

## Declaration of Conformity

**Manufacturer:** 3Shape TRIOS A/S  
 Holmens Kanal 7  
 1060 Copenhagen K.  
 Denmark  
**Tel:** +45 70 27 26 20  
**Conformity assessment Procedure:** Annex VII of the Medical Devices Directive  
 93/42/EEC with amendments until Directive  
 2007/47/EEC  
**Class:** Class I, Rule 12 according to Annex IX of the MDD  
**Product:** TRIOS® 3 Intraoral digital impression system for CAD/CAM  
**GMDN code & term:** 38597 – Dental CAD/CAM system, chairside  
**Type/Model family:** S1A-X, S1P-X, S1PI-X, S2A-X, S2P-X

Name of Product	Type/Model number	Description	Date of original CE-marking
TRIOS® 3	S1A-1	Intraoral digital impression system for CAD/CAM, Cart with handle-grip scanner	May 2015
TRIOS® 3	S1A-2	Intraoral digital impression system for CAD/CAM, Cart with pen-grip scanner	May 2015
TRIOS® 3	S1A-3	Intraoral digital impression system for CAD/CAM, Cart with Monochrome handle-grip scanner	September 2016
TRIOS® 3	S1A-4	Intraoral digital impression system for CAD/CAM, Cart with Monochrome pen-grip scanner	September 2016
TRIOS® 3	S1A-5	Intraoral digital impression system for CAD/CAM, Battery Cart with handle-grip scanner	September 2016
TRIOS® 3	S1A-6	Intraoral digital impression system for CAD/CAM, Battery Cart with pen-grip scanner	September 2016
TRIOS® 3	S1A-7	Intraoral digital impression system for CAD/CAM, Battery Cart with Monochrome handle-grip scanner	September 2016
TRIOS® 3	S1A-8	Intraoral digital impression system for CAD/CAM, Battery Cart with Monochrome pen-grip scanner	September 2016

TRIOS® 3	S1P-1	Intraoral digital impression system for CAD/CAD, Pod with handle-grip scanner	May 2015
TRIOS® 3	S1P-2	Intraoral digital impression system for CAD/CAD, Pod with pen-grip scanner	May 2015
TRIOS® 3	S1P-3	Intraoral digital impression system for CAD/CAD, Pod with Monochrome handle-grip scanner	September 2016
TRIOS® 3	S1P-4	Intraoral digital impression system for CAD/CAD, Pod with Monochrome pen-grip scanner	September 2016
TRIOS® 3	S1PI-1	Intraoral digital impression system for CAD/CAD, Chair integration pod with pen-grip scanner	July 2016

Name of Product	Type/Model number	Description	Date of original CE-marking
TRIOS® 3	S2A-1	Intraoral digital impression system for CAD/CAM, Cart with Wireless color handle-grip scanner	April 2017
TRIOS® 3	S2A-5	Intraoral digital impression system for CAD/CAM, Battery Cart with Wireless color handle-grip scanner	April 2017
TRIOS® 3	S2P-1	Intraoral digital impression system for CAD/CAM, Pod with Wireless color handle-grip scanner	April 2017



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

- 93/42/EEC Medical Device Directive
- 2011/65/EU ROHS2 Directive
- 2012/19/EU Waste Electrical and Electronic Equipment (WEEE) Directive
- 94/62/EC Packaging and Packaging Waste Directive

Date: April 6, 2017

Location: Copenhagen

Name: Flemming Thorup

A handwritten signature in blue ink, appearing to read "Flemming Thorup", written over a horizontal line. The signature is stylized and includes a large loop on the right side.

President and CEO

