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 109384 0006 Rev. 00

Manufacturer:

Xuchang Zhengde Environstar Medical Products Co., Ltd.
Area B, Baihua Road East
South Side of Erji river
Industry Cluster District
Yanling County
461200 Xuchang, Henan
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009427

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 109384 0006 Rev. 00

Report No.: SH2255401

Valid from: 2024-01-31
Valid until: 2029-01-30

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-01-31

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

No. G21 109384 0006 Rev. 00

Classification:	Class I
Device Group:	T020101 - INCISION DRAPES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T020102 - SPECIALISTIC SURGERY DRAPES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T020199 - SURGICAL DRAPES - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
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:	T0205 - NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T0299 - PROTECTION DRAPES AND GARMENTS - OTHER
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

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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 109384 0006 Rev. 00

Classification:	Class I
Device Group:	T030201 - MECHANICAL ARMS COVERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	T030202 - CAMERAS COVERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	T030203 - OPTICS COVERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	T030299 - ROBOTIC SURGERY COVERS - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following: - none -

Revision History:

Rev.	Dated	Report	Description
00	2024-01-31	SH2255401	Initial issuance

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Declaration of conformity

1. Manufacturer:

Name: Xuchang Zhengde Environstar Medical Products Co.,Ltd.

Address:

Site 1: No.3, Weilai Road, Industry Cluster District, Yanling County 461200 Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA

Site 2(Legal manufacturer): Area B, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County, 461200 Xuchang, Henan, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000009427

2. European Representative:

Name: Shanghai International Holding Corp.GmbH(Europe)
Address: Eiffestraße 80, 20537 Hamburg, Germany.
SRN: DE-AR-000000001

3. Notified Body:

Name: TÜV SÜD Product Service GmbH,
Ridlerstr, 65, 80339 München, Germany
Identification number: 0123

4. Product Name： Sterile Drapes (For product details please refer to attached the Product List)

Basic UDI-DI: 69317478SD000003GG
69317478SD000002GE
69317478SD000001GC

5. GMDN code: 47783

6. Intended use： Used as a protective covering or a barrier to isolate a site of surgical incision or a surgical field from contamination found in operating theatre or catheterization laboratory e.g. on instruments or tables.

7. Classification: I sterile

Based on MDR EU2017/745 Annex VIII rule 1
The specific sentence is :
All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

8.Conformity Assessment Route: MDR Annex XI Part A

9. Statement:

We declare the compliance of the above medical device with the applicable requirements of Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of Xuchang Zhengde Environstar Medical Products Co.,Ltd.

10. CS: NA

11. Standard Applied:

EN ISO 15223-1:2021 EN ISO 13485:2016
EN ISO 14971:2019 EN 13795-1:2019

12. (EC) Certificate(s) No.: G21 109384 0006 Rev.00

Expire date of the Certificate: 2029-01-30
Issue date of the Certificate: 2024-01-31

Signature: 

