



**EC Declaration of Conformity
Regarding Medical Device Regulation(2017/745)**

Manufacturer

Name: BYD Precision Manufacture Co., Ltd

Address: No. 3001 Baohe Road, Baolong Industrial City, Longgang, Shenzhen, China

EC REP

Company:Wellkang Ltd

Address:16 Castle St,Dover, Kent, CT16 1PW,England,UK

Product

Name: Single-use surgical mask

Model: FE2311

Type: Flat

Specification: 17.5*9.5cm, 20*7cm, 16"18"21"

Classification: Class I

Rule: Rule 1, Annex VIII, Medical Device Regulation (EU)2017/745

We confirm our product meets the requirements of Medical Device Regulation and the following harmonized standards.

EN ISO 14971: 2012

EN ISO 15223-1: 2016

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2010

EN 1041: 2008

IEC 62366-1:2015

EN 14683:2019

Signature:  Position: General Manager

Date: 2020/4/28 Stamp(company) 