

**EC Declaration of Conformity**  
**Regarding Medical Device Directive(93/42/EEC)**  
**including Directive 2007/47/EC**

**Applicant**

Name: Xiantao WellMed Protective Products Co.,Ltd  
Address: Special No.1 Hefeng Industrial Park, Pengchang Town, Xiantao City, Hubei Province

**EC Representative**

Name: SUNGO Europe B.V.  
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product**

Name: isolation gown

Type: YH-IG (reverse wear style) /YH-CO (suit style) /M(110×135) /L (115×137) /XL (120×140) /M(160×125) /L (165×130) /XL (170×135) or Customized

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)  
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

- EN ISO 14971:2012
- EN ISO 15223-1:2016
- EN 1041:2013
- EN ISO 10993-1:2009/AC:2010
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013

*On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.*

Signature:

Date:2020/5/6



A handwritten signature in blue ink, written over a horizontal line.

*Authorized Signature (S)*