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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 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. 01

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, 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:G21 090237 0020 Rev. 01

Report No.:	71333654
Preceding Certificate No.:	G21 090237 0020 Rev. 00
Valid from:	2024-09-18
Valid until:	2027-03-08
Date of Initial Issuance:	2022-03-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-18

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. G21 090237 0020 Rev. 01

Classification:	Class I
Device Group:	H900102 - BANDAGES FOR SUTURES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M0201020101 - COTTON GAUZES, FOLDED, WITHOUT X-RAY DETECTABLE THREAD, STERILE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M020106 - COTTON GAUZES IN PIECES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M0202010101 - NON-WOVEN FOLDED GAUZES, WITHOUT X-RAY DETECTABLE THREAD, STERILE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M030101 - HYDROPHILIC GAUZE BANDAGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M0303010101 - ELASTIC FIXING BANDAGES, NON-ADHESIVE, EXTENSIBLE IN ONE DIRECTION
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M04010101 - NON-WOVEN ADHESIVE DRESSINGS, WITH ABSORBENT PAD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M04010102 - POLYURETHANE (OR OTHER MATERIAL) ADHESIVE DRESSINGS, WITH ABSORBENT PAD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M04010201 - NON-WOVEN FIXING DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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No. G21 090237 0020 Rev. 01

Classification:	Class I
Device Group:	M04010202 - POLYURETHANE FIXING DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M040202 - ALUMINIUM NON-WOVEN ABSORBENT DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M040204 - NON-ADHERENT ABSORBENT DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T0201 - SURGICAL DRAPES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T02010101 - INCISION DRAPES, WITHOUT ANTIBACTERIAL AGENT
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T020401 - STANDARD SURGICAL GOWNS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T020402 - REINFORCED SURGICAL GOWNS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	V9001 - TONGUE DEPRESSORS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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

Revision History:

Rev.	Dated	Report	Description
00	2022-03-09	713208750	-
01	2024-09-18	71333654	Reduced: Device(s)/group of device(s) removed

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