DECLARATION OF NOTIFICATION

As the EU Representative, SUNGO Europe B.V., hereby declare that:

Shandong Zhushi Pharmaceutical Group Co., LTD
No.6 Shande Road,Shan County, Heze City, Shandong, China 274300

has signed the EC Declaration of Conformity in agreement with the Annex VII of the European Directive 93/42/EEC on In Medical Device Directive and has submitted the required technical documentation, for the following MDD products (for professional use only):

Name Device	Reference Numbers
Face Mask	20200674
Isolation Gown	20200674
Protective Suit	20200674

The notification to the Netherlands Competent Authorities has been carried out on March 17, 2020 by SUNGO Europe B.V., the appointed Authorized Representative of Shandong Zhushi Pharmaceutical Group Co., LTD

Information on the notification to the competent Authorities of other European countries is available upon request.

SUNGO Europe B.V.
Authorized Representative

File No: CE-MDR-ZS-01‑02

CE   CE

EC Declaration of Conformity

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:

Name: Shandong Zhushi Pharmaceutical Group Co., LTD
Address: No.6 Shande Road, Shan County, Heze City, Shandong, China 274300

European Authorized Representative :

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

Product:

Name: Face Mask
Model: Bandage type,Fat type,Foldiing type,Child
type;22cm*9.5cm,20cm*9cm,18cm*9.3cm,17.5cm*9.5cm,16.5cm*9.5cm,14.5*9.5cm,14.5
cm*9cm,12cm87cm;or customizd
Classification: I
Rule: According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation
(EU)2017/745.

SRN: -
UDI: -

Conformity Assessment Route:

Annex II&III in Medical Device Regulation (EU 2017/745)

We confirm our product can meet the requirement of Medical Device Regulation and the
following harmonized standards:
EN ISO 13485:2016/EN ISO 14971:2012
EN ISO 15223-1:2016 / EN 1041:2013
ISO 10993-1:2018 / EN ISO 10993-5:2009 / EN ISO 10993-10:2013
EN 14683:2019

Signature： *Jerry*   Date：2020/3/18

Position: