

**Declaration of Conformity**

Manufacturer:

Tel:

Conformity assessment Procedure: Annex VII of the Medical Devices Directive 93/42/EEC with amendments until Directive 2007/47/EEC

Class: I, Rule 12 according to Annex IX of the MDD

Product: TRIOS™ intraoral scanner system

Type/Model: S1A, S1P

Name of Product	Type/Model	Description
TRIOS® 3 - Scanner	S1A / S1P	Handheld 3D scanner with Ultrafast Optical Sectioning™
TRIOS® 3 - Cart with pen configuration	S1A	Intraoral Scanner System
TRIOS® 3 - Cart with handle configuration	S1A	Intraoral Scanner System
TRIOS® 3 - Pod with pen configuration	S1P	Intraoral Scanner System
TRIOS® 3 - Pod with handle configuration	S1P	Intraoral Scanner System
TRIOS® 3 - Chair Integration Kit with pen configuration	S1P	Intraoral Scanner System

We, the manufacturer hereby declare that the above mentioned product complies with the following European directives with amendments, and their relevant transposition into national laws of the member states into which we place the device:

- 2007/47/EEC Medical Device Directive
- 2011/65/EEC ROHS Directive
- 2005/20/EEC Packaging and Packaging Waste Directive
- 2002/96/EEC Waste Electrical and Electronic Equipment (WEEE)

**The conformity is achieved by the fulfilling of the following main standards:**

EN ISO 1640: 2009 - Dentistry - Medical devices for dentistry  
EN ISO 14971:2003 & 2012 - Application of risk management to medical devices  
EN ISO 13485:2003 & 2012 - Medical devices - Quality management systems  
EN (IEC) 60601-1:2012 - General safety, 3rd ed.  
EN (IEC) 60601-1-2:2007 - Electromagnetic compatibility - Requirements and tests 3<sup>rd</sup> ed.  
EN (IEC) 60601-1-6:2010 - Usability, 3<sup>rd</sup> ed.  
EN (IEC) 62366:2007 - Medical Devices - Application of Usability Eng. to Medical Devices  
EN (IEC) 62471:2006 - Photobiological safety of lamps and lamps system

Date: 07 May 2015

Location: Copenhagen

Name: