Ray Co., Ltd.

EC Declaration of Conformity

Manufacturer : Ray Co., Ltd.

332-7, Samsung 1-ro, Hwaseong-si, Gyeonggi-do, 18380, Korea

European representative : Emergo Europe

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Notified Body: SGS Belgium NV

Noorderlaan 87, BE-2030 Antwerpen, Belgium

Product : CBCT X-ray System

Model(Brand) : RAYSCAN α-3D, RAYSCAN α-SM3D, RAYSCAN α-M3DS, RAYSCAN α-M3DL, RCT700, RCT800

Certificate No. : KR19/81826254

Classification : Class IIb by Rule 10 of Annex IX, MDD 93/42/EEC as amended by Directive 2007/47/EC

Conformity Assessment Route : Annex II, exclude Section IV, MDD 93/42/EEC as amended by Directive 2007/47/EC

We hereby declare that the complies with the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) using Annex II as the conformity assessment procedure via SGS(NB 1639) as the Notified Body.

Applied Standard

- EN 60601-1(2013)
- EN 60601-1-3(2008)
- EN 60601-1-6(2010)
- EN 62304(2006)
- IEC 60601-2-63(2012)
- EN 60601-1-2(2015)
- IEC 61223-3-4(2000)
- IEC 61223-3-5(2004)

Date of issue : Dec 16, 2019

Signature :

Digitally signed by Savca Octavian
Date: 2025.01.03 02:02:22 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Quality Manager of Ray Co., Ltd.