EC Declaration of Conformity

CE

Manufacturers Name:	DONGGUAN AOXING AV EQUIPMENT CO.,LTD
Manufacturers Address:	2# Tian Sha Road, Tang Xia Town, Dongguan, Guangdong Province, 523710, P.R. China
SRN (Single Registration Number):	Not available yet
Authorized Representative Name (if applicable):	EC REP Wellkang Ltd
Authorized Representative Address (if applicable):	16 Castle St,Dover, Kent, CT16 1PW,England,UK
Basic UDI-DI:	Not available yet
Name of the Device (s):	Medical Face Mask
Model/Specification	AX-KF01 / 17.5cm*9.5cm
Standards:	See Annex I attached
Classification:	Class I, Rule 1
Conformity assessment route:	DONGGUAN AOXING AV EQUIPMENT CO.,LTD uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745: Class I: EC conformity declaration according to annex II + annex III

This declaration of conformity is issued under the sole responsibility of DONGGUAN AOXING AV EQUIPMENT CO.,LTD, We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.
All supporting documentation is retained at the premises of the manufacturer.

Signature:

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NAME Zhao Wen Fa

FUNCTION CEO

Place and date (dd.mm.yyyy) of issue:

MAY 19, 2020
Dongguan, China

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Annex I to EC Declaration of Conformity

List of standards:

LIST OF STANDARDS		
1	MDR 2017/745	Medical Devices Regulation
2	ENISO13485:2016	Medical devices - Quality management systems-Requirements for regulatory purposes
3	ENISO15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
4	EN1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
8	ENISO14971:2012	Medical devices - Application of risk management to medical devices
9	ENISO10993-1:2009/AC:2010	Biological evaluation of medical devices-Part 1:Evaluation and testing within a risk management process
10	ENISO10993-5 :2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
11	ISO10993-10 :2013	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
12	ISO 22609:2004	Clothing for protection against infectious agents - Disposable Medical Mask - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
13	EN 14683:2019	Disposable Medical Mask - Requirements and test methods

Medicines & Healthcare products Regulatory Agency

MHRA

Our Ref: CA017572

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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

03 June 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:- Dong Guan Aoxing AV Equipment Co., Ltd.** located at **Manufacturers Address:- 2# Tian Sha Road, Tang Xia Town, Dong Guan, Guangdong, China 523716** 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.

Please note this letter does not represent any form of accreditation, certification 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).

Thank you for registering the following generic groups of devices:

Class I Devices:
Surgical/medical face mask, single-use

Custom Made Devices:
None

Products Covered By Article 12:
None

Please note that the name and address of manufacturers and authorised representatives and their devices that have been registered will be published on our Public Access Registration Database (PARD).

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer

TEST REPORT

No.:WT204041769 (Replace No.WT204028238)

Sample Description: Medical Face Mask(Non-sterile)

Model/Specification/Grade: AX-KF01

Applicant: Dong Guan Aoxing AV Equipment Co.,Ltd

Applicant Address: 2# Tian Sha Road, Tang Xia Town , Dong Guan , Guang Dong , P.R. China

Date of Receipt: 2020-04-23

Test Period: 2020-04-23 to 2020-05-20

Test Location: Longhua Experimental Base

Shenzhen Academy of Metrology & Quality Inspection (Stamp)

Approved by: 何行月

Issue Date：2020-05-21

Signature: 何行月

TEST REPORT

No.：WT204041769

Sample Information：

Sample Description: Medical Face Mask(Non-sterile)
Trade Mark: AOXING
Model/Specification/Grade: AX-KF01
Serial/Batch No. of Sample: AX202004
Manufactured Date: 2020-04-20
Manufacturer: Dong Guan Aoxing AV Equipment Co.,Ltd
Manufacturer Address: 2# Tian Sha Road, Tang Xia Town , Dong Guan , Guang Dong , P.R. China
Sample Quantity: 200PCS
Sample Description before Testing: Normal.

