

## EU Declaration of Conformity

Heidenheim, 2025-05-05

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | 1631                                                                     |
| <b>Manufacturer</b>         | PAUL HARTMANN AG<br>Paul-Hartmann-Str. 12<br>89522 Heidenheim<br>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                  | <b>Risk Class</b>                                                                                                                                                      | <b>Rule</b>                                                   |
|                                 | 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)<br>No. G10 011858 0065 Rev. 04<br>Device Group: Z120190 – VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY |                                                               |
| Single Registration Number      | Manufacturer: DE-MF-000005861                                                                                                                                          |                                                               |
| Basic UDI-DI                    | 40495001631KG                                                                                                                                                          |                                                               |
|                                 | <b>Code</b>                                                                                                                                                            | <b>Term</b>                                                   |
| EMDN                            | Z120190                                                                                                                                                                | VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY |
| GMDN                            | 58949                                                                                                                                                                  | General-purpose surgical scissors, single-use                 |
| UMDNS                           | 13-492                                                                                                                                                                 | Scissors, Dissecting                                          |

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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**Martin Walther**  
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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                                             |
|--------|----------------------------------------------------------------|
| 991084 | Peha-instrument Metzenbaum scissors blunt/blunt curved 14.5 cm |

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