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

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

TÜV SÜD Product Service

Certificate

No. Q5 045222 0015 Rev. 03

Holder of Certificate: **Changzhou Hualian Health Dressing Co., Ltd.**
No.55 Yuejin Road, Zouqu Town
213144 Changzhou
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 Adhesive Dressing Series (including Non-sterile Medical Zinc Oxide Adhesive Plaster, Non-sterile Medical Tape, Non-sterile Medical Dressing Tape, Non-sterile Medical Self-Adhesive Bandage, Non-sterile Medical Plaster, Non-sterile Medical Liquid Bandage), First-Aid-Kit Sterile Hemostasis Adhesive Dressings Series (including Sterile Medical Plaster, Sterile Medical Adhesive Dressing, Sterile Medical Liquid Transfusion Plaster), Sterile Medical Face Mask, Sterile Medical Foam Dressing, Non-sterile Medical Diapers Pants, Sterile Medical Bandage Roll**

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 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:Q5 045222 0015 Rev. 03

Report No.: SH2314901

Valid from: 2023-09-01
Valid until: 2026-08-31

Date, 2023-08-18

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

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

TÜV SÜD Product Service

Certificate

No. Q5 045222 0015 Rev. 03

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):

Changzhou Hualian Health Dressing Co., Ltd.
No.55 Yuejin Road, Zouqu Town, 213144 Changzhou, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Adhesive Dressing Series (including Non-sterile Medical Zinc Oxide Adhesive Plaster, Non-sterile Medical Tape, Non-sterile Medical Dressing Tape, Non-sterile Medical Self-Adhesive Bandage), Non-sterile Medical Diapers Pants.

Jiangsu Excellence Medical Supplies Co., Ltd.
Zouqu Industrial Zone, Zouqu Town, 213144 Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Adhesive Dressing Series (including Non-sterile Medical Zinc Oxide Adhesive Plaster, Non-sterile Medical Tape, Non-sterile Medical Dressing Tape, Non-sterile Medical Self-Adhesive Bandage, Non-sterile Medical Plaster, Non-sterile Medical Liquid Bandage), First-Aid-Kit
Sterile Hemostasis Adhesive Dressings Series (including Sterile Medical Plaster, Sterile Medical Adhesive Dressing, Sterile Medical Liquid Transfusion Plaster), Sterile Medical Face Mask, Sterile Medical Foam Dressing, Non-sterile Medical Diapers Pants, Sterile Medical Bandage Roll.

.

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

TÜV®