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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 047330 0062 Rev. 01

Manufacturer:

FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)
Rm.901
Building No.2, Headquarters Center
Tian'an High-tech Ecological Park
Panyu
511400 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009645

Authorized Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, GERMANY

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 047330 0062 Rev. 01

Report No.: SH2318103_CN

Preceding Certificate No.: G21 047330 0062 Rev. 00

Valid from: 2024-08-02
Valid until: 2028-02-08

Date of Initial Issuance: 2023-02-09

Issue date: 2024-08-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class I
Device Group:	M03030202 - SKIN PROTECTIVE BANDAGES
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:	M04010199 - ADHESIVE DRESSINGS, WITH ABSORBENT PAD - OTHER
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:	T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M03030101 - ELASTIC FIXING BANDAGES, NON-ADHESIVE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation
Classification:	Class I
Device Group:	V0501 - CLINICAL EMERGENCY KITS
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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Product Service

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No. G21 047330 0062 Rev. 01

Revision History:

Rev.	Dated	Report	Description
00	2023-02-09	SH22181MDR01	-
01	2024-08-02	SH2318103_CN	Supplemented: Device(s)/group of device(s) added

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