EC Certificate Full Quality Assurance System: Certificate KR19/81826254

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The management system of

Ray Co., Ltd.

332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 18380, 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 α-OC, RAYSCAN α-P, RAYSCAN α-SC, RAYSCAN α-OCS, RAYSCAN α-OCL)
Dental imaging software (Model : SMARTDent);
Intraoral Imaging system (Model: RIS 500);
Computed Radiography Scanner (Model : RPS500);
CBCT X-ray system (Model : RCT710, RAYSCAN α-Multi3D, RAYSCAN α-3D, RAYSCAN α-SM3D, RAYSCAN α-M3DS, RAYSCAN α-M3DL, RCT700, RCT800);
Dental temporary resin for crown and bridge (Model: RAYDENT C&B).

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 16 December 2019 until 11 March 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 21 May 2009
and first certified by SGS Belgium NV since 16 December 2019

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

Authorised by

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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