

Declaration of Conformity

ACCORDING to (EU) 2017/745 MEDICAL DEVICE REGULATION

1. Manufacturer :

- 1) Company Name: DENTOZONE CORPORATION
- 2) Address: #1011, 10th FL, ACE HIGH-END TOWER I 5DIGITAL-RO 26-GIL, GURO-GU, SEOUL REPUBLIC OF KOREA
- 3) SRN : KR-MF-000040907

2. | | | |----|-----| | EC | REP | |----|-----|

- 1) Company Name: CMC MEDICAL DEVICE & DRUGS, S.I
- 2) Address: C/ Horacio Lengo n18 C.P 29006 Málaga-Spain
- 3) SRN: ES-AR-000000293

3. Production Information :

- 1) Product name: 99 Suction Block
- 2) Basic UDI-DI: 08800102200252
- 3) GMDN Code: 35085 Mouth gag, adjustable
- 4) Intended use : device used in dentistry to open a patient's mouth

4. Classification :

Regulation (EU) 2017/745 Class I
Class I Rule 5 MDR Regulation (EU) 2017/745

5. Conformity Assessment Route :

Annex I MDR 2017/745/

6. Applied Standard(s) :

EN ISO14971:2019, EN ISO13485:2016, EN ISO10993-1:2018, EN ISO10993-5:2009, EN ISO 10993-11:2009

EN ISO 15223-1:2021, EN ISO 20417:2021, ISO/TR 24971:2020, ISO/TR 20416:2020, MEDDEV.2.7.1 Rev.4

MEDDEV.2.12/1 Rev.8, MEDDEV.2.12/2 Rev.2, ASTM F88/F88M-15, ASTM F1980-16

We herewith declare that the above-mentioned products meet the requirement of Medical Device Regulation (EU)2017/745 and the applicable standards above.

This declaration shall cease to be valid if modifications are made to the device without our approval.



Date: 06, 03. 2024


Representative of DENTOZONE CORPORATION