



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Marble Solar Pty Ltd

for approval to supply

Marble Solar Pty Ltd - Public N95 respirator

ARTG Identifier	335062
ARTG Start date	24/04/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public N95 respirator
Intended Purpose	A filtering mask [KN95 (filter efficiency 95%)] designed to be placed over the nose and mouth to protect from particulates. This respirator may also help reduce breathing in some pathogenic biological airborne particulates such as influenza virus, but does not eliminate the risk of infection or disease. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Evangel Medical Technology (Shenzhen) Ltd	No1 Changfeng Industrial Park Dongkeng Guangming, Shenzhen, China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Public N95 respirator

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 335062
ARTG Start Date: 24/04/2020



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

**Evangel Medical Technology(Shenzhen)Ltd.
1 of ChangFeng Industrial Park,Dongkeng,Guangming
District,Shenzhen City,China**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10065663



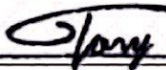
Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D382534	MSH	ACCESSORY, SURGICAL APPAREL	Disposable Face Mask EV-KY01,EV-KF01,
			KN95 Protective Mask EV-KY95,EV-KF95,
			Child Protective Mask EV-KC61,EV-KC95

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CCT is not affiliated with the U.S. Food and Drug Administration.

Shenzhen CCT Testing Technology Co.,Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916737


Chief engineer
Issued: 03/29/2020
Expiration Date:12/31/2020



Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov



CERTIFICATE OF CONFORMITY

Certificate No.: VIC200312-CBS-4031

The Certification Body of

VIC TESTING AND CERTIFICATION LTD

Certifies that

Applicant: Best Technology(Shenzhen) Inc.
NO.1 Changfeng Industrial Park,Dongkeng,Guangming, Shenzhen,
China

Manufacturer: Evangel Medical Technology (Shenzhen) Ltd.
NO.1 Changfeng Industrial Park,Dongkeng,Guangming, Shenzhen,
China

Product: SAFE MASK

Model No.: KN95

Report No.: VIC20200311-BSD33-CE-M

Complies with the requirements of the **Regulation (EU)2016/425 Personal Protective Equipment (PPE)**. The submitted products have been tested by us and found in compliance with the following European Standards:
EN 149:2001+A1:2009.

This certificate of conformity is based on an evaluation of a sample of the above mentioned products. It does not imply an assessment of the whole production. The CE marking as shown below can be affixed on the product after preparation of necessary technical documentation.

Signature: *Steven White*

Steven White

Date of issue: March 12, 2020

Expiry Date: March 11, 2025



VIC

VIC TESTING AND CERTIFICATION LTD

Add: CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K

Email: Info@victesting.com

Website: www.victesting.com





CERTIFICATE OF CONFORMITY

Certificate No.: VIC200312-CBS-4031

The Certification Body of

VIC TESTING AND CERTIFICATION LTD

Certifies that

Applicant: Best Technology(Shenzhen) Inc.
Add: NO.1 Changfeng Industrial Park,Dongkeng,Guangming,
Shenzhen, China

Manufacturer: Evangel Medical Technology (Shenzhen) Ltd.
Add: NO.1 Changfeng Industrial Park,Dongkeng,Guangming,
Shenzhen, China

Product: Disposable Medical Mask

Model No.: KN95

Report No.: VIC20200311-BSD33-CE-M

Complies with the requirements of the **Medical devices Directive 93/42/EEC (MDD)**.
The submitted products have been tested by us and found in compliance with the
following European Standards:
EN 14683:2014.

This certificate of conformity is based on an evaluation of a sample of the above mentioned
products. It does not imply an assessment of the whole production. The CE marking as shown
below can be affixed on the product after preparation of necessary technical documentation.

Signature: Steven White

Steven White

Date of issue: March 12, 2020

Expiry Date: March 11, 2025



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CERTIFICATE OF CONFORMITY

Certificate No.: VIC200319-CBS-4165

The Certification Body of

VIC TESTING AND CERTIFICATION LTD

Certifies that

Applicant: Best Technology(Shenzhen) Inc.
Add: NO.1 Changfeng Industrial Park, Dongkeng, Guangming,
ShenZhen , China

Manufacturer: Evangel Medical Technology (Shenzhen) Ltd.
Add: NO.1 Changfeng Industrial Park, Dongkeng, Guangming,
ShenZhen , China

Product: Disposable medical mask

Model No.: 0969- Follow YY-T0969 standard

Report No.: VIC20200318-BSD74-CE-M

Complies with the requirements of the **Medical Devices Directive 93/42/EEC (MDD)**.
The submitted products have been tested by us and found in compliance with the
following European Standards:
EN 14683:2014.

This certificate of conformity is based on an evaluation of a sample of the above mentioned
products. It does not imply an assessment of the whole production. The CE marking as shown
below can be affixed on the product after preparation of necessary technical documentation.

Signature: *Steven White*
Steven White

Date of issue: March 19, 2020

Expiry Date: March 18, 2025



VIC

VIC TESTING AND CERTIFICATION LTD

Add: CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K

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