

Shanghai Kinmed Import & Export Co., Ltd.		CE Technical Documentation	
1	Declaration of Conformity	Doc. No.	KM-CE 43-01
		Version	A/0
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		Validated Date	2011-11-01

Manufacturer

Name: Shanghai Kinmed Import & Export Co., Ltd.

Add: Suit L, 12th Floor, No.588 Yingkou Road, 200433, Shanghai, China

Tel: 0086-21-61172171/61172172 Fax: 0086-21-61172173

European Representative

Name: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80 , 20537 Hamburg, GERMANY

Tel: 0049-40-2513175 Fax: 0049-40-255726

Product Name: Wooden Tongue Depressors

Classification and relevant Rule of MDD: I Sterile MDD Annex IX, rule 5

Sizes/Models: 150×18×1.6, 140×14×1.6, 120×14×1.6, 200×25×2.2, 150×19×1.6, 114×10×2.0,
150×18×1.6, 150×18×1.6, 150×18×1.6

The UMDNS code: 16486

Approach of product conformity: Annex V.3

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promise of the manufacturer and the European Representative.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)

Standard Applied:

All applicable harmonized Standards (published in the Official Journal of the European Communities)
See KM-CE 43 Annex 1 "List of ENISO, EN and ISO Standards"

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse. 65, 80339 München, Germany

Identification Number: 0123

CE Certificate No.: G2S 17 06 79732 009

Effective Date of CE Certificate: 2017-9-27

Date CE mark was affixed: after certification

Signature of issue person:

Position: General Manager

Name: Mr. Zhong Zhigang

Date: 2017-9-27

Place: Shanghai, P. R. China

For and on behalf of

上海季美进出口有限公司
SHANGHAI KINMED IMPORT & EXPORT CO., LTD.

郑志刚

Authorized Signature(s)

