



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 Operating scissors straight sharp/blunt	1628	6 (1)	40495001628KT

PAUL HARTMANN AG

ppa.

Martin Walther

Senior Vice President Risk Prevention

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Valid until: 2024-06-30

GLN 404 9500 00000 0

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List of products falling under the respective Product Group Number: 1628

REF	Name - Description
991081	Peha-instrument Operating scissors sharp/blunt straight 14.5 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