



## 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 isolation gown (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 13795-1:2019

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:** 