
EC Declaration of Conformity

For the following equipment :

Product Name: Dental rotary instruments – Burs, **Model Designation:** FG/ RA/ HP, FG Round head, FG Round W head/ FG Inverted Cone head,/FG Inverted Cone W / Collar head,/ FG Inverted Cone-Long head

Product Classification: Class IIa

Is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the laws of Member States concerning Medical Devices Directive (93/42/EEC) amended by 2007/47/EC, Annex V of Medical Device Directive.

Complying the harmonized standards as below: EN Standard:

1. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.
2. EN ISO 14971:2012 Medical devices -- Application of risk management to medical devices.
3. EN ISO 15223-1:2016 Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
4. EN ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process
5. EN ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
6. EN ISO 10993-11:2009 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
7. EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Non-En standard:

8. ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity
9. ISO 8325: 2004: Dentistry -- Test methods for rotary instruments
10. ISO 1797-1: 2011: Dental rotary instruments. Part 1: Shanks made of metals
11. ISO 7711-1-1998+A1-2009: Dental rotary instruments--Diamond instruments. Part 1: Dimensions, requirements, marking and packaging.
12. ISO 7711-3-2004: Dentistry -- Diamond rotary instruments -- Part 3: Grit sizes, designation and colour code.
13. ISO 3823-1: 1997: Dental rotary instruments. Burs. Part 1: Steel and carbide burs.
14. ISO 3823-2-2003 +A1:2008: Dental rotary instruments. Burs. Part 2: Finishing burs

We explicitly designate Adronic Components GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

Notified Body : DNV GL Presafe (Presafe), **CE No. : 2460**

EU Rep.:

Company Name: Société NICODENT

Representative Address: BP10, 51873 REIMS CEDEX3, FRANCE.

Mr. Yao Chu Hung

Person solely responsible for making this declaration:

Manufacturer Name : Reco-Dent International Co., Ltd

Manufacture Address : 6F, No. 3 & 4F/6F No.5, Pa De St., Su Lin Dist., 238 New Taipei City, Taiwan

General Manager
(Position/Title)

cc-Hung
(Legal Signature)

2019.3.23
(Date)