

## **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) : RCT700**

**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 :**



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**Quality Manager of Ray Co., Ltd.**