

Declaration of Conformity

According to DIRECTIVE 93/42/EEC(MDD)

Manufacturer : Nakamura Dental MFG. co., Ltd.

Address : 59-2 Minamicho, Itabashiku, Tokyo 173-0027, Japan

We declare under our sole responsibility, that the following product

Device name: Contra Angle Handpiece (Vertical reciprocating)

Model No. EC-50VT, ECN-50VT, EG-50VT, EGN-50VT, EGG-50VT, EGGN-50VT,
CGM-13V, CGN-13V, TASK STR-50VT, CGM-04V, CGN-04V,
EC-20AP, ECN-20AP, EG-20AP, EGN-20AP, EC-20APS, ECN-20APS, EG-20APS, EGN-20APS,
EH-50VT, EHN-50VT, EH-10VT, EHN-10VT, EH-20AP, EHN-20AP,

Classification : Class IIa according to the Rule 9 in Annex IX of MDD

is in conformity with the provision and requirements of REGULATION(EU) 2017/745(MDR) as transposed into national law of the member state, and the following standards and regulation:

- ISO14457:2017 Dentistry – Handpieces and motors
- ISO13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO14971:2012 Medical devices. Application of risk management to medical devices
- ISO10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- RoHS Directive 2011/65/EU

The company's Quality system is satisfied with ISO13485.

Which is certified by DNV GL Nemko Presafe AS. (Notified under No.2460)

The Technical File "Contra Angle Handpiece" systems is maintained at

Nakamura Dental MFG. co., Ltd.

59-2 Minamicho, Itabashiku, Tokyo 173-0027, Japan

The authorized representative located within the Community is :

BDSI Limited.

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Place, date : Tokyo, November 9, 2018

Signature : 中村信一

Name : Nakamura Shinichi

Title : President