



DECLARATION OF CONFORMITY
Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Hubei Xianmeng Health Protection Commodity Co.,Ltd
Address: Industrial 1st Road, Chenchang Town, Xiantao , Hubei, China.

EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Non-woven Gowns
Type: S,M,L,XL,XXL,XXXL
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment
Procedure: Annex II+III of Regulation (EU) 2017/745
SRN: CN-MF-000002349
Basic UDI-DI: 697360954gownsJX

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

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|----------------------|----------------------|
| EN ISO 14971:2012 | EN ISO 15223-1:2016 |
| EN 1041:2008+A1:2013 | ISO 10993-1:2018 |
| EN ISO 10993-5:2009 | EN ISO 10993-10:2013 |

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

Hubei Xianmeng Health Protection Commodity Co.,Ltd.

Signature: _____

Name / Position: Du Zhu / GM

Date: _____

Place: Hubei / China

