EC Certificate Full Quality Assurance System: Certificate KR09/01272

The management system of

Ray Co.,Ltd.

332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 445-330, 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

Dental X ray system (Model: RAYSCAN Symphony, RAYSCAN Symphony V option, RAYSCAN Symphony B option, RAYSCAN α-OC, RAYSCAN α-P, RAYSCAN α-Multi3D, RAYSCAN α-3D, RAYSCAN α-SC, RAYSCAN α-SM3D, RAYSCAN α-OCS, RAYSCAN α-OCL, RAYSCAN α-M3DS, RAYSCAN α-M3DL, RCT700)
Dental imaging software (Model : SMARTDent);
Intraoral Imaging system (Model: RIS 500)

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.

This certificate is valid from 6 July 2015 until 17 November 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 March 2016
Issue 17. Certified since 21 May 2009

Certification is based on reports numbered KR/SEL Y-PC/08206

Authorised by

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