EC Certificate Full Quality Assurance System: KR11/01657

The management system of

Rayence Co., Ltd.

14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 17 December 2015 until 14 December 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2 November 2018
Issue 17. Certified since 1 July 2011

Certification is based on reports numbered KR/SEL Y-PC/11262

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Rayence Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 17

Detailed scope

Medical Image Processing Unit (Flat Panel Detector) (Model: 1717SGC, 1717SCC, 1417PCA, 1417PGA, 1012WCA, 1417WCA, 1417WGA, 1417WCC, 1417WGC, 1717SCN, 1717SGN);

Medical Image Processing Unit (Intra Oral Imaging System) (Model: EzSensor, EzSensor i, HDI 1000, HDI 1000A, EzSensor P, EzSensor Pi, HDI 2000, HDI 2000A, EzSensor Soft, EzSensor Soft i, EzSensor Bio, EzSensor Bio i, IOS-U10VB, IOS-U15VB, IOS-U10IB, IOS-U15IB, IOS-U10VF, IOS-U15VF, IOS-U10IF, IOS-U15IF, HDI-U10DB, HDI-U15DB, HDI-U10DF, HDI-U15DF, IOS-U20VF, IOS-U20IF, IOS-U20VB, IOS-U20IB, HDI-U20DB, HDI-U20DF);

Medical Image Processing Software (Model: Xmaru PACS)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market