RespoKare®

Protecting You with Science.

ANTI-VIRAL N95 RESPIRATOR PLUS

RK-200-3041

JLB Sourcing

www.jlbsourcing.com | Sales@jlbsourcing.com | (703) 349-3003

YOU’RE PROTECTED.

Our masks will be manufactured through rigorous tests based on the corresponding regulations.
We will ensure the demand and protection in accordance with the highest quality standards.

LONGKARE has a daily production capacity of 1,000,000 units per line. At the end of 2021, LONGKARE will have 96 functional production lines, reaching a total daily production capacity of over 100,000,000 units.

IN HOUSE PRODUCTION

PERSONALIZED SERVICE AND 24/7 ONLINE TRACKING SYSTEM

SHORT LEADTIME

OVERSEAS DISTRIBUTION

INCREASED EFFICIENCY

RAW MATERIAL SUPPLY CHAIN MANAGEMENT & CONTROL

RISK CONTROL & MANAGEMENT

SGS INSPECTION AND QUALITY CONTROL

RESOURCES INTEGRATION

Strong Supply System

Excellent Technology Team

Various Kinds of Products

With the experience and advantages of process control and test certifications, we have successfully developed anti-viral N95 mask with excellent physical properties, tactile sensitivity, chemical resistance and virus resistance, which can provide effective protection for people.

APPLICABLE STANDARD

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Mask, surgical, single use

ARTG Identifier	297583
ARTG Start date	15/12/2017
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	The device is a single use, disposable N95 face mask with a hydrophilic plastic coating on the outer layer, and a second inner layer treated with metal ions. The outer layer absorbs pathogen aerosol droplets into the inner antiviral layer where pathogens are inactivated. It helps to reduce risk of exposure to body fluids, particulate matter and both viruses and bacteria.

Manufacturer Details	Address	Certificate number(s)
Innonix Technologies Limited	13/F LiFung Centre 2 On Ping Street Siu Lek Yuen , Shatin, Hong Kong - SAR of 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. Mask, surgical, single use

Product Specific Conditions

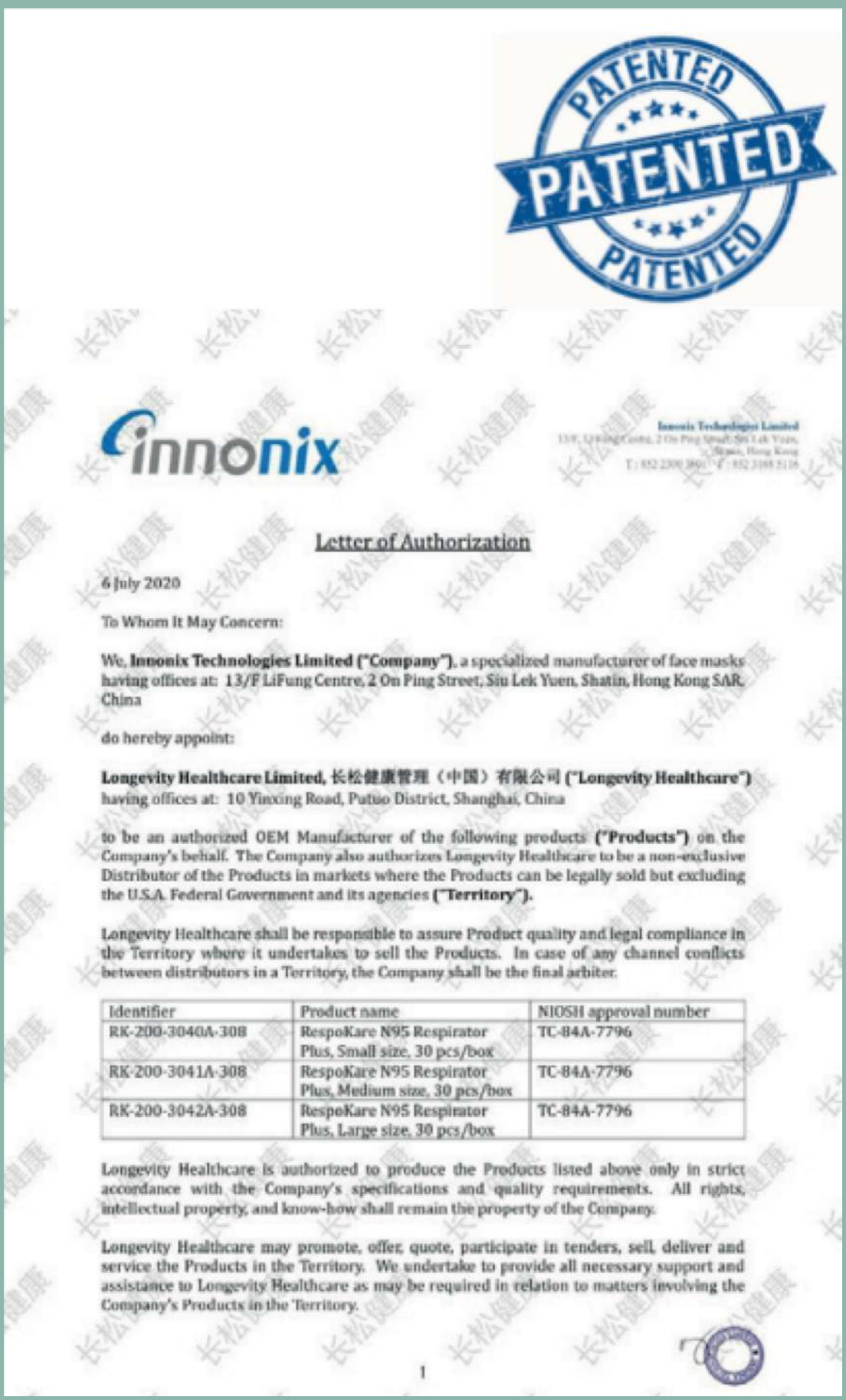
No specific conditions have been recorded against this entry.

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

ARTG Identifier: 297583
ARTG Start Date: 15/12/2017

TGA Approved

APPLICABLE STANDARD



innonix

Innonix Technologies Limited
13/F, LiFung Centre, 2 On Ping Street, Siu Lek Yuen, Shatin, Hong Kong
T : 852 2309 3801 F : 852 3165 5126

Letter of Authorization

6 July 2020

To Whom It May Concern:

We, **Innonix Technologies Limited ("Company")**, a specialized manufacturer of face masks having offices at: 13/F LiFung Centre, 2 On Ping Street, Siu Lek Yuen, Shatin, Hong Kong SAR, China

do hereby appoint:

Longevity Healthcare Limited, 长松健康管理（中国）有限公司 ("Longevity Healthcare") having offices at: 10 Yinxing Road, Putuo District, Shanghai, China

to be an authorized OEM Manufacturer of the following products **("Products")** on the Company's behalf. The Company also authorizes Longevity Healthcare to be a non-exclusive Distributor of the Products in markets where the Products can be legally sold but excluding the U.S.A. Federal Government and its agencies **("Territory")**.

Longevity Healthcare shall be responsible to assure Product quality and legal compliance in the Territory where it undertakes to sell the Products. In case of any channel conflicts between distributors in a Territory, the Company shall be the final arbiter.

Identifier	Product name	NIOSH approval number
RK-200-3040A-308	RespoKare N95 Respirator Plus, Small size, 30 pcs/box	TC-84A-7796
RK-200-3041A-308	RespoKare N95 Respirator Plus, Medium size, 30 pcs/box	TC-84A-7796
RK-200-3042A-308	RespoKare N95 Respirator Plus, Large size, 30 pcs/box	TC-84A-7796

