



## Declaration of Conformity

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Description of Device Intraoral Scanner

Model i500

Relevant EC Directive Medical Device Directive 93/42/EEC amended by 2007/47/EC Annex 2

Classification Class I, according to rules 12 in Annex IX

### Standards applied

EN 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012

EN 60601-1-2:2014

ISO 10993-5:2009, ISO 10993-10:2010

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC for medical devices

Date of issue January 2, 2019

Signature SB Lee / CEO