ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# CERTIFICATE

**No. Q4N 13 05 36356 008**

**Holder of Certificate:** **Institute of Radiation Technique Soochow University**

4756 Jiao-Tong Road, Songling Town
215200 Wujiang City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Institute of Radiation Technique Soochow University
4756 Jiao-Tong Road, Songling Town, 215200 Wujiang City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Suzhou CNNC Huadong Radiation Co.,Ltd
4756 Jiao-Tong Road, Songling Town, 215200 Wujiang City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

**Scope of Certificate:** **Gamma Sterilization of Medical Devices**

**Applied Standard(s):** **EN ISO 13485:2012/AC:2012**
**ISO 13485:2003**
**Medical Devices - Quality Management Systems - Requirements for regulatory purposes**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1303515

**Valid from:** 2013-08-01
**Valid until:** 2016-07-31

**Date,** 2013-07-12

Hans Heiner Junker

563780



TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

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# Supplement to Quality System Certificate Q4N.13.05.36356.008

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2013-08-01

**Institute of Radiation Technique Soochow University**
4756 Jiao-Tong Road, Songling Town
215200 Wujiang City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

for the facility
**Institute of Radiation Technique Soochow University**
4756 Jiao-Tong Road, Songling Town
215200 Wujiang City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

**Suzhou CNNC Huadong Radiation Co., Ltd.**
4756 Jiao-Tong Road, Songling Town
215200 Wujiang City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

The quality system certified as stated above additionally fulfills the applicable requirements of **EN ISO 11137-1: 2006 - Sterilization of health care products - Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** - as documented in the audit report no. SH1303515 dated 2013-06-09.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

**TÜV SÜD PRODUCT SERVICE GMBH**
**Certification Committee for Medical Devices**

Hans-Heiner Junker
Munich, 2013-07-12

TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.



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