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

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 011858 0065 Rev. 03

Manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

SRN Manufacturer - DE-MF-000005861

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer 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 IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 011858 0065 Rev. 03

Report No.: 713306137

Preceding Certificate No.: G10 011858 0065 Rev. 02

Valid from: 2024-06-12
Valid until: 2025-05-05

Date of Initial Issuance: 2020-05-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-06-12

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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(Class IIa and Class IIb Devices)

No. G10 011858 0065 Rev. 03

Classification:	Class IIb
Device Group:	M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
Intended Purpose:	Single-use, sterile, non-medicated dressings suitable for the treatment of wounds

Classification:	Class IIa
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	V030101 - THERMOMETERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	T010101 - LATEX SURGICAL GLOVES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	T010102 - SYNTHETIC SURGICAL GLOVES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M020102 - COTTON GAUZES, FOLDED
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M020201 - NON-WOVEN FOLDED GAUZES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M040403 - HYDROCOLLOID DRESSINGS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M040406 - POLYURETHANE DRESSINGS
Intended Purpose:	-

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(Class IIa and Class IIb Devices)

No. G10 011858 0065 Rev. 03

Classification:	Class IIa
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M020199 - COTTON GAUZES - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z121290 - VARIOUS OPHTALMOLOGY INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
Intended Purpose:	Sterile, non-medicated, products for negative pressure wound therapy

Classification:	Class IIa
Device Group:	Z120402 - GENERAL MEDICINE THERAPEUTIC TREATMENT INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	H900102 - BANDAGES FOR SUTURES
Intended Purpose:	-

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

Revision History:

Rev.	Dated	Report	Description
00	2020-05-06	713162860	-
01	2020-12-17	713162860	-
02	2022-12-29	713209018	-
03	2024-06-12	713306137	Supplemented: Device(s)/group of device(s) added

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