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

TÜV SÜD Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 090237 0020 Rev. 00

Manufacturer:

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

SRN Manufacturer: DE-MF-000000023

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.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

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:G21 090237 0020 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. G21 090237 0020 Rev. 00

Classification:	I
Device Group:	F9099 - DIALYSIS DEVICES - OTHERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	H900102 - ADHESIVE STRIPS, SKIN-CLOSURE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M0201020101 - COTTON GAUZES, FOLDED, NOT RX, STERILE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M020106 - GAUZES, PATCHES/ROLLS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M0202010101 - NON-WOVEN GAUZES, FOLDED, NOT RX, STERILE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M0202010102 - NON-WOVEN GAUZES, FOLDED, NOT RX, NOT STERILE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M030101 - BANDAGES, COTTON GAUZES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M0303010101 - ELASTIC BANDAGES, FIXING, NON-ADHESIVE MONOEXTENSIBLE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT PAD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 090237 0020 Rev. 00

Classification:	I
Device Group:	M04010101 - NON-WOVEN ADHESIVE DRESSINGS, WITH ABSORBENT PAD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M04010102 - POLYURETHANE ADHESIVE DRESSINGS, WITH ABSORBENT PAD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M040102 - DRESSINGS, FIXING CATHETERS AND OTHER DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M04010201 - NON-WOVEN DRESSINGS, FIXING CATHETERS AND OTHER DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M04010202 - POLYURETHANE DRESSINGS, FIXING CATHETERS AND OTHER DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M0402 - NON-ADHESIVE ABSORBENT DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M040202 - NON WOVEN ABSORBENT DRESSINGS, WITH ALUMINIUM
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M040204 - ABSORBENT DRESSINGS, WOUND-NONADHERENT
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS

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No. G21 090237 0020 Rev. 00

Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	T0201 - SURGICAL DRAPES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	T02010101 - SURGICAL DRAPES, INCISION WITHOUT ANTIBACTERIAL
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	T020401 - SURGICAL GOWNS, STANDARD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	T020402 - SURGICAL GOWNS, REINFORCED
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	V9001 - TONGUE DEPRESSORS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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