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

DAkkS
Deutsche
Akkreditierungsstelle
D ZM 11321 01 00

Product Service

Certificate

No. Q6 060968 0015 Rev. 02

Holder of Certificate: **Wujiang Kangxin Surgical Dressings Co., Ltd.**
No. 1309 Jinshe Road
Jinjiaba Town
215215 Wujiang City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate:

**Production and Distribution of
Non-sterile non-active measurement devices for single-use, Non-sterile non-active fluids collection container for single-use, Non-sterile non-active medical tapes for single-use, Non-sterile non-active dental devices for oral hygiene for single-use, Non-sterile non-active tourniquet for single-use, Non-sterile and sterile non-active needles accessories for single-use,
Non-sterile and sterile non-active devices for general and specialist dressings for single-use,
Non-sterile and sterile non-active patient protective equipment and incontinence aids for single-use,
Non-sterile and sterile non-active cutting devices for single-use, Non-sterile and sterile non-active non-IVD clinical use containers for single use,
Non-sterile non-active healthcare activities supportive equipment and aids for single use,
Non-sterile and sterile non-active tongue depressors for single-use,Non-active sterile skin markers for single-use**

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, 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 Q6 060968 0015 Rev. 02

Report No.: SH2402001

Valid from: 2024-12-01
Valid until: 2027-11-30

Date, 2024-11-28

Christoph Dicks
Head of Certification/Notified Body

TÜV®

TUV SUD 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):

Wujiang Kangxin Surgical Dressings Co., Ltd.
No. 1309 Jinshe Road, Jinjiaba Town, 215215 Wujiang City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

See scope of certificate

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