Place, Date of issue: Xuchang, 2024-3-11

Name: Chen Ming

Position: Regulatory Director

Product List

S/N	Ref.	Product name	Product Size	Sterility	EMDN Code
1	63835	Under Buttocks Drape, PRIMARY	75x100cm	Sterile	T020102
2	63818	Ophthalmic Drape w/pouch, PRIMARY	140x150cm ap. Inc	Sterile	T020102
3	63819	Ophthalmic Drape w/pouch, PRIMARY	140x150cm inc	Sterile	T020102
4	63820	Ophthalmic Drape w/pouches, PRIMARY	150x180cm	Sterile	T020102
5	63821	Ophthalmic Drape w/pouches, PRIMARY	150x195cm transp.	Sterile	T020102
6	63823	Ophthalmic Drape w/pouches, PRIMARY	150x300 ap. Inc	Sterile	T020102
7	63824	Ophthalmic Drape w/pouches, PRIMARY	150x300 inc.	Sterile	T020102
8	63814	OP-Towel, PRIMARY	37,5x45 cm	Sterile	T020199
9	63815	OP-Towel, PRIMARY	45x75 cm	Sterile	T020199
10	63816	OP-Sheet, PRIMARY	90x150 cm	Sterile	T020199
11	63817	Armrest Cover, PRIMARY	35x73 cm	Sterile	T020199
12	63810	OP-Sheet, PRIMARY	150x175 cm	Sterile	T020199
13	63811	OP-Sheet, PRIMARY	150x240 cm	Sterile	T020199
14	63812	OP-Sheet, PRIMARY	90x150cm	Sterile	T020199
15	63813	Adhesive OP-Towel, PRIMARY	50x50 cm	Sterile	T020199
16	63836	Adhesive aperture drape, PRIMARY	45x75cm, aperture 7cm	Sterile	T02010101
17	63837	Apertue drape, PRIMARY	50x60cm, aperture 6x8cm	Sterile	T02010101
18	63838	Adhesive aperture drape, PRIMARY	60x75cm, aperture 6x9,5cm	Sterile	T02010101
19	63873	Adhesive Aperture Drape, Variable, PRIMARY	50x75cm	Sterile	T02010101
20	63875	Adhesive Aperture Drape, Variable, PRIMARY	75x100cm	Sterile	T02010101
21	63839	Adhesive aperture drape, PRIMARY	100x125 cm, aperture 11 cm	Sterile	T02010101
22	63840	Adhesive aperture drape, PRIMARY	120x150cm, aperture 5x7cm	Sterile	T02010101
23	63624	Adhesive Aperture Drape, PRIMARY	120x150cm, aperture 5x7cm	Sterile	T02010101
24	63841	Adhesive Aperture Drape, PRIMARY	120x150 cm, apertured incise 7,5cm	Sterile	T02010101
25	63842	Adhesive Aperture Drape, PRIMARY	150x180cm, aperture 5x15cm	Sterile	T02010101

26	63843	Adhesive Aperture Drape, PRIMARY	200x240cm, aperture 12cm	Sterile	T02010101
27	63844	Adhesive Aperture Drape, PRIMARY	200x240cm, aperture 12cm	Sterile	T02010101
28	63845	Adhesive Aperture Drape, PRIMARY	200x280cm, aperture15 cm	Sterile	T02010101
29	63846	Adhesive Aperture Drape, PRIMARY	200x280cm, aperture 14x14cm	Sterile	T02010101
30	63847	Adhesive Aperture Drape, PRIMARY Plus	200x300 cm, aperture 12x16,5 cm	Sterile	T02010101
31	63853	Table Cover, PRIMARY	100x150cm	Sterile	T020199
32	63854	Table Cover, PRIMARY	150x150cm	Sterile	T020199
33	63855	Table Cover, PRIMARY	150x170cm	Sterile	T020199
34	63856	Table Cover, PRIMARY	150x210cm	Sterile	T020199
35	63857	Table Cover, PRIMARY	150x240cm	Sterile	T020199
36	63858	Table Cover, PRIMARY	150x190cm	Sterile	T020199
37	63850	Lithotomy Leggings, PRIMARY	75x120 cm	Sterile	T020199
38	63851	Lithotomy Leggings, PRIMARY	75x150 cm	Sterile	T020199
39	63852	Tube Pocket, PRIMARY	90x92 cm, absorbent 70x50cm	Sterile	T020199
40	63849	Preparation pad, PRIMARY	120x150 cm	Sterile	T020199
41	63825	Ophthalmic Drape	50x60cm perforated inc.	Sterile	T020102
42	63826	Ophthalmic Drape	75x85cm ap. Inc.	Sterile	T020102
43	63827	Ophthalmic Drape	75x85cm perforated inc.	Sterile	T020102
44	63828	Ophthalmic Drape w/pouch	100x120cm inc.	Sterile	T020102
45	63829	Aperture Drape	115x100cm inc. 19x8cm	Sterile	T02010101
46	63830	Ophthalmic Drape	140x150cm ap. Inc.	Sterile	T020102
47	63832	Ophthalmic Drape w/pouch	140x150cm inc.	Sterile	T020102
48	63833	Ophthalmic Drape w/pouches	150x180cm inc.	Sterile	T020102
49	63834	Ophthalmic Drape w/pouches	150x180cm inc.	Sterile	T020102
50	63859	Hand Drape, PRIMARY Plus	150cm/370cmx280cm, aperture 3,5cm	Sterile	T020102
51	63860	Hand and Foot Drape, PRIMARY Plus	230cmx315cm, aperture 3,5cm	Sterile	T020102
52	63848	Laparotomy Drape, PRIMARY Plus	200x315cm, aperture 11x22cm	Sterile	T020102