SHENZHEN DENCO MEDICAL CO., LTD

Addr: Room 301,No.8 1st of road of Xiawei Industrial Zone, Zhangkengjing Community Guanhu Street, Longhua District, 518110,Shenzhen China TEL/FAX: +86 0755-23764065

EU DECLARATION OF CONFORMITY
DECLARACIÓN UE DE CONFORMIDAD

Name and address of the manufacturer: / *Nombre y dirección del fabricante*

Shenzhen Denco Medical Co.,Ltd.
Room 301, No.8 1st road of Xiawei Industrial Zone, Zhangkengjing Community Guanhu Street, Longhua District, 518110 Shenzhen, P.R. China.
（SRN in EUDAMED: CN-MF-000014271）

We declare under our sole responsibility that / *Declaramos bajo nuestra exclusiva responsabilidad que*

the medical device: / *el producto sanitario*

Dental Root Canal Instruments / Instrumentos de endodoncia

1. Dental Root Canal Instruments BlueShaper
2. Dental Root Canal Instruments Z-Glider
3. Dental Root Canal Instruments Z-Condensor
4. Dental Root Canal Instruments RetreatAll
5. Dental Root Canal Instruments SlimShaper
6. Dental Root Canal Instruments ApicalShaper
7. Dental Root Canal Instruments K-File
8. Dental Root Canal Instruments K Flex
9. Dental Root Canal Instruments Excalibur

of class: / *de clase*

Class IIa

according to Annex VIII Rule 6 of directive 93/42/EEC
de acuerdo con el Anexo VIII Regla 6 de la directiva 93/42/ECC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /
cumple las disposiciones de la directiva 93/42/CEE y sus transposiciones en las legislaciones nacionales que le son aplicables. La declaración es válida en relación con el "informe de inspección final" del aparato. /

Conformity assessment procedure: / *Procedimiento de evaluación de la conformidad*

Directive 93/42/EEC Annex V

Applied standards:/ *Estándares aplicados*:

1. **ISO 13485：2016**
2. **ISO 3630-1: 2019 Dentistry – Endodontic instruments – Part 1: General requirements**
3. **ISO 3630-2: 2013 Dentistry – Endodontic instruments – Part 2: Enlargers**
4. **ISO 3630-3: 2021 Dentistry – Endodontic instruments – Part 3: Compactors: pluggers and spreaders**
5. **ISO 3630-4: 2009 Dentistry – Endodontic instruments – Part 4: Auxiliary instruments**
6. **ISO 3630-5: 2020 Dentistry – Endodontic instruments – Part 5: Shaping and cleaning instruments**
7. **ISO 1797:2017 Dentistry-Shanks for rotary and oscillating instruments**
8. **ISO14971:2019 Medical Device – Risk Management**
9. **EN 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices**
10. **ISO 10993-1:2018 Biological evaluation of medical devices— Part 1: Evaluation and testing within a risk**
11. **ISO 10993-5:2009 Biological evaluation of medical device— Part 5: Test for in vitro cytotoxicity**
12. **ISO 10993-10:2009 Biological evaluation of medical devices— Part 10: Tests for irritation and delayed-type hypersensitivity**
13. **EN ISO 15223-1: 2012 Medical devices. Symbols to be used with medical device Labels, labelling and information to be supplied - Part 1: General requirements**

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14. ISO 17664: 2017 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices

Registration No.: / Nº Registro:	DD 60147804 0001 of Aug 7th, 2020
Expiry Date:/ *Fecha de expiración*:	2024-5-26
Notified Body: / *Organismo Notificado*	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**
Authorised Representative: *Representante Autorizado*	**Wellkang Ltd** **Enterprise Hub, NW Business Complex,** **1 Beraghmore Rd. Derry, BT48 8SE,** **Northern Ireland;** **(SRN in EUDAMED: XI-AR-000001836.)**

Shenzhen 17th Mar., 2022
Place, date / *Lugar, fecha*

ROGER WU
Name and function / *Nombre y Función*