



DECLARATION OF CONFORMITY

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

Manufacturer:

Name: SHAN DONG DS SAFETY TECHNOLOGY CO.,LTD
Address: WEST OF YAOQIAN ROAD,YAOGEZHUANG COMMUNITY ECONOMIC DEVELOPMENT ZONE,GAOMI CITY,WEIFANG CITY,SHANDONG PROVINCE,CHINA
Telephone:0536-2587046
Email: rita@dsgloves.com

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
DISPOSABLE NITRILE EXAMINATION GLOVES	Gloves	I, Rule1 (Annex VIII of MDR)	DS2003

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:

<i>ISO 13485:2016</i>	<i>ISO 14971:2019</i>	<i>ISO 10993-1: 2018</i>
<i>ENISO 10993-5: 2009</i>	<i>ENISO 10993-10: 2013</i>	<i>EN 388-2016</i>
<i>EN 1041:2008</i>	<i>EN 15223-1:2016</i>	<i>EN 455-1:2020</i>
<i>EN 455-2:2015</i>	<i>EN 455-3:2015</i>	

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: Lei Zhao

Signature: *Lei Zhao*

Position held in the company: General Manager

Date: *2021-02-19*

Place: Shandong, China

Seal/Stamp:

SHAN DONG DS SAFETY TECHNOLOGY CO.,LTD