



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: 34814 - Dental material, abrasive/polishing

NPDM: Q01010403 – Abrasivos e Pasta de Polimento para odontologia

DIAMOND POLISHING PASTE

PASTA DIAMANTADA - Registro ANVISA: 80676920046



CODE / CÓDIGO	10.213.001	10.213.002	10.213.003	10.213.004	10.213.005	10.213.006
L2	3.0 gr	3.0 gr	3.0 gr	6.0gr	6.0gr	6.0gr
GRIT SIZE GRANULACIÓN	1.0µ	3.0µ	6.0µ	1.0µ	3.0µ	6.0µ

Reference	Description	UDI	
		DI	PI
10.213.001	DIAMOND PASTE 3.0G/1.0µ	7908516833750	080324(17)2553321(10)
10.213.002	DIAMOND PASTE - 3.0G/3.0MICRONS	7908516833767	051124(17)4536021(10)