大连荣邦医疗卫生用品股份有限公司 Dalian Rongbang Medical Healthy Devices Co.,Ltd

地址: 大连市甘井子区大连湾镇毛茔子村

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Declaration of Conformity

Dalian Rongbang Medical Healthy Devices Co., Ltd. Manufacturer:

Address: Maoyingzi Hamlet, Dalianwan Town, Ganjingzi District,

Dalian 116113 Liaoning, China.

SRN: CN-MF-000022752

European Representative: Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The

Hague, Netherlands.

SRN: NL-AR-000000121

Name of Device: Tongue Depressors Model No.: W-1609, W-1617, W-1620 Basic UDI-DI: 697306998TD-sterileHV

Classification MDD Class I s

Conformity Route: Self Declaration

We herewith declare in our own responsibility that the above mentioned products meet the council MDD directive 93/42/EEC. It is possible to use CEmarking to demonstrate the compliance with this MDD Directive.

Standards: EN ISO 13485: 2016, ISO 14971:2019, EN 1041:2008+A1:2013,

EN 62366:2015+AC:2015, EN ISO 15223-1:2021

The EU declaration of conformity is issued under the sole responsibility of manufacturer.

On behalf of: Dalian Rongbang Medical Health

Dalian, China Place: Date of issue:

Signed by: Position: General Manager