

EC Declaration of Conformity

Document number / version : WUXI-04-CE/B

Manufacturer: Wuxi Medical Instrument Factory Co., Ltd

Add: No.43 Xixin Road ,Zhangjing , Xibei Town,Wuxi City,Jiangsu,214194 China

European representative : Lotus NL B.V.

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

Tel: 0031626669008

Product: Alcohol Pad

Model: D-010(aluminum foil 50*x50MM, non-woven 65*30MM, 70% Isopropyl alcohol);

Classification: I According to Rule 15, Annex IX of MDD 93/42/EEC amended by 2007/47/EC

Harmonized Standards:

EN ISO 15223-1:2012, EN 1041:2008, EN ISO 14971:2012, YZB(SU)XI 0053-2011

Conformity Assessment Route: Annex V, MDD 93/42/EEC amended by 2007/47/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Ding Yan Ping/ General Manager

Signature:

Date: Oct.25th. 2018

