Certificate

TÜVRheinland®

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.

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

TÜV Rheinland LGA Products GmbH
TUVRheinland
Zertifizierungsstelle

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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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

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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