



Personal Protective Equipment Handling Data - Disposable Face Mask (Non-Medical)

Manufacturer

Fujian Shishi Yihao Plastic Products Co., Ltd

FDA and CE listing documentations attached as (1) and (2).

Importer

Nanoleaf Canada Limited

100 Front St E, Toronto, ON M5A 1E1, Canada

Materials

- Non-woven fabric, melt-blown fabric
- None of the materials are classified as hazardous under WHMIS 1988

Construction

- 3-ply design: outer / blue (non-woven), filter (melt-blown), inner / white
- Pleated, adjustable size with ear loops
- GB/T 32610-2016 standard

Packaging

- Inner Carton: 50pc, plastic wrapped, packed in cardboard box (cautions and warnings printed on box in English)
- Case Pack: 40 inners (2,000 pc)

Storage

- Store in a cool, dry location, with relative humidity < 83%
- Shelf life: 2 years from date of manufacture
- Date of manufacture and production lot printed in each inner

Cautions, Usage, Disposal

- If mask becomes wet or damaged while wearing, discard immediately
- Do not allow mask to come in contact with open flame (will melt or deform)
- Disposable, single-use mask—do not re-use
- To dispose properly, remove using the ear loops and tie securely with the white side out before placing in garbage. Do not touch blue side with ungloved hands. Immediately wash hands after disposal and do not touch face, eyes, or open wounds.

[1]



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

Fujian Shishi Yihao plastic products Co., Ltd
No.2, zone 6, HouAn Industrial Zone, Baogai Town, Shishi
City, Quanzhou City, Fujian Province 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: 10066864

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D384821	QKR	FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE	disposable daily protective MASK

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

A handwritten signature in black ink, appearing to read 'Gary'.

Chief engineer

Issued: 04/03/2020

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 Compliance

No. OB200331E.FSY00078

Technical Construction File no.

Certificate's Holder:

Fujian Shishi Yihao Plastic Products Co., Ltd.
 No.2, Zone 6, HouAang Industrial Zone, Baogai Town, Shishi City, Quanzhou City, Fujian Province, China

Certification ECM Mark:



Product:

Disposable daily protective mask (Not Sterile)

Model(s):

YH-001, YH-002, YH-003, YH-004, YH-005 (FFP2 NR D)

Verification to:

Standard:
 EN 149:2001+A1:2009

related to CE Directive(s):
 R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 31 March 2020

Expiry date: 30 March 2025

Reviewer
 Technical expert
 Amanda Payne

Approver
 ECM Service Director
 Luca Bedonni

合格证
CERTIFICATE

产品名称: 一次性防护口罩 (非医用)

Product Name: Disposable Protective Mask (non-medical)

执行标准: GB/T 32610-2016

Executive Standard: GB/T 32610-2016

产品尺寸: 17.5x9.5 (± 0.5) cm

Product Size: 17.5x9.5 (± 0.5) cm

主要原料: 无纺布、熔喷布

Main Raw Materials: non-woven fabric, melt-blown fabric

产品颜色: 蓝色、白色

Product colors: blue, white

生产批号/Production Batch: 2020420

生产日期/Production Date: 2020/04/20

有效期/Shelf Life: 2 years / 2年

使用周期: 一次性

Life cycle: one-time

生产厂商: 石狮市益豪塑料制品有限公司

Manufacturer: Shishi Yihao Plastic Products Co., Ltd.

生产地址: 福建省石狮市宝盖镇后坑工业区B片区2号

Address: No. 2, District 6, Hou'an Industrial Zone,

Baogai Town, Shishi City, Fujian Province

联系电话/Telephone: 0595-88706660

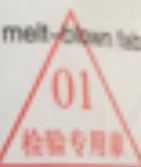
产品使用范围: 本产品不得用于发热门诊隔离病房(区)

隔离留观病房(区)手术室、隔离重症监护室等区域

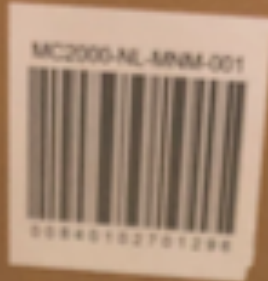
本产品为非医疗器械 仅供应急使用

This product is a non-medical device for emergency use only

中国制造
MADE IN CHINA



N.W. 7.8 kg
MEAS: 44X39X41CM



YI HAO

**DISPOSABLE
PROTECTIVE MASK**

This Product Is a Non-medical Device



Plane Lug type

50
PCS

BACTERIOSTASIS

Anti flying Foam

Dust Proof

Three layer filter protection