PREMIUM PLUS INTERNATIONAL LIMITED

Flat 1001, Yuen Long Trading Centre, No. 33 Wang Yip Street West, Yuen West, Yuen Long, Hong Kong
Tel: +852-2761-3211 Fax: +852-2761-3210

Date: 26/02/2024

CE Certificate Manufacturer Declaration

To whom it may concern,

We, Premium Plus International Ltd., hereby confirm as of 21/02/2024 the CE Certificate No: G2 062760 00113 Rev. 00 has been extended in accordance with Regulation 2023/607.

Premium Plus International Ltd. CE Certificate under Directive 93/42/EEC on Medical Devices No: G2 062760 00113 Rev. 00 shall remain valid for the devices indicated in Annex I, after the date indicated on the certificate until the 31/12/2028 as per paragraph 3a Article 1(1) of Regulation 2023/607.

Premium Plus International Ltd. signed a written agreement with Notified Body TÜV SÜD Products Service GmbH for conformity assessment based on MDR (EU) 2017/745 on 16/01/2024, before the CE Certificate expiry date of 26/05/2024.

Premium Plus International Ltd. guarantees that all manufactured devices will continue to comply with Directive 93/42/EEC.

In accordance with Regulation 2023/607 devices lawfully placed on the market pursuant to Directive 93/42/EEC may continue to be made available on the market or put into service indefinitely.

Yours Sincerely,

[name] Roy Wei

[signature] 

[position] General Manager

Premium Plus International Ltd.

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APPENDIX I

DEVICES COVERED WITH THE DECLARATION

Generic Device Group	Product Code
Dental Prophy Cups	220, 221, 225, 226, M222, P222, S221, S222, T-220, T-221, T-M222, T-P222, T-S221, T-S222, SS-222, SS-T222
Dental Prophy Brushes	260F, 260T, 261F, 261T, 262F, 262T, 265, 265-1, 268, 268-1, 269, 269-1, SS-262F, SS-262T, SS-265, SS-268, SS-269
Dental Prophy Angles	3399-090, C3399-090, CS3399-090, CT3399 090, 3399-105, C3399-105, CS3399-105, CT3399-105, 3399-090F, 3399-090T, 3399-105F, 3399-105T, CT3399-60, CTS3399-60, C3399-60-261F, C3399-60-261T, C3399-60-269
Dental Suction Tips	301, 308, 001, ST001, 205M, 206P, 335L, 335M, 336P, 005L, 005M, 006P, 007, 008, 008V, 009, 009V
Dental Saliva Ejectors	300, 333
Dental Syringe Tips	012, 018, 028, G-018, G-028, 011A, 011E