CE EC Declaration of Conformity CE

according to the Medical Devices Directive 93/42/EEC

Class I Medical Device

(non-sterile, without measuring function)

Manufacturer:	BYD Precision Manufacture Co., Ltd
Address:	No. 3001 Baohe Road, Baolong Industrial City, Longgang, Shenzhen, China .
Tel:	Tel: 0755-89888888
Fax	Fax:
EC Rep:	Wellkang Ltd 16 Castle Street, Dover, CT16 1PW, England, UK

We,the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Single-use face mask
	Type/model, identification of product allowing traceability (Where applicable)	Flat/17.5cm×9.5cm
of class	according to annex IX of directive 93/42/EEC	**Class I** Medical Device (non-sterile, without measuring function)

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	EN 14683:2005 EN ISO 15223-1:2016 EN 1041:2008 EN ISO 14971:2012 EN ISO 10993-1:2009 EN ISO 10993-5:2009
Conformity assessment procedure	**Module A (EC Declaration of Conformity (Annex VII) + Technical Files)**
Notified Body (name & number) Certificate & number	**NOT applicable**

Signed on: 9 March 2020. Place: Shenzhen, Guangdong, China

Signature (on behalf of the manufacturer) : 刘晓亮 Liu Xiao Liang

Name of authorized signatory: 刘晓亮 Liu Xiao Liang

Position held in the company: General Manager

Official Seal:

Medicines & Healthcare products
Regulatory Agency

MHRA

Our Ref: CA017418

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
Kent
CT16 1PW

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

18 March 2020

Dear Dr Wang

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of the details of ***Manufacturers* Name:- BYD Precision Manufacture Co., Ltd.** located at **Manufacturers Address:- No.1 Bao Ping Road,Baolong Industrial Park, Longgang, Shenzhen, Guangdong, China 518118** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation, certifcation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

For Manufacturers of Custom-made devices and Custom Made Active Implantable

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of the following chargable changes:

- the company information e.g. name and address
- additional generic groups of devices (not individual products within an existing generic group)
- Change of authorised representative

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device from your registration record, change of contact person, postcode, telephone number and/or email address, for which payment of our statutory fee does not apply. Though, you are required to provide these non-chargeable changes in writing we will not provide an updated letter of registration. As the updated information does not affect your regulatory obligations or the information published on our Public Access Registration Database (PARD).

Medicines & Healthcare products
Regulatory Agency

MHRA

Thank you for registering the following generic groups of devices:

Class I Devices:
Surgical face mask, single-use

Custom Made Devices:
None

Products Covered By Article 12:
None

Confidentiality

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidentiality under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

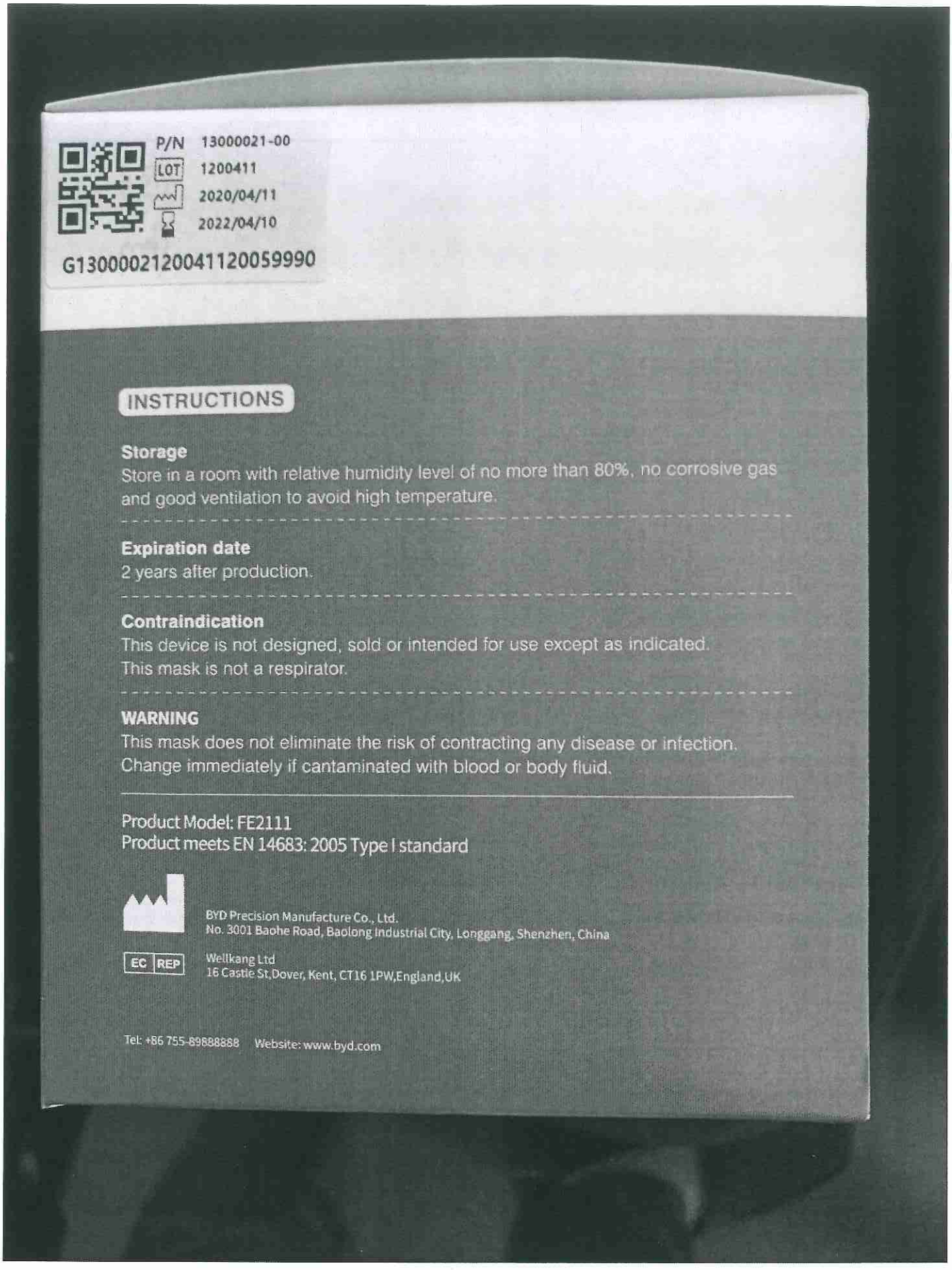
If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer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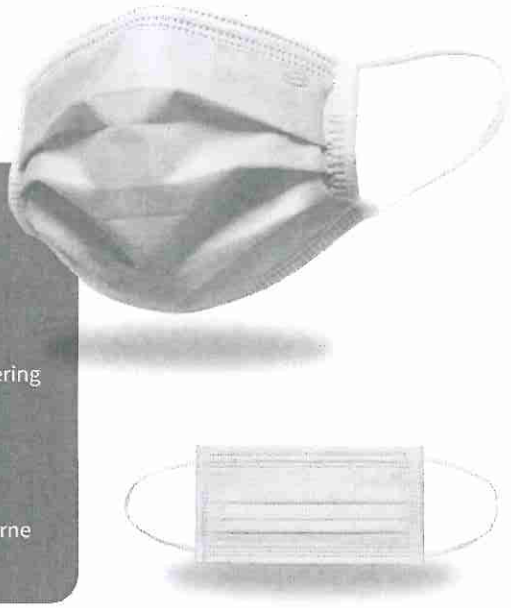
INSTRUCTIONS
Storage
Store in a room with relative humidity level of no more than 80%, no corrosive gas and good ventilation to avoid high temperature.
Expiration date
2 years after production.
Contraindication
This device is not designed, sold or intended for use except as indicated.
This mask is not a respirator.
WARNING
This mask does not eliminate the risk of contracting any disease or infection.
Change immediately if cantaminated with blood or body fluid.
Product Model: FE2111
Product meets EN 14683: 2005 Type I standard
BYD Precision Manufacture Co., Ltd.
No. 3001 Baohe Road, Baolong Industrial City, Longgang, Shenzhen, China
EC REP
Wellkang Ltd
16 Castle St,Dover, Kent, CT16 1PW,England,UK
Tel: +86 755-89888888 Website: www.byd.com

