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

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

TÜV SÜD
Product Service

Certificate

No. Q5 064834 0028 Rev. 01

Holder of Certificate:

Oiarso Medical Kunshan Co., Ltd.
West site of Huang Pu Jiang Rd. Qian Deng
215341 Kunshan, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Oiarso Medical Kunshan Co., Ltd.
West site of Huang Pu Jiang Rd. Qian Deng, 215341 Kunshan,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

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

Scope of Certificate:

Production and Distribution of
Infusion Sets, Transfusion Sets,
Extension Tube with/without Stopcock,
Burette Sets, Vaginal Speculum,
Enteral Nutrition Bags,
Endocervical Brush and other Gynecology Assets,
Wooden Scraper, Caps, Disposable Surgical Drapes &
Disposable Surgical Sets & Disposable Surgical Gowns,
Plastic Cover for Surgical Instruments,
Three Way Stopcock

Design and Development,
Production and Distribution of
Disposable Infusion Pump, Foley Catheter

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: SH1936601

Valid from: 2020-02-01
Valid until: 2023-01-31

Date, 2019-11-07

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

A4 / 07.17