DAKKS CRT2 / 10.13



CERTIFICATE

No. Q1N 15 10 93400 001

Holder of Certificate: Suzhou Coming Chengye

Medical Technology Co., Ltd.

No.258, Huajin Road, Tongan Town

High & New Technology Development Zone

215153 Suzhou

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Suzhou Coming Chengye Medical Technology

Co., Ltd.

No.258, Huajin Road, Tongan Town, High & New Technology Development Zone, 215153 Suzhou,

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution

of IVD Reagent for Hematology Analyzer, Auxiliary Reagent for Biochemistry Analyzer, Immunology Analyzer, Coagulation Analyzer

Applied

Standard(s):

EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -

Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)

DIN EN ISO 13485:2012

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.:

SH15100901

Valid from:

2016-02-03

Valid until:

2019-02-02

Date, 2016-02-03

Hans-Heiner Junker

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