RAYENCE Co.,Ltd.
14, Samsung 1ro 1-gil, Hwaseong-si,
Gyeonggi-do, Korea

EC Declaration of Conformity

This document declare that the following designated product;

Manufacture	Rayence Co., Ltd 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
EC Representative	VATECH Dental Manufacturing Ltd. Chancery House, St. Nicholas Way, Sutton, SM1 1JB, United Kingdom, Tel : +44 208 652 1990, Fax : 44 208 652 1909
Product Name	Medical Image Processing Unit (Intra Oral Imaging System)
Model Name	IOS-U15VF, IOS-U10VF, IOS-U15IF, IOS-U10IF, IOS-U15VB, IOS-U10VB, IOS-U15IB, IOS-U10IB
Classification	Class IIa According to Rule 16, Annex IX of 93/42/EEC as amended by 2007/47/EC
Notified Body	SGS United Kingdom Ltd (code no. : 0120)

Related standards;

Safety	EN 60601-1:2006, IEC 60601-1:2005+CORR.1(2006)+CORR.2(2007)
EMC	EN 60601-1-2:2007, IEC 60601-1-2:2007 CISPR 11:2009/A1:2010 EN 61000-3-2:2006/A1:2009/A2:2009 EN 61000-3-3:2008

The above product herewith complies with the requirements of Medical device directive 93/42/EEC as amended by directive 2007/47/EC Annex II (excluding Sec.4) and relevant harmonized standards applied for the above product, and a declaration of conformity with the medical device directive has been completed and signed by the manufacturer.

Digitally signed by Sajin Alexandru
Date: 2019.10.24 16:52:32 EEST
Reason: MoldSign Signature
Location: Moldova

Republic of Korea / July 23, 2015

KeeDock Kim

Deputy General Manager / Quality Management Department

For and on behalf of Rayence Co., Ltd.