



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, January 19, 2022.



Bruno Ribeiro Magri
BS In Chemical
Technical Responsible Person



ANNEX I

Brand: Microdont

Class I Medical Devices

GMDN: 15572 – Cups

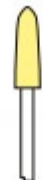
NPDM: Q0199 – Dispositivos para Odontologia - outros

PROPHY CUP

TAÇA E CONE DE BORRACHA PARA ODONTOLOGIA - POLIMENTO E ACABAMENTO

Registro ANVISA: 80676920004

COMPOSITE POLISHING KIT KIT PULIDO DE RESINA

												
CODE CÓDIGO	10.206.001	10.206.002	10.206.003	10.204.029	10.204.028	10.204.030	10.203.027	10.203.026	10.203.025	10.202.012	10.202.013	10.202.011
ISO / FIG	292	292	292	257	257	257	022	022	022	304	304	304
Ø	0.55	0.55	0.55	0.50	0.50	0.50	0.90	0.90	0.90	10.5	10.5	10.5
L1	12.5	12.5	12.5	8.5	8.5	8.5	6.0	6.0	6.0	4.0	4.0	4.0
L2	25.0	25.0	25.0	25.0	25.0	25.0	24.0	24.0	24.0	19.0	19.0	19.0
BOX CAJA	100	100	100	100	100	100	100	100	100	50	50	50
GRIT SIZE GRANULACIÓN	●	●	●	●	●	●	●	●	●	●	●	●
10.218.032	✗	✗	✗	✗	✓	✓	✗	✓	✓	✗	✓	✓
10.218.033	✗	✓	✓	✗	✓	✓	✗	✓	✓	✗	✓	✓
10.218.034	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Reference	Description	UDI
10.218.011	Composite Polishing Kit C/9	7908516833880
10.218.032	Mini Composite Polishing Kit	7908516833972
10.218.033	Fast Composite Polishing Kit	7908516833989
10.218.034	Complete Composite Polishing Kit	7908516833996