

CERTIFICATE



Registration no.	KM 20002	Technical Area	B202
First issue date	2019-11-19	Issue date	2019-11-19
Expiry date	2022-11-18	Reissue date	2020-12-02

- Quality Management System Certificate

KS P ISO 13485:2016/ISO 13485:2016

We certify that the Quality Management System of the Organization:

iRay Korea Limited.

Is in compliance with the standard KS P ISO 13485:2016/ISO 13485:2016
for the following products/services:

Manufacture, sales and service of medical device equipment (flat panel X-ray detector)

General Manager
Seung-Chan Lee

Maintenance of the certification is subject to continual surveillance audit and dependent upon the observance of Kiwa Korea's certification criteria.

Kiwa Korea Ltd.
411, SJ Technoville,
278, Beotkkot-ro,
Geumcheon-gu,
Seoul, Korea
Tel +82.2.3397.0101
Fax +82.2.3397.0105
URL: www.kiwa.kr

Certified Sites
#1833, 5, Gasan digital 1-ro, Geumcheon-gu, Seoul, Korea



KAB-MC-03



Nguyễn Hoàng Châu
TỔNG GIÁM ĐỐC

Certificate

Quality Management System
EN ISO 13485:2016



Registration No.: SX 2028202-1

Organization: iRay Technology Co. Ltd.
RM 202, Building 7,
No. 590, Ruiqing RD., Zhangjiang East, Pudong
201201 Shanghai
P.R. China



The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o iRay Technology Co. Ltd. Building 45, No. 1000, Jinhai RD., Pudong New Area, 201206 Shanghai P.R. China	Design and Development of Flat Panel X-Ray Detectors
/02	c/o iRay Technology Taicang Ltd. No. 33 Xinggang Road, Taicang Port Economic and Technological Development Zone, Taicang, 215434 Jiangsu P.R. China	Manufacture and Distribution of Flat Panel X-Ray Detectors

Report No.: 244339931-200
Effective date: 2021-10-15
Expiry date: 2024-10-14
Issue date: 2021-10-15



Fuxiu-Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Quality Management System
EN ISO 13485:2016

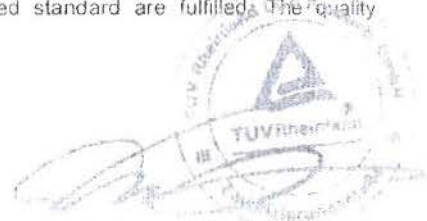


Registration No.: SX 2028202-1
Organization: iRay Technology Co. Ltd.
RM 202, Building 7
No. 590, Ruiqing RD., Zhangjiang East, Pudong
201201 Shanghai
P.R. China

Scope: Design and Development, Manufacture and Distribution of Flat Panel X-Ray Detectors

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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