



Certificate

No. Q6 089714 0006 Rev. 02

Holder of Certificate: **Changshu Kangbao Medical Appliance Factory**
Furong Village, Baimao, Guli Town
215500 Changshu City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of Urine Bag, Enteral Feeding Set (Bag), Connecting Tube with Yankauer Handle, Connecting Tube without Yankauer Handle, Disposable Enema Bag, Urine Meter (with Urine Sampling Blunt Cannula)**

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). See also notes overleaf.

Report No.: SH2090401

Valid from: 2020-10-15

Valid until: 2023-10-14

Date, 2020-08-12

Christoph Dicks
Head of Certification/Notified Body

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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):

Changshu Kangbao Medical Appliance Factory
Furong Village, Baimao, Guli Town, 215500 Changshu City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Changshu Leo Medical Appliance Co., Ltd
1# Furong Village, Baimao, Guli Town, 215500 Changshu City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA