



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: Forlong Medical Co., Ltd
Address: No. 33 Zhihui Road Huishan District Wuxi
China
Tel: 0086 510 83599863

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document MDR-FL02.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: Tray Paper
Model: 33cm*45cm
Special specifications according to customer needs
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

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

Signature:



Date: 2023.02.23

Position: GM

Place: Wuxi China



World Class Technology Corporation (WCT)
1300 NE Alpha Drive
McMinnville, Oregon 97128 USA

EC Declaration of Conformity

UMDNS Code	GMDN Code	UMDNS Description	Classification
16351	58106	Alginate Mixing Systems	I
-26598	44828	Cheek Retractors	I
30101	31797	Coil Springs (Open/Closed)	II
-29651	N/A	Dental Bibs	I
-3536	35850	Dental Impression Trays	I
16189	45251	Dental Wax	I
-30528	44732	Elastics, Ligatures, Chains, Bumper Tubes, Threads	Ila
16191	31757	Face Mask	I
16192	35700	Facebows	I
18082	44730	IPR Strips/Spacers, Teeth	I
15652	15652	Loupes	I
39870	46581	Lingual Buttons	Ila
33128	41678	Lip Bumper	Ila
-27707	41678	Mouth Protector	I
16198	46338	Orthodontic Bands	Ila
16360	46581	Orthodontic Brackets	Ila
-20116	31750	Orthodontic Cement/Adhesive	Ila
11160	33209	Orthodontic Hand Instruments	I
16199	31759	Orthodontic Tube	Ila
16204	41397	Orthodontic Wire	Ila
12374	41678	Quad Helix/Lingual Palatal Bars	Ila
36761	N/A	Retainer Cases	I

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World Class Technology Corporation, located at 1300 NE Alpha Drive, McMinnville, Oregon 97128 USA, declares under its sole responsibility that the above listed medical devices comply with the essential requirements of the Annex VII of Medical Device Directive no. 93/42/EEC as amended by Directive 2007/47/EEC.

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen to act as European Authorized Representative according to the provisions of Article 14, §2 of Directive 93/42/EEC.

This product also complies with the ISO 13485 Standard. All applicable verification and validation activities, including the Risk Assessment Process, were conducted as described in ISO 14971. The results of the design, development and manufacturing activities demonstrate that the Essential Requirements and applicable Annex V requirements of the MDD 93/42/EEC have been met.



Notified Body:

TUV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nurnberg
Germany
Notified Body No.: 0197
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Grace deVos *Regulatory Affairs*

2020-07-28

Date

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