ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Systems and Procedure Packs sterilised in accordance with the manufacturer's instructions, Article 22(3))

No. G24 011858 0072 Rev. 01

Certificate Holder: **PAUL HARTMANN AG**
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

SRN Sys./Proc. Pack - DE-PR-000019925

The Certification Body of TÜV SÜD Product Service GmbH certifies that the Certificate Holder has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.
The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G24 011858 0072 Rev. 01

Report No.:	713298912
Preceding Certificate No.:	G24 011858 0072 Rev. 00
Valid from:	2023-08-18
Valid until:	2028-01-02
Date of Initial Issuance:	2023-01-03

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-08-18

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No. G24 011858 0072 Rev. 01

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003142KA
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003143KC
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003144KE
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003145KG
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003146KJ
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003147KL
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003148KN
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

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No. G24 011858 0072 Rev. 01

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003150K9
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003151KB
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003152KD
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003153KF
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003154KH
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003302K8
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003303KA
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

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No. G24 011858 0072 Rev. 01

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003304KC
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003305KE
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003306KG
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003307KJ
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003308KL
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003310K7
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003311K9
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

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No. G24 011858 0072 Rev. 01

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003312KB
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003141K1
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

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40495003149KQ
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

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2023-01-03	713251619	-
01	2023-08-18	713298912	Supplemented: Change to the approved type(s)/device(s)

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