



# DECLARATION OF CONFORMITY

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

**Manufacturer: Whose Authorized Representative:**

Company name: Jiangxi Jaysun medcare CO., Ltd  
Address: No.1 Jaysun Road, Penghuwan Industrial park Pengze County, Jiujiang, JiangXi, China  
332708  
Tel: 86-792-7198155

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 Examination Gloves	Gloves	I, Rule 1 (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: 2020.4.7

Name of authorized signatory:

Position held in the company: General Manager

Place: JiangXi, China

Seal/Stamp:

Jiangxi Jaysun medcare CO., Ltd

