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

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

TÜV SÜD Product Service

Certificate

No. Q5 002039 0002 Rev. 04

Holder of Certificate: **Hantech Medical Device Co., Ltd.**
No.288, Sanheng Road
Changhe Industrial Park,Cixi
315326 Ningbo
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of Syringe, Gasket, Amniotic Membrane Perforator, Umbilical Cord Clamp, Disposable Foley Catheter, Disposable Cervical Dilatation Balloon Catheter, Disposable Enteral Feeding Catheter, Disposable Enteral Feeding Set, Disposable Infusion Sets, Extension Sets, Gutta-Percha Points, Disposable Swab, Disposable Medical Safety Hypodermic Needle**

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 002039 0002 Rev. 04

Report No.: SH20119803

Valid from: 2021-02-12

Valid until: 2024-02-07

Date, 2021-02-12

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

TÜV SÜD
Product Service

Certificate

No. Q5 002039 0002 Rev. 04

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):

Hantech Medical Device Co., Ltd.
No.288, Sanheng Road, Changhe Industrial Park,Cixi, 315326
Ningbo, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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

TÜV®