

## EU and UKCA Declaration of Conformity No 001

1. PPE

Glove Description: **Polyethylene Gloves (PE glove)**  
Product Reference: **SD-PE -001**  
Size: **13**  
Risk Category: **III**

2. Name and Address of the manufacturer

Manufacturer: **Shanghai Shengda Medical Applications Co., Ltd.**  
Address: **No. 608, Xingwen Rd., Jiading, Shanghai, China**

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:  
**Shanghai Shengda Medical Applications Co., Ltd.**

4. Object of the declaration (color image shown as below):



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

**Registration (EU) 2016/425 on Personal Protective Equipment  
Regulation 2016/425 as brought into UK law and amended**

6. References to the relevant harmonised standards used in relation to which conformity is declared:

**EN ISO 21420:2020  
EN ISO 374-1:2016+A1:2018**

7. The notified body:

**CTC** (Notified Body No: 0075), 4, rue Hermann. Frenkel - 69367 Lyon Cedex 07, France,  
performed the EU type-examination (Module B) and issued the EU-Type Examination Certificate:  
**0075/4472/162/12/21/2127**  
**SATRA Technology** (Approved Body No: 0321), Wyndham Way, Telford Way, Kettering,  
Northamptonshire, NN16 8SD, United Kingdom,  
performed the UKCA Type-Examination (Module B) and issued the UKCA Type-Examination Certificate:  
**AB0321/22248-01/E00-00**

8. The PPE is subject to the conformity assessment procedure (conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)) under surveillance of the notified body **CTC** (Notified Body No: 0075), , **SATRA Technology** (Approved Body No: 0321)..

Signed for and on behalf of:

**Shanghai China**      **Sep. 14, 2022**

**Place**                      **date of issue**



**Zongqiu Su,**      **Title (G.M)**