



DECLARATION OF CONFORMITY

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

Manufacturer:

Company name: Jiang Su Jaysun Glove Co., Ltd.
Address: No.199, Jianling Road, Economic
Developing Area, Suqian City, Jiangsu Province,
China
Tel: 86-527-8831-9931

Whose Authorized Representative:

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e
Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Product Name	Medical Device	Device Class	Model	Basic UDI-DI
Disposable Vinyl Gloves	Gloves	I, Rule1 (Annex VIII of MDR)	Small, Medium, Large, X-Large	/

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

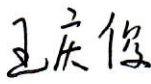
Applicable Standards:

ISO 13485:2016
ENISO 10993-5: 2009
EN 1041:2008
EN 15223-1:2016

ISO 14971:2019
ENISO 10993-10: 2013
EN 455-1:2000
ISO 374-1:2016

ISO 10993-1: 2018
EN 455-2:2015
EN 455-3:2015
EN 420:2003+A1:2009

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 on:  2023.7.12

Place: Jiang Su, China

Name of authorized signatory: Wang Qingjun
Position held in the company: General Manager

Seal/Stamp:

Jiang Su Jaysun Glove Co., Ltd.

