

**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

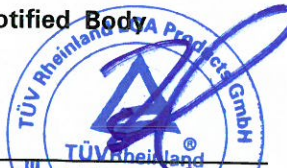
**Products:** Flat Panel X-Ray Detectors  
  
(see attachment for additional site included)  
  
Replaces Approval, Registration No.: HD 60137404 0001

**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  
  
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.

**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

**Date:** 2020-01-22

**Notified Body**



**Herbert Zhong**

# 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

TÜV Rheinland

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



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

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



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



# EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

**iRay Technology Co., Ltd.**

**iRay Europe GmbH**

**RM202, Building 7, No.590, Ruiqing RD,  
Zhangjiang East, Pudong, Shanghai,  
China**

**Tel: +86-21-50720560**

**Fax: +86-21-50720561**

**Website: [www.iraygroup.com](http://www.iraygroup.com)**

**In den Dorfwiesen 14, 71720  
Oberstenfeld Germany**

**[www.irayeuropa.com](http://www.irayeuropa.com)**

**Tel: +49-7062-977 88 00**

**Fax: +49-7062-976 05 71**

**e-mail: [S.feng@iraychina.com](mailto: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*

**053-406-08 A0**

**EC Declaration of Conformity**

Xunzhong Fan, Representative of Management

*Legally binding signature, Function*

