

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
12. Dental Root Canal Instruments C+ File
13. Dental Root Canal Instruments SlimShaper Pro
14. Dental Root Canal Instruments Excalibur Pro
15. Dental Root Canal Instruments Excalibur Glider

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: /

Directive 93/42/EEC Annex V

Procedimiento de evaluación de la conformidad

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**

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- 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
- 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.: / N° 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: Share info GmbH
Representante Autorizado Heerdter lohweg 83, 40549 Dusseldorf,
Germany
(SRN in EUDAMED: DE-AR-000005132)

Shenzhen, March 20, 2024

Place, date / Lugar, fecha


ROGER WU CEO
Name and function / Nombre y Función



Attached product list

Reference	Description
ZAS2103003	ApicalShaper sterile 21mm Z30/03
ZAS2103503	ApicalShaper sterile 21mm Z35/03
ZAS2104003	ApicalShaper sterile 21mm Z40/03
ZAS2105003	ApicalShaper sterile 21mm Z50/03
ZAS21ASST1	ApicalShaper sterile 21mm Z30-Z50
ZAS2503003	ApicalShaper sterile 25mm Z30/03
ZAS2503503	ApicalShaper sterile 25mm Z35/03
ZAS2504003	ApicalShaper sterile 25mm Z40/03
ZAS2505003	ApicalShaper sterile 25mm Z50/03
ZAS25ASST1	ApicalShaper sterile 25mm Z30-Z50
ZAS3103003	ApicalShaper sterile 31mm Z30/03
ZAS3103503	ApicalShaper sterile 31mm Z35/03
ZAS3104003	ApicalShaper sterile 31mm Z40/03
ZAS3105003	ApicalShaper sterile 31mm Z50/03
ZAS31ASST1	ApicalShaper sterile 31mm Z30-Z50
ZBS19000ZX	BlueShaper sterile 19mm ZX
ZBS19PROZX	BlueShaper Pro sterile 19mm ZX
ZBS21APRO4	BlueShaper Pro sterile 21mm Z1-Z4
ZBS21APRO6	BlueShaper Pro sterile 21mm ZX-Z5
ZBS21ASST4	BlueShaper sterile 21mm Z1-Z4
ZBS21ASST6	BlueShaper sterile 21mm ZX-Z5
ZBS21Z0001	BlueShaper sterile 21mm Z1
ZBS21Z0002	BlueShaper sterile 21mm Z2
ZBS21Z0003	BlueShaper sterile 21mm Z3
ZBS21Z0004	BlueShaper sterile 21mm Z4
ZBS21Z0005	BlueShaper sterile 21mm Z5
ZBS21Z0006	BlueShaper sterile 21mm Z6
ZBS21Z0007	BlueShaper sterile 21mm Z7
ZBS21ZPRO1	BlueShaper Pro sterile 21mm Z1
ZBS21ZPRO2	BlueShaper Pro sterile 21mm Z2
ZBS21ZPRO3	BlueShaper Pro sterile 21mm Z3
ZBS21ZPRO4	BlueShaper Pro sterile 21mm Z4
ZBS21ZPRO5	BlueShaper Pro sterile 21mm Z5
ZBS21ZPRO6	BlueShaper Pro sterile 21mm Z6
ZBS21ZPRO7	BlueShaper Pro sterile 21mm Z7
ZBS25APRO4	BlueShaper Pro sterile 25mm Z1-Z4
ZBS25APRO6	BlueShaper Pro sterile 25mm ZX-Z5
ZBS25ASST4	BlueShaper sterile 25mm Z1-Z4
ZBS25ASST6	BlueShaper sterile 25mm ZX-Z5
ZBS25Z0001	BlueShaper sterile 25mm Z1
ZBS25Z0002	BlueShaper sterile 25mm Z2
ZBS25Z0003	BlueShaper sterile 25mm Z3
ZBS25Z0004	BlueShaper sterile 25mm Z4
ZBS25Z0005	BlueShaper sterile 25mm Z5
ZBS25Z0006	BlueShaper sterile 25mm Z6
ZBS25Z0007	BlueShaper sterile 25mm Z7
ZBS25ZPRO1	BlueShaper Pro sterile 25mm Z1
ZBS25ZPRO2	BlueShaper Pro sterile 25mm Z2
ZBS25ZPRO3	BlueShaper Pro sterile 25mm Z3
ZBS25ZPRO4	BlueShaper Pro sterile 25mm Z4
ZBS25ZPRO5	BlueShaper Pro sterile 25mm Z5
ZBS25ZPRO6	BlueShaper Pro sterile 25mm Z6
ZBS25ZPRO7	BlueShaper Pro sterile 25mm Z7
ZBS31APRO4	BlueShaper Pro sterile 31mm Z1-Z4
ZBS31APRO6	BlueShaper Pro sterile 31mm ZX-Z5
ZBS31ASST4	BlueShaper sterile 31mm Z1-Z4

