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 H-File
9. Dental Root Canal Instruments K Flex
10. Dental Root Canal Instruments Excalibur
11. Dental Root Canal Instruments BlueShaper Pro

See attached detailed product list

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**

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

the product has not undergone relevant changes in its design or its intended purpose after the Declaration of Conformity initially issued on date Aug 7th,2020 as established in the MDCG.2020-3
el producto no ha sufrido cambios relevantes en su diseño ni en la finalidad prevista después de la Declaración de conformidad emitida inicialmente con fecha Aug 7th, 2020, según lo establecido en el MDCG.2020-3

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, March 1,2023
Place, date / *Lugar, fecha*

ROGER WU, CEO
Name and function / *Nombre y Función*