



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

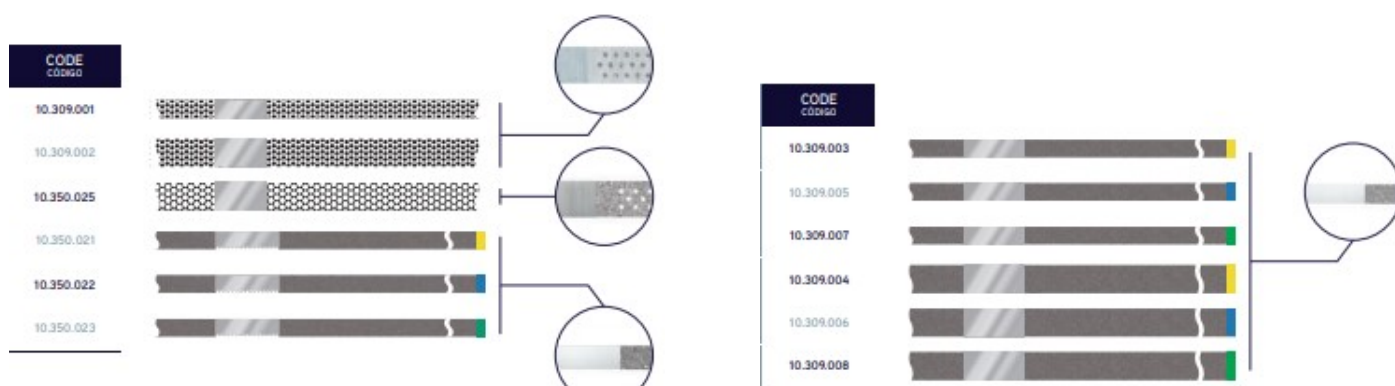
Class I Medical Devices

GMDN: 16201 – Polishing Strip, Dental

NPDM: Q01010403 – Abrasivos e pasta de polimento para odontologia

STAINLESS STEEL DIAMOND STRIP

TIRAS DIAMANTADAS DE AÇO GALVANIZADO - Registro ANVISA: 80676920013



Reference	Description	UDI	
		DI	PI
10.309.003	Stainless Steel Diamond Strips with Gapped Center - 2,5 mm - Fine	7898229802061	100132(17)4933521(10)
10.309.005	Stainless Steel Diamond Strips with Gapped Center - 2,5 mm - Médium	7898229802337	180132(17)4933622(10)
10.309.007	Stainless Steel Diamond Strips with Gapped Center - 2,5 mm – Coarse	7898229802924	180132(17)4933722(10)