EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60146185 0001

Report No.: 15044963 018

Manufacturer:
iRay Technology Co. Ltd.
RM202, Building 7
No. 590, Ruiqing RD.
Zhangjiang East, Pudong
201201 Shanghai
P.R. China

Products:
Flat Panel X-Ray Detectors

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60137404 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-01-22

Date: 2020-01-22

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Lungu Ion
Date: 2023.06.16 13:22:31 EEST
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Morozov Maria
Date: 2023.10.24 14:48:19 EEST
Reason: MoldSign Signature
Location: Moldova

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146185 0001
Report No.: 15044963 018

Manufacturer:
iRay Technology Co. Ltd.
RM202, Building 7
No. 590, Ruiqing RD.
Zhangjiang East, Pudong
201201 Shanghai
P.R. China

Site included:

Building 45, No. 1000, Jinhai RD., Pudong New Area,
201206 Shanghai, China

Notified Body

Date: 2020-01-22

Herbert Zhong

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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

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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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

EC Declaration of Conformity

Manufacturer:

iRay Technology Co., Ltd.

RM202, Building 7, No.590, Ruiqing RD, Zhangjiang East, Pudong, Shanghai, China
Tel: +86-21-50720560
Fax: +86-21-50720561
Website: www.iraygroup.com

whose single Authorized Representative:

iRay Europe GmbH

In den Dorfwiesen 14, 71720 Oberstenfeld Germany
www.irayeurope.com
Tel: +49-7062-977 88 00
Fax: +49-7062-976 05 71
e-mail: S.feng@iraychina.com

We, the manufacturer, herewith declare that the products

Mars1717X (Brand name: Mars1717X)
Wireless Digital Flat Panel Detector

GMDN-Code: 61108

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II, excluding Section 4 of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: **HD 60146185 0001**
Issue date: **2020-01-22**
Expiry date: **2024-05-26**

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: iRay Technology Co., Ltd.

Address: RM202, Building 7, No. 590, Ruiqing RD. , Zhangjiang East, Podong 201201, Shanghai, China

Shanghai,10/15/2020 — *Place, date*

Xunzhong Fan，Representative of Management — *Legally binding signature, Function*

053-406-08 A0
EC Declaration of Conformity