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 CCT Testing Service

Chief engineer
Issued: 04/03/2020
Expiration Date:12/31/2020

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

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 0B200331E.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:	European Conformity – Type Approved
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:

CE

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

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it


MC20
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
01
检验专用章
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埭工业区6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