Declaration of Conformity

Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Hunan EEXI Technology&Service Co., Ltd. Address: No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

European Authorised Representative

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

Product

Name: Disposable Medical Face Mask Model: Flat earloop 14.5*9cm

SRN: -

UDI-DI: -

Classification: I Rule: According to Rule 1, Annex VIII, EU Medical Device Regulation (2017/745)

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Regulation (EU) 2017/745 and the following harmonized standards.

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Gerneral Manager

EN ISO 14971: 2012 EN ISO 15223-1: 2016 ISO 10993-1: 2018 EN ISO 10993-5: 2009 EN ISO 10993-10: 2013 EN 1041: 2008 EN 14683:2019+AC: 2019 Type I