CE

DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:

Company name: Wuxi Medical Instrument Factory Co.,Ltd

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

Tel: +86-510-83791818

E-mail：wxmedical@vip.126.com

SRN: CN-MF-000002277

Whose Authorized Representative:

Name:： Lotus NL B.V.

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

E-mail：peter@lotusnl.com

SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	Alcohol Pad(Alcohol Swab)		
Model	D-014,D-010,D-013,D-015, D-016		
Intend use	Alcohol pad(Alcohol swab) are used for cleaning skin in hospital and home. This product is non-sterile.		
EMDN code	Z120113	**Basic UDI-DI**	69486470ALCOHOLPADS94
Classification and rule	I, rule1	**Conformity Assessment Route**	Article 19, Annex II and Annex III

Applicable Standards and CS:

ISO 13485:2016	ISO 14971:2019	ISO 10993-1:2018
ENISO 10993-5:2009	ENISO 10993-10:2013	ENISO 15223-1:2021
EN 1041:2008	EN62366-1:2015	EN 14885:2015
EN 13697:2012	EN 14348:2005	EN 13727:2012

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Signed: Ding Yanping **Name of authorized signatory:** Yanping Ding

Date: October 8, 2021 **Position held in the company**: General Manager

Place: Jiangsu , China Wuxi Medical Instrument Factory Co.,Ltd

WUXI MEDICAL INSTRUMENT FACTORY CO., LTD.
无锡市医用仪表厂有限公司