

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](http://www.hartmann.info)



## MDR Statement of System and Procedure Pack Producer

Heidenheim, 2025-08-12

We herewith declare under sole responsibility that the System and Procedure Packs listed below, first placed on the market by PAUL HARTMANN AG (Registration Number DE-PR-000019925), satisfy the applicable provisions described in Article 22 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

We have verified the mutual compatibility of the devices and, if applicable other products, in accordance with their manufacturers' instructions and have carried out our activities in accordance with those instructions.

We package the System or Procedure Pack and supply relevant information to users incorporating the information supplied by the manufacturers of the devices or other products that are put together.

The activity of combining devices and, if applicable, other products, is subject to appropriate methods of internal monitoring, verification and validation.

Sterilization, if applicable, is carried out in accordance with the manufacturer's instructions. The sterilization process is under the supervision of the Notified Body: TÜV Süd Product Service, Identification No. 0123, Certificate No. G24 011858 0072 rev 02.

PAUL HARTMANN AG

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i.V

**Martin Walther**  
Senior Vice President  
Risk Prevention

**Christiana Hofmann**  
Head of Regulatory Affairs  
Risk Prevention

**Valid until: 2028-01-02**

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

**Procedure Pack Article 22 (EU) 2017/745 in conjunction with the EU Quality Assurance Certificate (MDR) No. G24 011858 0072 Rev. 02**

| Device Group                                 | EMDN code                                                                                                                                                           | EMDN term                                                                 |               |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|---------------|
|                                              | V0599                                                                                                                                                               | CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER            |               |
| Device Properties                            | MDS 1005.1 - Ethylene Oxide Sterilization                                                                                                                           |                                                                           |               |
| Intended Purpose                             | A CombiSet is characterized by the customized compilation of defined components used for medical treatments. These are single-use products for surgical procedures. |                                                                           |               |
| Product Name                                 | Product Group Number                                                                                                                                                | Classification Rule (according to Annex VIII of Regulation (EU) 2017/745) | Basic-UDI-DI  |
| CombiSet Neuro surgery                       | 3141                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003141K8 |
| CombiSet General surgery                     | 3142                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003142KA |
| CombiSet Plastic surgery                     | 3143                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003143KC |
| CombiSet Urology                             | 3144                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003144KE |
| CombiSet Angiography                         | 3145                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003145KG |
| CombiSet Radiology                           | 3146                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003146KJ |
| CombiSet Gynecology and Obstetrics           | 3147                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003147KL |
| CombiSet Vascular surgery                    | 3148                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003148KN |
| CombiSet Orthopedics                         | 3149                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003149KQ |
| CombiSet Cardiac / Thoracic / Hybrid surgery | 3150                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003150K9 |
| CombiSet Ophthalmology                       | 3151                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003151KB |
| CombiSet ENT (ear/nose/throat) surgery       | 3152                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003152KD |
| CombiSet Maxillofacial surgery               | 3153                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003153KF |
| CombiSet Anesthesia                          | 3154                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003154KH |

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Helps. Cares. Protects.

| Device Group                    | EMDN code                                                                                                                                                                   | EMDN term                                                                 |               |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|---------------|
|                                 | V9099                                                                                                                                                                       | VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER                     |               |
| Device Properties               | MDS 1005.1 - Ethylene Oxide Sterilization                                                                                                                                   |                                                                           |               |
| Intended Purpose                | A MediSet is the compilation of defined components used to perform a medical care. The components are single-used products and are used together to perform a medical care. |                                                                           |               |
| Product Name                    | Product Group Number                                                                                                                                                        | Classification Rule (according to Annex VIII of Regulation (EU) 2017/745) | Basic-UDI-DI  |
| MediSet Anesthesia              | 3302                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003302K8 |
| MediSet Dental examination      | 3303                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003303KA |
| MediSet Injection / infusion    | 3304                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003304KC |
| MediSet Mouth care              | 3305                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003305KE |
| MediSet Obstetrics              | 3306                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003306KG |
| MediSet Pre-op preparation      | 3307                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003307KJ |
| MediSet Small surgery           | 3308                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003308KL |
| MediSet Suture / thread removal | 3310                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003310K7 |
| MediSet Urinary catheterization | 3311                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003311K9 |
| MediSet Wound care              | 3312                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003312KB |
| MediSet Injection / Infusion    | 3497                                                                                                                                                                        | Procedure Pack Article 22                                                 | 40495003497LJ |

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