



Product Service

CERTIFICATE

No. Q4N 16 06 71270 001

Holder of Certificate: Suzhou CNNC Huadong Radiation Co.,Ltd

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

Facility(ies):

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
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.: SH1603518

Valid from: 2016-08-10
Valid until: 2019-07-31



Date, 2016-08-10

Stefan Preiß

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Product Service

Supplement to Quality System Certificate Q4N.16.06.71270.001

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2016-08-10 to

Suzhou CNC Huadong Radiation Co.,Ltd

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

for the facility

Suzhou CNC 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: 2015 - 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. SH1603518 dated 2016-08-09.

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

Stefan Preiß

Munich, 2016-08-10

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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