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

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

TÜV SÜD Product Service

Certificate

No. Q5 109397 0001 Rev. 02

Holder of Certificate:

Xuchang Zhende Surgical Dressing Co., Ltd.
Area A, Baihua Road East
South Side of Erji river
Industry Cluster District
Yanling County
461200 Xuchang Henan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

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

Scope of Certificate:

**Design and Development,
Production and Distribution of
Gauze Product with X-ray Thread,
Gauze Product without X-ray Thread,
Non-woven Products, Cotton Products, Medical Tape,
Lap Sponges, Procedural Dressing Trays, Alcohol Prep Pad,
OR Towel, First Aid Kit, Dressing Pack, Cotton Undercast
Padding (refer to next pages for further details)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 109397 0001 Rev. 02

Report No.: SH2449502

Valid from: 2024-10-01
Valid until: 2027-09-30

Date, 2024-09-30

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Xuchang Zhende Surgical Dressing Co., Ltd.
Area A, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County, 461200 Xuchang Henan, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Gauze Product with X-ray Thread, Gauze Product without X-ray Thread, Non-woven Products, Cotton Products, Medical Tape, Lap Sponges, Procedural Dressing Trays, Alcohol Prep Pad, OR Towel, First Aid Kit, Dressing Pack, Cotton Undercast Padding

Xuchang Zhende Surgical Dressing Co., Ltd.
No.1 Jinhui Road, Industry Cluster District, Yanling County, 461200 Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Gauze Product with X-ray Thread, Gauze Product without X-ray Thread, Non-woven Products, Cotton Products, Medical Tape, Lap Sponges, Procedural Dressing Trays, Alcohol Prep Pad, OR Towel, First Aid Kit, Dressing Pack, Cotton Undercast Padding

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Product(s)/Product Category(ies)

Gauze Products With X-ray Thread
Gauze Swab, Gauze Sponge, Gauze Roll, Gauze Ball, Zig-zag Gauze, Gauze

Gauze Products Without X-ray Thread
Gauze Swab, Gauze Sponge, Gauze Roll Gauze Ball, Zig-zag Gauze, Gauze, Fluffy Gauze Swab, Fluffy Gauze Bandage

Non-woven Products
Non-woven Swab, Non-woven Sponge, Non-woven Ball, Medical Face Mask, Disposable Cap

Cotton Products
Cotton Swab, Cotton Roll, Cotton Pad, Cotton Bud, Cotton Ball

Medical Tape
Non-woven Tape, PE Tape, Silk Tape, Zinc Oxide Tape, Silicon Tape

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