

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

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

www.irayeuropa.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

053-406-08 A0

EC Declaration of Conformity

Xunzhong Fan, Representative of Management

Legally binding signature, Function

