



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: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

Product Name: Non-woven Caps
Type: 16",18",21",610x110mm,640x130mm
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: 697360954CapWS

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

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: 2017.1.10

Place: Hubei / China