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MDR Statement of System and Procedure Pack Producer

Heidenheim, 2023-01-02

We herewith declare under our 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 provides 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 GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G24 011858 0072.

PAUL HARTMANN AG

ppa.

François Georgelin
Member of the Management Board

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2023-03-01

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Procedure Pack Article 22 (EU) 2017/745) in conjunction with the EU Quality Management System 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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Device Properties	MDS 1005.1 - Ethylene Oxide Sterilization
Intended Purpose	A care set 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