewith declare under our sole responsibility that the class IIa medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (6) and Annex IX have been performed and the Technical Documentation is kept available.

The conformity assessment procedures are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G10 011858 0065.

Device Group	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY		
Intended Purpose	Single-use, non-active, non-implantable instruments for medical interventions to be used in sterile condition		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Peha-instrument Mayo-Hegar needle holders	1655	7 (1)	40495001655KW

PAUL HARTMANN AG

ppa.

Martin Walther

Senior Vice President Risk Prevention

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2024-06-30

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:

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info

P.O. Box 1420
89504 Heidenheim
Germany



Helps. Cares. Protects.

List of products falling under the respective Product Group Number: 1655

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

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Oliver Neubrand
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB