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 052712 0033 Rev. 00

Manufacturer:

Jianerkang Medical Co., Ltd.
NO.1, Jianerkang Road, Zhixi Town Industrial Zone
Jintan District
213251 Changzhou City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000011206

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, 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 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 052712 0033 Rev. 00

Report No.: SH21037MDR01

Valid from: 2023-02-09
Valid until: 2028-02-08

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-02-09

Digitally signed by Cosnicean Mihai
Date: 2023.05.26 16:41:30 EEST
Reason: MoldSign Signature
Location: Moldova

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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 052712 0033 Rev. 00

Classification:	I
Device Group:	M010101 - HYDROPHILIC COTTON
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M0201020101 - COTTON GAUZES, FOLDED, WITHOUT X-RAY DETECTABLE THREAD, STERILE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M0202010101 - NON-WOVEN FOLDED GAUZES, WITHOUT X-RAY DETECTABLE THREAD, STERILE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	M020107 - COTTON GAUZES IN ROLLS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	Q019003 - DENTAL FLOSS AND OTHER DEVICES FOR ORAL HYGIENE (FOR PROFESSIONAL USE)
Device Properties:	MDS 1005.2 - Sterilisation by irradiation
Classification:	I
Device Group:	T020401 - STANDARD SURGICAL GOWNS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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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 052712 0033 Rev. 00

Classification:	I
Device Group:	T020603 - MEDICAL USE FACE MASKS, TYPE I (NOT FOR HEALTHCARE PROFESSIONALS)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	I
Device Group:	T020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 052712 0029 Rev. 06

Holder of Certificate:

Jianerkang Medical Co., Ltd.
NO.1, Jianerkang Road, Zhixi Town Industrial Zone
Jintan District
213251 Changzhou City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate:

Production and Distribution of Absorbent Cotton Rolls, Gauze Bandages, Gauze Rolls, Sterile Gauze Swab(Sponge), Gauze Sponges, Surgical Towels, Non-woven Sponges, Non-sterile urine Bag, Alcohol Prep Pad (Swab), Towelette, Impregnated Sponges Sticks, Alcohol Swabsticks, Sterile lubricating Jelly, Scrub Brush, medical face mask, Sterile surgical Gown, Medical Dressing, Gauze Fluff Roll, Swabs Cotton, Lemon Glycerin Swabsticks, Sterile Surgical drapes, Cotton Gauzes folded, Elastic Fixing Bandages, Oxygen administration Humidification systems, Ultrasound scanners-consumables

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). 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:Q6 052712 0029 Rev. 06

Report No.: SH2203702

Valid from: 2023-04-06
Valid until: 2025-05-31

Date, 2023-04-06

Christoph Dicks
Head of Certification/Notified Body

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 052712 0029 Rev. 06

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Jianerkang Medical Co., Ltd.
NO.1, Jianerkang Road, Zhixi Town Industrial Zone, Jintan District, 213251 Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

See scope of certificate

.

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