



DECLARATION OF CONFORMITY

MANUFACTURER ADDRESS: 3R Indústria E Comércio Ltda.
Rua: Ptolomeu, 290 – Zip Code: 04762-040
São Paulo – SP – Brazil,

EC REPRESENTATIVE: CINTERQUAL, Soluções De Comércio Internacional, Lda
Avenida Defensores de Chaves, nº4 – 1000-117- Lisboa -
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

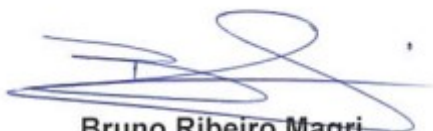
Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

Notified body: NOT APPLICABLE – AUTO DECLARATION.

Reference Certificate:

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

Sao Paulo, July 06, 2022.



Bruno Ribeiro Magri
BS In Chemical
Technical Responsible Person



ANNEX I

Brand: Microdont

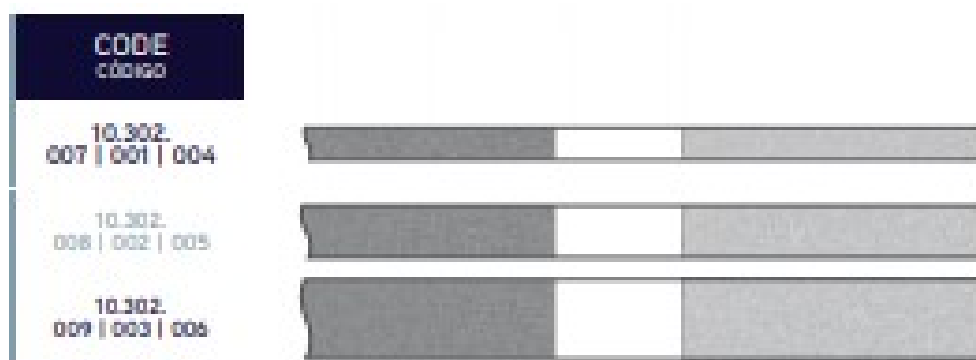
Class I Medical Devices

GMDN: 35702 – Abrasive Strip, Dental

NPDM: Q01010403 - Abrasives and polishing pastes for dentistry

ABRASIVE STRIP

TIRA ABRASIVA ODONTOLOGICA - Registro ANVISA: 80676920008



Reference	Description	UDI	BASIC UDI
10.302.001	ABRASIVE POLYESTER STRIPS 2,5MM CX C/ 100 PC	7898229800548	79085168stripsB2
10.302.002	ABRASIVE POLYESTER STRIPS 4,0MM CX C/ 100 PC	7898229800562	79085168stripsB2
10.302.003	ABRASIVE POLYESTER STRIPS 6,0MM CX C/ 100 PC	7898229800623	79085168stripsB2
10.302.004	ABRASIVE POLYESTER STRIPS 2,5MM CX C/ 150 PC	7898229800661	79085168stripsB2
10.302.005	ABRASIVE POLYESTER STRIPS 4,0MM CX C/ 150 PC	7898229800708	79085168stripsB2
10.302.006	ABRASIVE POLYESTER STRIPS 6,0MM CX C/ 150 PC	7898229800746	79085168stripsB2
10.302.007	ABRASIVE POLYESTER STRIPS 2,5MM CX C/ 50 PC	7898229800975	79085168stripsB2
10.302.008	ABRASIVE POLYESTER STRIPS 4,0MM CX C/50	7898229801323	79085168stripsB2
10.302.009	ABRASIVE POLYESTER STRIPS 6,0MM CX. C/50	7898229801569	79085168stripsB2