PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

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

HARTMANN
Helps. Cares. Protects.

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 Pean forceps anatomic straight	1648	7 (1)	40495001648KZ

PAUL HARTMANN AG

ppa.

Martin Walther

Senior Vice President Risk Prevention

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2024-06-30

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List of products falling under the respective Product Group Number: 1648

REF	Name - Description
991040	Peha-instrument Pean forceps anatomic straight 14 cm