Reference	Description
ZHEDST2506	Hedstroem sterile 25mm 06
ZHEDST2508	Hedstroem sterile 25mm 08
ZHEDST2510	Hedstroem sterile 25mm 10
ZHEDST2515	Hedstroem sterile 25mm 15
ZHEDST2520	Hedstroem sterile 25mm 20
ZHEDST2525	Hedstroem sterile 25mm 25
ZHEDST2530	Hedstroem sterile 25mm 30
ZHEDST2535	Hedstroem sterile 25mm 35
ZHEDST2540	Hedstroem sterile 25mm 40
ZHEDST2545	Hedstroem sterile 25mm 45
ZHEDST3106	Hedstroem sterile 31mm 06
ZHEDST3108	Hedstroem sterile 31mm 08
ZHEDST3110	Hedstroem sterile 31mm 10
ZHEDST3115	Hedstroem sterile 31mm 15
ZHEDST3120	Hedstroem sterile 31mm 20
ZHEDST3125	Hedstroem sterile 31mm 25
ZHEDST3130	Hedstroem sterile 31mm 30
ZHEDST3135	Hedstroem sterile 31mm 35
ZHEDST3140	Hedstroem sterile 31mm 40
ZHEDST3145	Hedstroem sterile 31mm 45
ZKF21ASST1	K File Assorted 21mm 15-40
ZKF21ASST2	K File Assorted 21mm 45-80
ZKF25ASST1	K File Assorted 25mm 15-40
ZKF25ASST2	K File Assorted 25mm 45-80
ZKF31ASST1	K File Assorted 31mm 15-40
ZKFILE2106	K File 21mm 06
ZKFILE2108	K File 21mm 08
ZKFILE2110	K File 21mm 10
ZKFILE2115	K File 21mm 15
ZKFILE2120	K File 21mm 20
ZKFILE2125	K File 21mm 25
ZKFILE2130	K File 21mm 30
ZKFILE2135	K File 21mm 35
ZKFILE2140	K File 21mm 40
ZKFILE2145	K File 21mm 45
ZKFILE2506	K File 25mm 06
ZKFILE2508	K File 25mm 08
ZKFILE2510	K File 25mm 10
ZKFILE2515	K File 25mm 15
ZKFILE2520	K File 25mm 20
ZKFILE2525	K File 25mm 25
ZKFILE2530	K File 25mm 30
ZKFILE2535	K File 25mm 35
ZKFILE2540	K File 25mm 40
ZKFILE2545	K File 25mm 45
ZKFILE3106	K File 31mm 06
ZKFILE3108	K File 31mm 08
ZKFILE3110	K File 31mm 10
ZKFILE3115	K File 31mm 15
ZKFILE3120	K File 31mm 20
ZKFILE3125	K File 31mm 25
ZKFILE3130	K File 31mm 30
ZKFILE3135	K File 31mm 35
ZKFILE3140	K File 31mm 40
ZKFILE3145	K File 31mm 45
ZKFLEX2115	K Flex 21mm 15