CE EN 14683 Type II NON STERILE MD

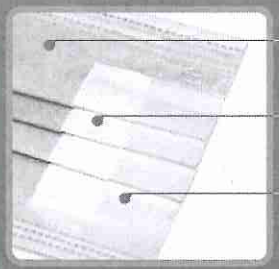
Single-use Face Mask

BYD CARE



Product Introduction

BYD Single-use face masks consist of three layers of nonwoven material:



Outer Layer
Blue polypropylene spunbond nonwoven

Middle Layer
Polypropylene melt-blown nonwoven with pathogen filtering

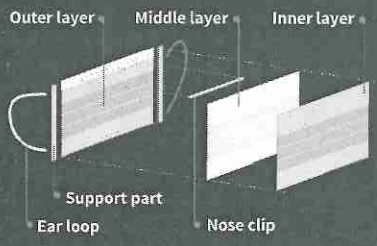
Inner Layer
White polypropylene spunbond nonwoven.

Suitable for general use, blocking both the exhalation and inhalation of pathogens and airborne liquid droplets expelled by coughing, sneezing and respiration.

Product Specifications

Product Size Specification and Appearance Requirements

1. Mask length: > 170 mm
2. Mask expansion width: 165 mm. Post-stack width is 95 mm with three stacks in the middle. Each stack width is not less than 10 mm. The nose clip is located on the upper edge of the mask, and the outside of the mask is darker in color.
3. The width of the support part is not more than 10 mm, and the position of the upper nose clip is not more than 16 mm.
4. Nose clip: length > 80 mm; width approximately 3 mm
5. Ear loop: 180 mm in length and 3 mm in diameter, composed of polyester, spandex and other materials, welded on the inner layer not more than 10 mm from the edge.



Parameter of BYD Single-use face mask

Name	Parameter
Product name	Single-use face mask
Material	Polypropylene spunbond nonwoven, polypropylene melt-blown nonwoven, metal core plastic nose clip, polyester and spandex ear loops
Model	Flat
Size	175 mm*95 mm / 6.89in.*3.72in.
Product application scope and purpose	For protection against inhalation of pathogens and airborne liquid droplets
Expiration date	2 years after date of production
Packaging specification	10pcs per bag; 50pcs per box; 2000pcs per carton
Sterilization	Non-sterile
Usage	1. Flatten the mask and put both ear loops on your ears. 2. Bend the nose clip to match the shape of the nose to prevent unfiltered air from entering. 3. Pull the mask to the lower jaw to produce a tight seal.
Storage	Store in a well-ventilated place with relative humidity below 80%; avoid high temperatures and exposure to flame.