EC Declaration of Conformity

Manufacturer:

iRay Technology Co., Ltd.

RM202, Building 7, No.590, Ruiqing RD, Zhangjiang East, Pudong 201201, Shanghai, P.R.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

PlutoX series(brand name: Pluto 0001X and Pluto0002X)
Digital Intraoral X-ray imaging system

GMDN-Code: 44905

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, Pudong 201201, Shanghai, P.R.China

Shanghai,30/03/2021
Place, date

Xunzhong Fan, Management Rep.
Legally binding signature, Function