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.

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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