

EU Declaration of Conformity

Heidenheim, 2025-05-05

| | |
|-----------------------------|--|
| Product Group Number | 1658 |
| 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 |
| | Class IIa | Rule 6 |
| Conformity Assessment Procedure | Article 52 (6) and Annex IX | |
| Notified Body | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123 | |
| EU Certificates | EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04 Device Group: Z120190 – VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY | |
| Single Registration Number | Manufacturer: DE-MF-000005861 | |
| Basic UDI-DI | 40495001658L4 | |
| | Code | Term |
| EMDN | Z120190 | VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY |
| GMDN | 64262 | Bone curette, single-use |
| UMDNS | 11-084 | Curets |

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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PAUL HARTMANN AG

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Martin Walther
Senior Vice President
Risk Prevention

i.V.

Christiana Hofmann
Head of Regulatory Affairs
Risk Prevention

Valid from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

| REF | Name - Description |
|--------|--|
| 991013 | Peha-instrument Fox bone curette 14.5 cm |

GLN 404 9500 00000 0

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