



## 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, Folding type, Child

type; 22cm\*9.5cm, 20cm\*9cm, 18cm\*9.3cm, 17.5cm\*9.5cm, 16.5cm\*9.5cm, 14.5\*9.5cm, 1

4.5cm\*9cm, 12cm\*8.7cm; or customized

**Classification:** Class I

**Rule:** According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU)2017/745

**Conformity assessment procedure:** Annex II+III

**SRN:** -

**UDI-DI:**

Product Mod - Size	UDI-DI	Product Mod - Size	UDI-DI

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008

ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2010

EN 14683:2014

**Signature:**

**Date:** 2020/3/18

**Position:**

*Jerry*

