



DECLARATION OF CONFORMITY

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

Manufacturer:

Company name: Jiangsu sunshine group co.,ltd
Address: No.18, Taoxin Road, Xinqiao Town,
Jiangyin city, Jiangsu Province, P.R. China
Tel: +86 0510-86121888

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
Medical disposable protective clothing (non sterile)	Gowns	I, Rule I (Annex VIII of MDR)	Coverall	

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:

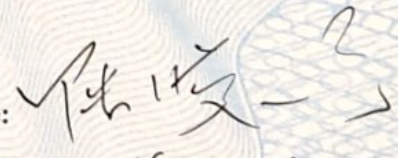
ISO 13485:2016
ENISO 10993-5: 2009
EN 1041:2008

ISO 14971:2019
ENISO 10993-10: 2013
EN 15223-1:2016

ISO 10993-1: 2018
EN 14126-2003

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.

Name of authorized signatory: Xiaoming Lu

Signature: 

Position held in the company: General Manager

Date:

13-04-2020

Place: Jiangsu, China

Jiangsu sunshine group co.,ltd

Seal/Stamp:

