



Product Service

# 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



Hans-Heiner Junker

**Date,** 2016-02-03

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