

**Änderungsnummer / Change Master: C2365\_593**

**Objektverknüpfungen / Object Links:**

JBK 40039014 000 01 MDR Propax Gauze Swabs, NST, Type 13

**Dokumentenstückliste / References:**

Status	Responsible	Date
IE in Erstellung	DEHNINA	20.05.2021
AF Freigabeanford.	DEHESSO	20.05.2021
FR freigegeben	DEHKIRO	21.05.2021

Shanghai ISO Medical Products Co. Ltd CE Technical Documentation Gauze swabs Manufacturing site activities	Document No	CE/26-09
	Version	A
	Effective Date	15-April-2020

**Shanghai ISO Medical Products Co. Ltd**

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

**Declaration of Conformity**

**For the following products:**

Gauze swabs (Class I)

(Product Name)

Width: 2cm~50cm; Length: 2cm~50cm

(Model Designation)

Gauze swabs are intended for cleaning wound and absorbing blood

(Intended purpose)

(Basic UDI-DI)

T22(Type 13 Heavy) T23(Type 13 heavy) T24(Type 13 heavy) T25(Type 17) T26(Type 13 Light)  
 T27(Type 12) T28(Type 20) T29(Type 22)

*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 13726-1:2002EN、 EN 13726-4-2003、 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)

2020-04-15  
 (Date)