

Sira

CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to Certify that the QUALITY MANAGEMENT SYSTEM of

**SHANGHAI SHENWANG RADIATION PROTECTIVE
EQUIPMENT CO., LTD.**

Registered Address: Nanmei Lane, Weixing Village, Huacao Town, Minhang District,
Shanghai, P. R. China

Business Address: No. 149, Lane 1510, Jizhai Road, Huacao Town, Minhang District,
Shanghai, P. R. China

has been assessed by Sira Certification Service
and found to comply with

GB/T19001-2008 idt ISO9001:2008

for the

Production and related management activities of X-Ray protection
lead glass

Certificate No.	129333
Organization Code	913101121472609794
Initial Certification	7 December 2012
Date of Issue/Reissue	3 November 2010
Certificate Expiry	30 October 2017



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[Signature]

On behalf of SCS



GIAM ĐỐC

Đoàn Quốc Hưng



Recertification Date: 11 September 2015

This certificate is subject to the company maintaining its system to the required standards, which will be monitored by Sira.
The use of this Certificate and the Sira Certification Mark are subject to the Regulations Applicable to Holders of Sira Certificates.
This certificate is provided by Shanghai Sira Quality Certification Co., Ltd. For complete information is available on the SCSA website <http://www.sira.com.cn>

Sira Certification Service

This certificate is the property of Sira and shall be returned when requested. It may only be reproduced in its entirety and without change.
(Use of elements includes: Firm Name/number, CMC SCS, United Kingdom Email: sira@sira.com.cn)

CE Technical Documentation Review Report

Manufacturer:

Shanghai Shenwang Radiation Protective
Equipment Co., Ltd.
No.146, Lane 1510, Jia Road, Huacao Town
Minhang District, Shanghai, PRC

Report Number:

15097024-001

Examination Intent:

Examination the completeness of the Technical
Documentation according to the requirements of the
Medical Devices Directive 93/42/EEC Annex VII

Product(s):

Radiation Shielding Material for medical use
Lead Sheets
Leaded Glass
Leaded Goggles
Lead Aprons

Type(s)/Model(s):

Lead Sheets, custom-made sizes
Leaded Glass: ZF2, ZF3, ZF6, ZF7
Leaded Goggles for eye-radiation shield
Lead Aprons: S, M, L

Classification:

Class 1, rule 1
(according to manufacturer's declaration)

Review result:

During the examination of the provided Technical
Documentation (No.: SW/TF-001, Rev. A/D, 2016-05-
29), no Non-compliance according to the
requirements of the Medical Devices Directive
93/42/EEC Annex VII was detected.



Shanghai, 2016-08-24



GIAM ĐỐC

Trần Quốc Trung



TUV Rheinland (Shanghai) Quality Assurance

Daniel ZHU

Daniel ZHU
Lead Auditor, Product Assessment
Medical Device Services