Client Information：

Applicant: Dong Guan Aoxing AV Equipment Co.,Ltd
Applicant Address: 2# Tian Sha Road, Tang Xia Town , Dong Guan , Guang Dong , P.R. China
Applicant Telephone: 13824316273
Applicant Post Code: ----------

Test Information：

Date of Receipt: 2020-04-23
Applicant No.: 7700319
Enviroment Condition: （18～25）℃ （30～70）%RH
Sampling Method: Delivered by Applicant
Judgment Basis: EN 14683:2019+AC:2019
Test Standard: ISO 22609:2004 and other method standards refer to next pages.

Test Conclusion：

Test result refer to next pages.

Tested by: 廖惠萍 廖惠萍 Checked by: 刘石磊 刘石磊

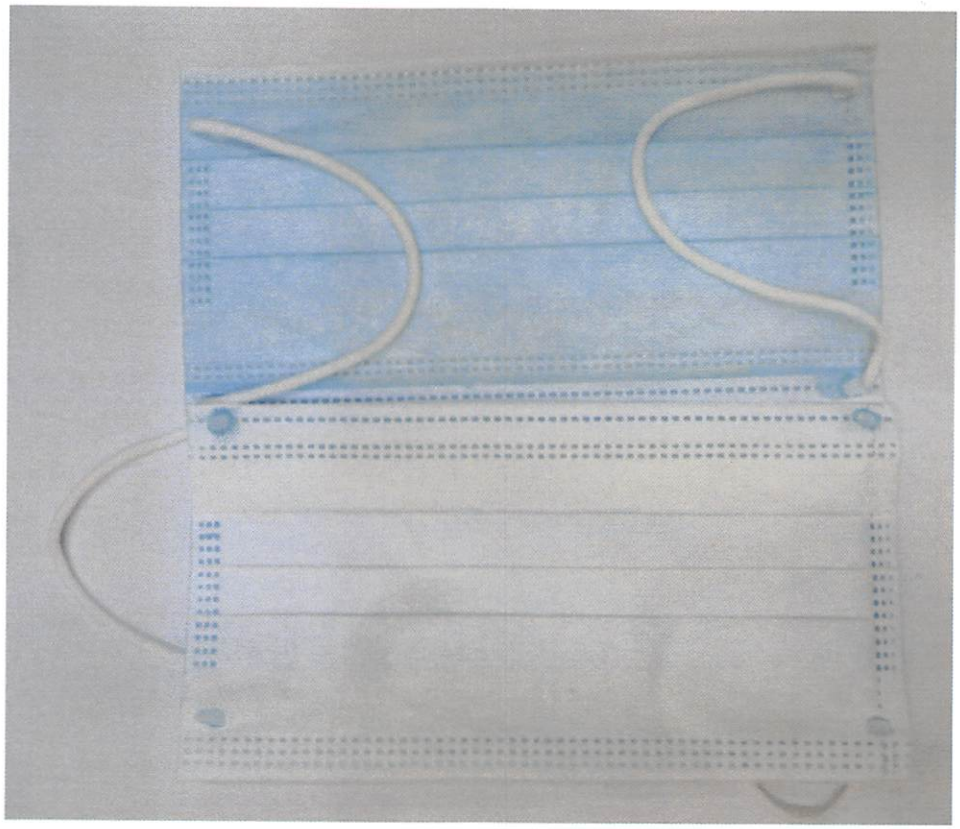
TEST REPORT

No.: WT204041769

Test Item	Requirement	Test Result	Conclusion
Bacterial filtration efficiency (BFE) (%)	Type IIR ≥98	Sample 1: 100.0 Sample 2: 99.9 Sample 3: 100.0 Sample 4: 100.0 Sample 5: 100.0 EN 14683:2019+AC:2019, Annex B	PASS
Differential pressure (Pa/cm^2)	Type IIR <60	Average value: 58.0 Flow rate:8L/min EN 14683:2019+AC:2019, Annex C	PASS
Splash resistance pressure (kPa)	Type IIR ≥16.0	AQL4.0%, the highest corresponding blood pressure: 21.3 ISO 22609:2004	PASS
Microbial cleanliness (cfu/g)	Type IIR ≤30	Sample 1: 4.5 Sample 2: 7.1 Sample 3: 2.0 Sample 4: 7.9 Sample 5: 5.8 EN 14683:2019+AC:2019	PASS

TEST REPORT

No.: WT204041769



END OF REPORT