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

No. G21 005225 0005 Rev. 01

Manufacturer:

Hangzhou Primecare Medical Co., Ltd.
Room 408-409, Zancheng Center West
Shangcheng District
310008 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000011403

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 005225 0005 Rev. 01

Report No.: SH24132003

Preceding Certificate No.: G21 005225 0005 Rev. 00

Valid from: 2024-11-29
Valid until: 2028-07-17

Date of Initial Issuance: 2023-07-18

Issue date: 2024-11-29

Christoph Dicks
Head of Certification/Notified Body

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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No. G21 005225 0005 Rev. 01

Classification:	Class I
Device Group:	A020107 - PREFILLED SYRINGES
Device Properties:	MDS 1005.2 - Sterilisation by irradiation

Classification:	Class I
Device Group:	A0304 - ADMINISTRATION KITS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	A0801 - NUTRITION BAGS AND CONTAINERS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	F0399 - DIALYSIS KITS - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	T0203 - DRESSING AND ASSISTANCE KITS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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

Revision History:

Rev.	Dated	Report	Description
00	2023-07-18	SH22132002	Initial issuance
01	2024-11-29	SH24132003	Supplemented: Device(s)/group of device(s) added

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