Reference	Description
ZBS31ASST6	BlueShaper sterile 31mm ZX-Z5
ZBS31Z0001	BlueShaper sterile 31mm Z1
ZBS31Z0002	BlueShaper sterile 31mm Z2
ZBS31Z0003	BlueShaper sterile 31mm Z3
ZBS31Z0004	BlueShaper sterile 31mm Z4
ZBS31Z0005	BlueShaper sterile 31mm Z5
ZBS31Z0006	BlueShaper sterile 31mm Z6
ZBS31Z0007	BlueShaper sterile 31mm Z7
ZBS31ZPRO1	BlueShaper Pro sterile 31mm Z1
ZBS31ZPRO2	BlueShaper Pro sterile 31mm Z2
ZBS31ZPRO3	BlueShaper Pro sterile 31mm Z3
ZBS31ZPRO4	BlueShaper Pro sterile 31mm Z4
ZBS31ZPRO5	BlueShaper Pro sterile 31mm Z5
ZBS31ZPRO6	BlueShaper Pro sterile 31mm Z6
ZBS31ZPRO7	BlueShaper Pro sterile 31mm Z7
ZCFILE2106	Limas C+ 21 mm 06
ZCFILE2108	Limas C+ 21 mm 08
ZCFILE2110	Limas C+ 21 mm 10
ZCFILE2115	Limas C+ 21 mm 15
ZCFILE2506	Limas C+ 25 mm 06
ZCFILE2508	Limas C+ 25 mm 08
ZCFILE2510	Limas C+ 25 mm 10
ZCFILE2515	Limas C+ 25 mm 15
ZCFILE3106	Limas C+ 31 mm 06
ZCFILE3108	Limas C+ 31 mm 08
ZCFILE3110	Limas C+ 31 mm 10
ZCFILE3115	Limas C+ 31 mm 15
ZCON02521	Z Condensor 21mm 025
ZCON02525	Z Condensor 25mm 025
ZCON03021	Z Condensor 21mm 030
ZCON03025	Z Condensor 25mm 030
ZCON03521	Z Condensor 21mm 035
ZCON03525	Z Condensor 25mm 035
ZCON04021	Z Condensor 21mm 040
ZCON04025	Z Condensor 25mm 040
ZCON04521	Z Condensor 21mm 045
ZCON04525	Z Condensor 25mm 045
ZHD21ASST1	Hedstroem sterile Assorted 21mm 15-40
ZHD21ASST2	Hedstroem sterile Assorted 21mm 45-80
ZHD25ASST1	Hedstroem sterile Assorted 25mm 15-40
ZHD25ASST2	Hedstroem sterile Assorted 25mm 45-80
ZHD31ASST1	Hedstroem sterile Assorted 31mm 15-40
ZHD31ASST2	Hedstroem sterile Assorted 31mm 45-80
ZHEDST2106	Hedstroem sterile 21mm 06
ZHEDST2108	Hedstroem sterile 21mm 08
ZHEDST2110	Hedstroem sterile 21mm 10
ZHEDST2115	Hedstroem sterile 21mm 15
ZHEDST2120	Hedstroem sterile 21mm 20
ZHEDST2125	Hedstroem sterile 21mm 25
ZHEDST2130	Hedstroem sterile 21mm 30
ZHEDST2135	Hedstroem sterile 21mm 35
ZHEDST2140	Hedstroem sterile 21mm 40
ZHEDST2145	Hedstroem sterile 21mm 45

