EC Declaration of Conformity

1.Name of Manufacturer:

Hangzhou DTC Medical Apparatus Co.Ltd

Add:Room 302, Building 1, No. 5, JiuQuGang Road, LiangZhu Street, YuHang District, Hangzhou,

Zhejiang Province, P.R. China Tel:+86-571-89774162 Fax:+86-571-89774164 Website:www.dtchz.com Email:jaymie@dtchz.com

2. European Community Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: +49-40-2513175 Fax: +49-40-255726 E-mail: shholding@hotmail.com

We, the manufacturer, herewith declare that the products

Bath back rest/seats(Adaptable Class III Mask Blues)----- UMDNS-Code:16191

Dental Mirrors(Reflectors)----- UMDNS-Code:32865

Orthodontic Bracket Measuring Gauges (Bracket positioning gauges)(Force

gauge)-----UMDNS-Code:16664

Orthodontic Pliers----- UMDNS-Code:12726

Ligture Directors(Arch Turrets)----- UMDNS-Code:16664

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

The product concerned has been designed and manufactured under a quality management system according to Annex V of Council Directive 93/42/EEC (MDD 93/42/EEC as amended by directive 2007/47/EC).

Compliance of the designated product with the Council Directive 93/42/EEC (MDD 93/42/EEC as amended by directive 2007/47/EC) has been assessed and certified by the Notified Body

> TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD 2184523-1 Issue date: 2020-08-11 Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Council Directive 93/42/EEC (MDD 93/42/EEC as amended by directive 2007/47/EC). This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Hangzhou DTC Medical Apparatus Co.,Ltd

Add: Room302, Building 1, No. 5, jiuqugang Road, Liangzhu Street, Yuhang District, Hangzhou Zhejiang Province,

P.R. China

argzhou, China, 1, Jan, 2022
Place. date

Jaymie Koney Soules Director

Legally binding signature, Function

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Tel: +49-40-2513175 Fax: +49-40-255726 E-mail: shholding@hotmail.com

We, the manufacturer, herewith declare that the products

Orthodontic Brackets----- UMDNS-Code:16360
Orthodontic Tubes----- UMDNS-Code:16199
Orthodontic Bands----- UMDNS-Code:16198
Orthodontic wires----- UMDNS-Code:16204
Lingual Buttons----- UMDNS-Code:12035
Crimpable Hooks----- UMDNS-Code:15225



The product concerned has been designed and manufactured under a quality management system according to Annex V of Council Directive 93/42/EEC (MDD 93/42/EEC as amended by directive 2007/47/EC).

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Page 1/1