

# EU DECLARATION OF CONFORMITY

**Personal protective equipment:** Filtering half masks to protect against particles

**Name and address of the manufacturer:** Changzhou Shuangma Medical Devices Co., Ltd.  
San He Kou Development Zone, Zhenglu, Tianning Changzhou,  
Jiangsu, China. 213115

**EC Authorized Representative:** CMC Medical Devices & Drugs S.L  
C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain  
The manufacturer is solely responsible for issuing this declaration of conformity.

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**Product Name:** Filtering Half Mask

**Product photograph:**



**Type/Class:** FFP2 NR

**Model:** SMK-02 SZMDK (logo)

**It is certified that the manufacturer's technical file and PPE have been assessed and found to meet the applicable:** Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

**References to the relevant harmonized standards used:** EN 149:2001+A1:2009 (Respiratory protective devices – filtering half masks to protect against particles) device classification: FFP2 NR

**Notified body:** SGS FIMKO OY, Notified Body 0598, Takomotie 8, FI-00380, Helsinki, Finland

**has carried out an EU-type examination (module B) on:** 06 / 10 / 2020

**and issued an EU-type examination certificate** FI20/966779

**Notified body also carried out an EU type examination (module D) for manufacturer and issued certificate:** CN21/42503  
**and is valid:** 07.07.2021 – 6.7.2024

**Personal protective equipment shall be subject to a conformity assessment procedure as detailed in:** Article 19 (c) of the Regulation. Appropriate checks are implemented and maintained while the model is in production.

**Under the supervision of the notified body:** SGS FIMKO OY, Notified Body 0598, Takomotie 8, FI-00380, Helsinki, Finland

Changzhou, 2021-12-07  
Changzhou, 2021-12-07  
Place, date

Xu Aiping, General Manager  
Xu Aiping, General Manager  
Name and function

