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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 Production number record (EXPJ Production number list).

Product : DENTAL UNIT AND CHAIR

Model : SP-CLEO II

MDD classification: CLASS IIa

CLASS IIa has been defined by the rule 9 of MDD Annex IX.

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

- EN 1041:2008+A1:2013
- EN 1639:2009
- EN 1640:2009
- EN ISO 6875: 2011
- EN ISO 7494-1:2011
- EN ISO 10993-1:2009/AC:2010
- EN ISO 13485:2016
- EN ISO 14971:2012
- EN ISO 15223-1:2016
- EN ISO 17664:2004
- EN 50581:2012
- EN 60601-1:2006/ A1:2013
- EN 60601-1-2:2015
- EN 60601-1-6: 2010
- 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.

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Signature

Date: December 20th, 2019

Tatsuo Sugai
Managing Director

No. 1E027LL0