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 090237 0021 Rev. 00

Manufacturer: **NOBAMED Paul Danz AG**
Höltkenstr. 1-5
58300 Wetter (Ruhr)
GERMANY

SRN Manufacturer: DE-PR-000000025

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 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 090237 0021 Rev. 00

Report No.: 713208750

Valid from: 2022-03-09
Valid until: 2027-03-08

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-09

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No. G24 090237 0021 Rev. 00

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815220002U
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815221002Z
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40318152220036
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815223003B
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40318152310038
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815232003D
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815233003J
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815241003F
Intended Purpose:	Catheterisation
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815053003A
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40318151900042

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No. G24 090237 0021 Rev. 00

Intended Purpose:	Catheterisation
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815204053C
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40318152300033
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815240003A
Intended Purpose:	Catheterisation
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815250003H
Intended Purpose:	Catheterisation
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815243003R
Intended Purpose:	Catheterisation
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815259004W
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815316003W
Intended Purpose:	underdraw surgical glove
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815322904C
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815610003Z
Intended Purpose:	Wound Care

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No. G24 090237 0021 Rev. 00

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815639005U
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815642004Y
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815678106N
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815679106T
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815690005R
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815691506D
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815693306H
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40318156947072
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815730004S
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40318157320054

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No. G24 090237 0021 Rev. 00

Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	4031815737005V
Intended Purpose:	Wound Care
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Basic UDI-DI:	40318157380062
Intended Purpose:	Wound Care
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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