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## MDR Statement of System and Procedure Pack Producer

We herewith declare under sole responsibility that the System a placed on the market by PAUL HARTMANN AG (Registration N the applicable provides described in Article 22 of the Regulation Parliament and of the Council of 5. April 2017 on medical device

We have verified the mutual compatibility of the devices and, if a accordance with their manufacturers' instructions and have carri accordance with those instructions.

We package the System or Procedure Pack and supply relevant incorporating the information supplied by the manufacturers of th that are put together.

The activity of combining devices and, if applicable, other produc methods of internal monitoring, verification and validation.

Sterilization, if applicable, is carried out in accordance with the m The sterilization process is under the supervision of the Notified TÜV Süd Product Service, Identification No. 0123, Certificate No

PAUL HARTMANN AG

i.V.



**François Georgelin**  
Member of the Management Board

**Jens Hahn**  
Director Regulatory Affairs Excellence

Valid until: 2024-06-30

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
(Vorsitzende des Vorstands/CEO), François Georgelin,  
Stefan Grote, Stefan Müller  
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  
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**Procedure Pack Article 22 (EU) 2017/745** in conjunction with the EU Quality Assurance Certificate (MDR) No. G24 011858 0072

| 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                                                 | 40495003152KC |
| CombiSet Maxillofacial surgery               | 3153                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003153KF |
| CombiSet Anesthesia                          | 3154                                                                                                                                                                | Procedure Pack Article 22                                                 | 40495003154KH |

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|                                 |                                                                                                                                                                             |                                                                                  |                     |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------|
| <b>Device Properties</b>        | MDS 1005.1 - Ethylene Oxide Sterilization                                                                                                                                   |                                                                                  |                     |
| <b>Intended Purpose</b>         | 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. |                                                                                  |                     |
| <b>Product Name</b>             | <b>Product Group Number</b>                                                                                                                                                 | <b>Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)</b> | <b>Basic UDI-DI</b> |
| 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       |

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