

WUXI MEDICAL INSTRUMENT FACTORY CO., LTD

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

Declaration of Conformity

Manufacturer: Wuxi Medical Instrument Factory Co., Ltd

Address: No.43 Xixin Road, ZhangJing, Xibei Town, Wuxi City, Jiangsu 214194, China

European Agent: LotusNL B.V.

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

Tel: 0031626669008

E-mail: peter@lotusnl.com

Product Description: Stethoscope

Model Information:

DR-400D; DR-510; DR-530

Classification(MDD, Annex VI): I

We herewith declare that the above mentioned products meet the provision of following EC Council directives and standards. All supporting documents are retained under the premises of the manufacturer and notified body.

DIRECTIVES

General applicable directives:

Medical device Directive: EC Directive 93/42/EEC Annex II , Article 3, Full Quality Assurance System Medical Device.

Standard: all applicable harmonized standards.

Notified Body: TÜV Rheinland LGA Products GmbH-Tillystraße 2,-90431 Nürnberg

Place Date: Wuxi city, Jiangsu, China. 02.12.2020

Signature:

Name: Ding Yan Ping

Position: General manager

