



## 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: 16470 – Disks Abrasive**

**NPDM: Q010501 – Fresas e Discos Abrasivos Odontológicos de Uso Único**

### **POLIDONT POLISHERS KIT**

DISCO DE POLIMENTO POLIDONT - Registro ANVISA: 80676920001

**POLIDONT COMPLETE KIT**  
KIT POLIDONT COMPLETO

| QUANTITY<br>CANTIDAD       | 1   | 100                      | 10                      | 1            |
|----------------------------|-----|--------------------------|-------------------------|--------------|
| Ø                          | 040 |                          |                         | 045          |
| DESCRIPTION<br>DESCRIPCIÓN |     | ABRASIVE POLYESTER STRIP | DIAMOND POLYESTER STRIP | MANDREL SNAP |
| GRIT SIZE<br>GRANULACIÓN   |     | 240 / 320                | 20µ                     |              |

| QUANTITY<br>CANTIDAD       | 12  | 12  | 12  | 12  | 4   | 4   | 4   |
|----------------------------|-----|-----|-----|-----|-----|-----|-----|
| Ø                          | 120 | 120 | 120 | 120 | 120 | 120 | 120 |
| DESCRIPTION<br>DESCRIPCIÓN |     |     |     |     |     |     |     |
| GRIT SIZE<br>GRANULACIÓN   | ●   | ●   | ●   | ●   | ●   | ●   | ●   |

**GRIT SIZE  
GRANULACIÓN**

- Coarse Grain | Grano Grueso
- Medium Grain | Grano Mediano
- Fine Grain | Grano Fino
- Extra Fine Grain | Grano Extra Fino

**CODE  
CÓDIGO**  
10.810.001

| Reference  | Description                                                                                                                                                               | UDI           |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 10.810.001 | Polident Complete Kit (84 abrasive discs, 1 mandrel, 100 Polishing and Finishing Polyester Strips and 10 Stainless Steel Abrasive Strip)                                  | 7908516838205 |
| 10.810.003 | Polident Introductory Kit (28 Abrasive Discs And 1 Mandrel)                                                                                                               | 7908516838212 |
| 10.810.005 | Diamond Kit Polident Introductory (12 Diamond Abrasive Discs And 1 Mandrel)                                                                                               | 7908516838236 |
| 10.810.004 | Polident Complete Kit - Extra (150 abrasive discs, 4 mandrel, 50 Polishing and Finishing Polyester Strips, 2 Arkansas Polishing Stone RA and 1 Composite Polishing Stone) | 7908516838229 |