

Verification of Compliance



No. EC.1282.1P140922.WWTTS56

Certificate's Holder: Weishan Weilong Trading Co., Ltd.
No. 1, Guangming Road, Xiping Township, Weishan
County, Jining, Shandong, China (Mainland)

Product: Tongue Depressor
Model(s): 114*15*2mm, 120*15*2mm, 125*16*2mm,
130*15*2mm, 140*15*1.6mm, 140*18*1.6mm,
140*18*2mm, 150*18*1.6mm, 150*18*2mm

Verification to Standard:
EN ISO 10993-10:2010

related to:
Directive 93/42/EEC (Medical Devices)

Remark: This Verification of Compliance has been issued on a voluntary basis. ECM confirms that a Technical Construction File (TCF) is existent for the above listed product(s). The TCF satisfactorily covers the essential requirements of the above listed standards related to **Directive 93/42/EEC (Medical Devices)**. Other relevant Directives have to be observed in case they are applicable. This Document is only valid for the equipment and configuration described and in conjunction with the TCF detailed above. Whereas the Manufacturer is responsible of the certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market. The Manufacturer is also responsible of the internal production control to ensure the product(s) are in compliance with the essential requirements of the above mentioned Directive(s). This certificate can be checked for validity at www.entecerma.org

Date of issue 22 SEPTEMBER 2015

Expiry date 21 SEPTEMBER 2020

Certification Chief Manager
Tim Mahan



Certification Deputy Manager
Viola Miller



Ente Certificazione Macchine Srl

Via Ca' Bella, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 📠 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

E C Declaration Of Conformity

According to annex VII of the Council Directive 93/42/EEC concerning medical devices
We,

WEISHAN WEILONG WOOD PRODUCT CO., LTD(W.W.L)
No.1 of Guangming Road, Xiping Town, Weishan County,
Jining City, Shandong Province,
China
Tel:86-15621833085 Fax:86-537-8341698

Our Factory

WEISHAN WEILONG WOOD PRODUCT CO., LTD
No.1 of Guangming Road, Xiping Town, Weishan County,
Jining City, Shandong Province,
China

Declare under our sole responsibility that the following non-sterile products under Class I:
Wood tongue depressor, under below brand name see Appendix I

Meets the provisions of the council Directive 93/42/EEC concerning medical devices which apply to them. The products are intended to be used for Non-sterile practice in absorbing the body fluids and to act as a barrier between the skin and the surrounding environment.

Conformity assessment was performed according to the article II,Annex VII sections 3.
The following standards are used to prove the products conformity with the essential requirement of the above directive

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Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Ente Certificazione Macchine Srl
Via Ca' Bella, 243-Loc. Castello Di Serravalle
40053 Valsamoggia(BO)-ITALY
Tel: +39 051 6705141 Fax +39 051 6705156
info@entecerma.it www.entecerma.it

For and on behalf of
WEISHAN WEILONG WOOD PRODUCT CO., LTD
Sherry Wei
.....
Authorized Signature(s)

Li Xiang Bo Manager