Reference	Description
ZKFLEX2120	K Flex 21mm 20
ZKFLEX2125	K Flex 21mm 25
ZKFLEX2130	K Flex 21mm 30
ZKFLEX2135	K Flex 21mm 35
ZKFLEX2140	K Flex 21mm 40
ZKFLEX2145	K Flex 21mm 45
ZKFLEX2515	K Flex 25mm 15
ZKFLEX2520	K Flex 25mm 20
ZKFLEX2525	K Flex 25mm 25
ZKFLEX2530	K Flex 25mm 30
ZKFLEX2535	K Flex 25mm 35
ZKFLEX2540	K Flex 25mm 40
ZKFLEX2545	K Flex 25mm 45
ZKFLEX3115	K Flex 31mm 15
ZKFLEX3120	K Flex 31mm 20
ZKFLEX3125	K Flex 31mm 25
ZKFLEX3130	K Flex 31mm 30
ZKFLEX3135	K Flex 31mm 35
ZKFLEX3140	K Flex 31mm 40
ZKFLEX3145	K Flex 31mm 45
ZKX21ASST1	K Flex Assorted 21mm 15-40
ZKX25ASST1	K Flex Assorted 25mm 15-40
ZKX31ASST1	K Flex Assorted 31mm 15-40
ZRE2102005	Excalibur sterile 21mm E20
ZRE2102505	Excalibur sterile 21mm E25
ZRE2103505	Excalibur sterile 21mm E35
ZRE2104505	Excalibur sterile 21mm E45
ZRE21ASST1	Excalibur sterile 21mm E20-E45
ZRE2502005	Excalibur sterile 25mm E20
ZRE2502505	Excalibur sterile 25mm E25
ZRE2503505	Excalibur sterile 25mm E35
ZRE2504505	Excalibur sterile 25mm E45
ZRE25ASST1	Excalibur sterile 25mm E20-E45
ZRE3102005	Excalibur sterile 31mm E20
ZRE3102505	Excalibur sterile 31mm E25
ZRE3103505	Excalibur sterile 31mm E35
ZRE3104505	Excalibur sterile 31mm E45
ZRE31ASST1	Excalibur sterile 31mm E20-E45
ZRETREATA	RetreatAll - sterile retreatment files
ZSS2100001	SlimShaper sterile 21mm ZS1
ZSS2100002	SlimShaper sterile 21mm ZS2
ZSS2100003	SlimShaper sterile 21mm ZS3
ZSS21ASST6	SlimShaper sterile 21mm ZS1-ZS3
ZSS2500001	SlimShaper sterile 25mm ZS1
ZSS2500002	SlimShaper sterile 25mm ZS2
ZSS2500003	SlimShaper sterile 25mm ZS3
ZSS25ASST6	SlimShaper sterile 25mm ZS1-ZS3
ZSS3100001	SlimShaper sterile 31mm ZS1
ZSS3100002	SlimShaper sterile 31mm ZS2
ZSS3100003	SlimShaper sterile 31mm ZS3
ZSS31ASST6	SlimShaper sterile 31mm ZS1-ZS3
ZSS21ASST3	SlimShaper sterile 21mm ZS1-ZS3
ZSS25ASST3	SlimShaper sterile 25mm ZS1-ZS3
ZSS31ASST3	SlimShaper sterile 31mm ZS1-ZS3



Reference	Description
ZSS210PRO1	SlimShaper PRO sterile files 21mm ZS1
ZSS250PRO1	SlimShaper PRO sterile files 25mm ZS1
ZSS310PRO1	SlimShaper PRO sterile files 31mm ZS1
ZSS210PRO2	SlimShaper PRO sterile files 21mm ZS2
ZSS250PRO2	SlimShaper PRO sterile files 25mm ZS2
ZSS310PRO2	SlimShaper PRO sterile files 31mm ZS2
ZSS210PRO3	SlimShaper PRO sterile files 21mm ZS3
ZSS250PRO3	SlimShaper PRO sterile files 25mm ZS3
ZSS310PRO3	SlimShaper PRO sterile files 31mm ZS3
ZSS21APRO6	SlimShaper PRO sterile files 21mm ZS1-ZS3
ZSS25APRO6	SlimShaper PRO sterile files 25mm ZS1-ZS3
ZSS31APRO6	SlimShaper PRO sterile files 31mm ZS1-ZS3
ZSS21APRO3	SlimShaper PRO sterile files 21mm ZS1-ZS3
ZSS25APRO3	SlimShaper PRO sterile files 25mm ZS1-ZS3
ZSS31APRO3	SlimShaper PRO sterile files 31mm ZS1-ZS3
ZRE25PRO25	Excalibur PRO sterile 25mm E25 3unit

Reference	Description
ZZG000021	Z-Glider sterile files 21mm
ZZG000025	Z-Glider sterile files 25mm
ZZG000031	Z-Glider sterile files 31mm
ZGE211502	Excalibur Glider 21mm
ZGE251502	Excalibur Glider 25mm
ZGE311502	Excalibur Glider 31mm

