



DECLARATION OF CONFORMITY

MANUFACTURER ADDRESS:

**3R INDÚSTRIA E COMÉRCIO EIRELI.
PTOLOMEU, 290 – CEP 04762-040
SÃO PAULO – SP – BRAZIL,**

EC REPRESENTATIVE:

**CINTERQUAL SOLUÇÕES DE COMÉRCIO INTERNACIONAL LDA
RUA FRAN PACHECO, 220 – 2ºANDAR AND 2900-374 –
SETÚBAL - PORTUGAL**

We herewith declare that the products listed on the Annex I, meet the requirements of Regulation (EU) 2017/745 of the European Parliament of the Council, 05 April 2017, concerning the medical devices and the following harmonized standards:

EN ISO 13485:2016

EN ISO 14971:2019

EN ISO 15223-1:2016

Classification: Class I

Rule: Rule 05, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

Notified body: NOT APPLICABLE – AUTO DECLARATION.

Reference Certificate:

220002SJ EN ISO 13485: 2016 dated January 6, 2022;

Sao Paulo, March 02, 2022.



Bruno Ribeiro Magri
BS In Chemical
Technical Responsible Person



ANNEX I

Brand: Microdont

Class I Medical Devices

GMDN: 16201 – Polishing Strip, Dental

NPDM: Q0199 – Dispositivos para odontología - outros

MIR – MICRODONT INTERPROXIMAL REDUCTION

M.I.R - Microdont Interproximal Reduction – Registro Anvisa: 80676920040

MIR

**Microdont
Interproximal
Reduction**

Interproximal reduction strips
Tiras para reducción interproximal

To obtain the indicated interproximal wear, follow the MIR kit's sequence (starting from the saw to the extra fine until extra coarse)

Para obtener la apertura interproximal indicada, siga la secuencia creciente (empezando por la sierra, después la tira extra fina hasta la tira extra gruesa) del kit MIR.



CODE CÓDIGO	INTERPROXIMAL WEAR DESARTE INTERPROXIMAL	GRIT SIZE GRANULACIÓN	TECHNICAL DESCRIPTION DESCRIPCIÓN TÉCNICA
10.323.100	0,05mm	SAW SIERRA	It doesn't have any abrasive. Identified by color WHITE. No tiene ningún abrasivo. Identificado por color BLANCO.
10.323.101	0,10mm	STRIP EXTRA FINE TIRA EXTRA FINA	Grit size extra fine. Identified by color YELLOW. Grano de tamaño extra fino. Identificado por el color AMARILLO.
10.323.102	0,20mm	STRIP FINE TIRA FINA	Grit size fine. Identified by color RED. Tamaño de grano fino. Identificado por el color ROJO.
10.323.103	0,30mm	STRIP STANDARD TIRA REGULAR	Grit size standard. Identified by color BLUE. Tamaño de grano regular. Identificado por el color AZUL.
10.323.104	0,40mm	STRIP COARSE TIRA GRUESA	Grit size coarse. Identified by color GREEN. Tamaño de grano grueso. Identificado por el color VERDE.
10.323.105	0,50mm	STRIP EXTRA COARSE TIRA EXTRA GRUESA	Grit size extra coarse. Identified by color PURPLE. Tamaño de grano extra grueso. Identificado por el color PÚRPURA.



MIR HANDLE MANGO MIR



CODE CÓDIGO	10.330.002
MODEL MODELO	SILVER PLATEADO

135 °C



AVAILABLE IN 1 COLOR.
DISPONIBLE EN 1 COLOR.

AUTOCLAVABLE.
AUTOCLAVABLE.

Reference	Description	UDI	
		DI	PI
10.323.001	ARCO MIR SERRILHADO - S/ DIAM. - CX C/10 - WHITE	7908516835501	120132(17)4933921(10)
10.323.002	ARCO MIR COLMÉIA - D. FACE 4MM - EF - C/10 - YELLOW	7908516835518	180132(17)4966721(10)
10.323.003	ARCO MIR COLMÉIA - D. FACE 4MM - FINA - C/10 - RED	7908516835525	120132(17)4935921(10)
10.323.004	ARCO MIR COLMÉIA - D. FACE 4MM - MEDIA - C/10 - BLUE	7908516835532	180132(17)4934321(10)
10.329.001	KIT PRIME MIR	7908516801476	180132(17)4933422(10)
10.329.002	KIT MIR 1.0 - 12 MODELOS	7908516836232	070132(17)4934722(10)