

Wellmed Dental Medical Supply Co., Ltd

Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China.

Tel: 0086-755-85258716

To whom it may concern

Date : 2024.11.28

Declaration of Conformity

MANUFACTURER: Wellmed Dental Medical Supply Co., Ltd

301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China.

MANUFACTURER SRN REGISTRATION NUMBER : CN-MF-000003243

PRODUCT NAME :

<u>Face Masks</u> CP-003,CP- 007,CP-008,CP-009,CP- 010,CP-011,CP- 012,CP-014,CP4- 003,CP4-004,CP4-006,CP4- 007,CP4- 008,CP4-009,CP4-010,CP4-011,CP4-012,CP4-014,CP4- 019,ISM-ASS-23	<u>Micro Applicators</u> MA-001,MA-003,MA-004,MA-005,MA- 007,MA-008	<u>Barrier Envelopes</u> DCS-002VKB
<u>Bite Block Covers</u> HL-BC01-BIO	<u>Air Water Syringe Tips</u> AWST-RC-100	<u>Disposable Toothbrushes</u> DTB-001,DTB-003,DTB-005
<u>Cephalo sleeves</u> CS-001-150	<u>Capillary tips</u> DN-001-DB30	<u>Braided Cotton Rolls</u> BCRG-002
<u>Cardboard Protectors</u> CDP-002	<u>Full Chair Sleeves</u> HL-6576B	<u>Cotton Roll Substitutes</u> DA-001,DA-002
<u>Surgeon Caps</u> SCT-007, SCT-008, SCT-009, SCT-010, SCT-011		

Applicable Standards:

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417: 2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2023

ISO 13485: 2016

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CLASSIFICATION: Class I (RULE 1)

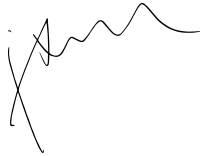
We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Eu representative :SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
SRN: NI -AR-NNN0009247

SIGNATURE:

Name: Renxian Tang
Signed:



Position in organization: CEO

Date: 28th November, 2024 SHENZHEN, CHINA