

Best Hope Precision Device Co.,Ltd CE Production Documentation	Document No.	SP/CE-13-01
	Edition/Revision	A/0
Product Introduction	Effective Date	2020-03-01
	page	Page 1 of 1

## CE Declaration of Conformity

### Manufacturer:

Best Hope Precision Device Co.,Ltd

Add: Bld45, No.99, Xinda Rd. Huimin Street, Jiashan City, Zhejiang, China

Zip code: 314199

### European Representative:

MedPath GmbH

Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

**Product Name:** Disposable face mask

**Types/Sizes:** FM-01

**UMDNS code:** 12458

**Basic UDI-DI :** not available

**Classification and relevant Rule:** Class I, Annex VIII, Rule 1 of 2017/745/EU MDR

**Conformity Assessment Route:** Annex IX excluding chapter II of 2017/745/EU MDR

**Test Standards:** EN 14683:2019

We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulations and Standards. All technical documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity

### REGULATIONS

General applicable regulations:

Medical Device Regulation: Regulation (EU) 2017/745 of the European Parliament and of the Council

Name: *WUXUAN*

Date: March 1, 2020

Place: Jiashan

