



# DECLARATION OF CONFORMITY



Regarding Medical Device Regulation (EU) 2017/745

## Product Identification

Product name: Surgical Mask  
Model: F-PEF99/FFP2x5DM  
UMDNS code: 12447  
UDI-DI: 764017313LOT20210701H7  
Trade name: NA

## Manufacturer

Company name: Zhangjiagang 56 Friends Masks Co ,Ltd.  
Address: Xinghuo Village. Jinfeng Town, Zhangjiagang, Jiangsu, China

## Authorized Representative

Company name: HELVEI SRL  
Address: VIA FIESCHI 3 int 4 16121 GENOVA-Italy  
Contact: Tel: + 41793182923

## Conformity Assessment

Device classification: Class 1

According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Harmonized Standards: EN 14683:2019

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

Declaration of Conformity is valid until: 2024-04-30

Company Representative: Zhou Fangcheng

Title: General Manager

Date: 15<sup>th</sup> July, 2021

Place: Zhangjiagang, Jiangsu, P R,China

Signature:



*Zhou Fangcheng*