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# DECLARATION OF CONFORMITY

## CE CONFORMITY

We hereby declare that the product listed below complies with the essential requirements of the Medical Device Directive:93/42/EEC and RoHS Directive :2011/65/EU based on category 8 of Annex I.
We are exclusively responsible for the DECLARATION OF CONFORMITY.
This statement of conformity is valid in connection with the release document for the respective batch of produced devices as required in the Packing list (A1-D1-19).

Product : DENTAL X-RAY
Model : PHOT-X IIs 505
MDD classification : CLASS IIb
*"CLASS IIb" has been defined by the rule 10 subclause 2 of MDD Annex IX.

The product has been designed and manufactured in accordance with the European standards as follows;

- EN 1041:2008+A1:2013
- EN ISO 10993-1:2009 /AC:2010
- EN ISO 13485:2016
- EN ISO 14971: 2012
- EN ISO 15223-1:2016
- EN 50581:2012
- EN 60601-1:2006/ A1:2013
- EN 60601-1-2:2015
- EN 60601-1-3:2008/ A1 : 2013
- EN 60601-1-6: 2010
- EN 60601-2-65:2013
- EN 62304:2006/AC:2008
- EN 62366:2008

Our full quality assurance system has been approved to MDD ANNEX II, excluding section 4 (Registration No. HD 60143723 0001) by Notified Body, TUV Rheinland LGA Products GmbH (NO.0197).

The DECLARATION OF CONFORMITY is valid until May 26th, 2024.

Representative in EU:
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Signature

Date: December 20th, 2019

Tatsuo Sugai
Managing Director

No.06