

Shanghai ISO Medical Products Co. Ltd CE Technical Documentation Sponge stick Manufacturing site activities	Document No	CE/25-09
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**Shanghai ISO Medical Products Co. Ltd**

999 Liu Chen Rd, Pudong New Area Shanghai, P.R. China

**Declaration of Conformity**

**For the following products:**

Sponge stick

(Product Name)

The shape of sponge: Plum, Hexagon, rectangle or rectangle, etc

For plum and hexagon	Diameter	10mm~40mm
	Height	10mm~50mm
For rectangle	Length	20mm~60mm
	Width	10mm~40mm
	Height	10mm~60mm

The length of stick : 7.5~20cm

(Model Designation)

Sponge stick is intended for external cleaning and oral care

(Intended purpose)

T19(Type Plum) T20(Type hexagon) T21(Type rectangle)

(Basic UDI-DI)

*hereby declare under our own responsibility, that this product family complies with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR)*

Applicable harmonized standards are:

EN ISO 10993-1:2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN 1041:2008, EN ISO 15223-1:2012, EN 980:2008, ISO 14644-1: 1999, ISO 14698-1: 2003, ASTM D 1489-09(2016), EN ISO 11737-1:2006, EN ISO14971: 2012,

**Conformity Assessment Route:**

Annex II+III

**Classification: Class I**

**The following European Authorized Representative is stated to the declaration:**

Company Name: Lotus NL B.V.

Company Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

**The following manufacturer is exclusively responsible for making this declaration:**

Company Name: Shanghai ISO Medical Products Co., Ltd.

Company Address: 999 LiuChen Rd. Pudong New Area Shanghai,P.R.China.

Tang Xinyi

(Legal Signature)

Registration Specialist

(Position/title)

2021-04-16

(Date)