Takara Belmont Corporation
2-1-1, Higashishinsaibashi,
Chuo-ku,Osaka, 542-0083, Japan
Phone : 81-6-6213-5945
Fax : 81-6-6212-3680

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 Order and shipment list (7550-2).

Product : DENTAL UNIT
Model : CLESTA II/CELEB
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 9680:2014
- 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 ISO 22374:2005
- EN 60601-1: 2006+A1:2013
- EN 60601-1-2: 2015
- EN 60601-1-6: 2010+A1:2015
- EN 62304:2006+AC:2008
- EN 62366-1:2015
- EN IEC 63000:2018

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:
TAKARA COMPANY EUROPE GmbH
Berner Strasse 18, 60437
Frankfurt am Main, Germany
TEL:+49 69 506878 0
FAX:+49 69 506878 20

Signature

Tatsuo Sugai
Managing Director

Date: May 20th, 2021