

# Declaration Of Conformity

## Manufacturer:

**Name:** S.E.S Healthcare Products(Hefei) Co., Ltd.

**Address:** Fengxia Road Shuang Feng Development Zone, Hefei, China, 231131

**E-mail:** cyndichai@seshealthcare.com

**Tel:** +86-55166391161

## Whose Authorized Representative:

**Name:** Shanghai International Holding Corp.GmbH (Europe)

**Address:** Eiffestrasse 80, 20537 Hamburg, Germany

We, the manufacturer, herewith declare that the product(s)

|                     |  |                       |                                |
|---------------------|--|-----------------------|--------------------------------|
| <b>Product Name</b> | Isolation Gown   | <b>Classification</b> | I, (MDR, Annex VIII Rule 1 )   |
| <b>UMDNS Code</b>   | 15037 (Gowns, Isolation)   | <b>Model</b>          | XS,S,M,L,XL,XXL,XXXL,Free Size |
| <b>Intend Use</b>   | It is used to minimize the spread of infective agents to patients' surgical sites and equipment, through prevention of dispersal of bacteria-carrying skin scales from the operating room staff, thereby helping to prevent post-operative surgical site infections. It is mainly used for the general isolation of clinics, wards and laboratories in medical institutions. |                       |                                |

Meet(s) the provisions of the REGULATION (EU) 2017/745 which apply to them.

**Conformity Assessment Route:** Article 19, Annex II, Annex III and Annex IX according to REGULATION (EU) 2017/745.

### Applicable Standards:

*ISO 13485:2016*                      *EN ISO 14971:2012*                      *ISO 10993-1: 2018*  
*ISO 10993-5: 2009*                      *ISO 10993-10:2010*                      *DIN EN 14126:2004*  
*EN 1041:2008*                      *EN 15223-1:2016*

The aforementioned device has been assigned to class I according to Appendix VIII of the Regulation (EU) 2017/745. It bears the CE mark



following the conformity assessment procedures relating to the EU Declaration of Conformity set out in Annex IX of Regulation (EU) 2017/745.

The above mentioned declaration of conformity is exclusively under the responsibility of

**S. E.S Healthcare Products(Hefei) Co.,Ltd**

**Fengxia Road Shuang Feng Development Zone, Hefei, China, 231131**

**Name of authorized signatory:** Chai Guihua

**Signature:**

**Position held in the company:** Management Representative

**Date:** 2020-05-15



**Place:** Anhui Province, China

**Seal/Stamp:**