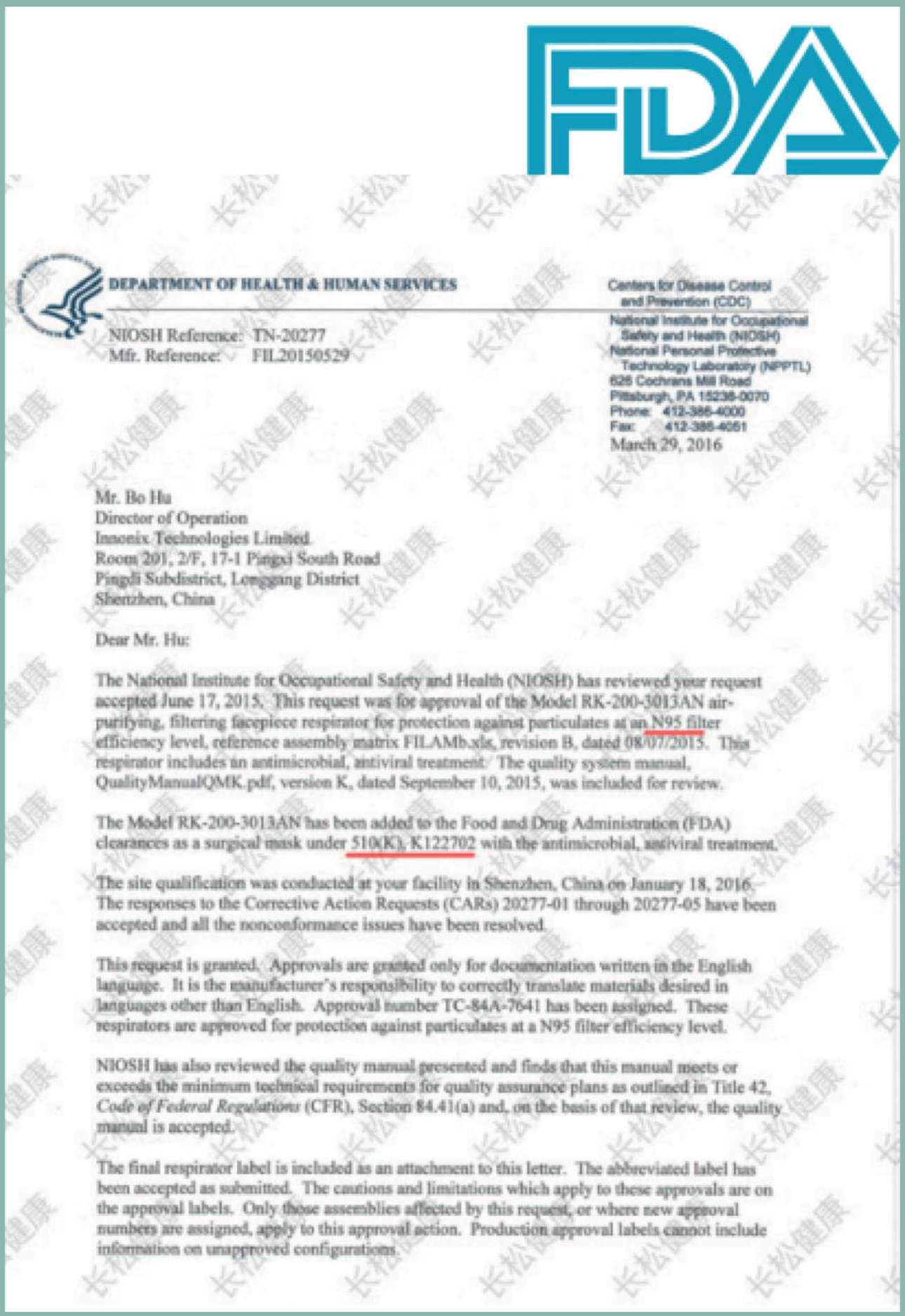
Longevity Healthcare is authorized to produce the Products listed above only in strict accordance with the Company's specifications and quality requirements. All rights, intellectual property, and know-how shall remain the property of the Company.

Longevity Healthcare may promote, offer, quote, participate in tenders, sell, deliver and service the Products in the Territory. We undertake to provide all necessary support and assistance to Longevity Healthcare as may be required in relation to matters involving the Company's Products in the Territory.

1

Annonix Authorized

APPLICABLE STANDARD



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-20277
Mfr. Reference: FIL20150529

March 29, 2016

Mr. Bo Hu
Director of Operation
Innonix Technologies Limited
Room 201, 2/F, 17-1 Pingxi South Road
Pingdi Subdistrict, Longgang District
Shenzhen, China

Dear Mr. Hu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted June 17, 2015. This request was for approval of the Model RK-200-3013AN air-purifying, filtering facepiece respirator for protection against particulates at an N95 filter efficiency level, reference assembly matrix FILAMb.xls, revision B, dated 08/07/2015. This respirator includes an antimicrobial, antiviral treatment. The quality system manual, QualityManualQMK.pdf, version K, dated September 10, 2015, was included for review.

The Model RK-200-3013AN has been added to the Food and Drug Administration (FDA) clearances as a surgical mask under 510(K), K122702 with the antimicrobial, antiviral treatment.

The site qualification was conducted at your facility in Shenzhen, China on January 18, 2016. The responses to the Corrective Action Requests (CARs) 20277-01 through 20277-05 have been accepted and all the nonconformance issues have been resolved.

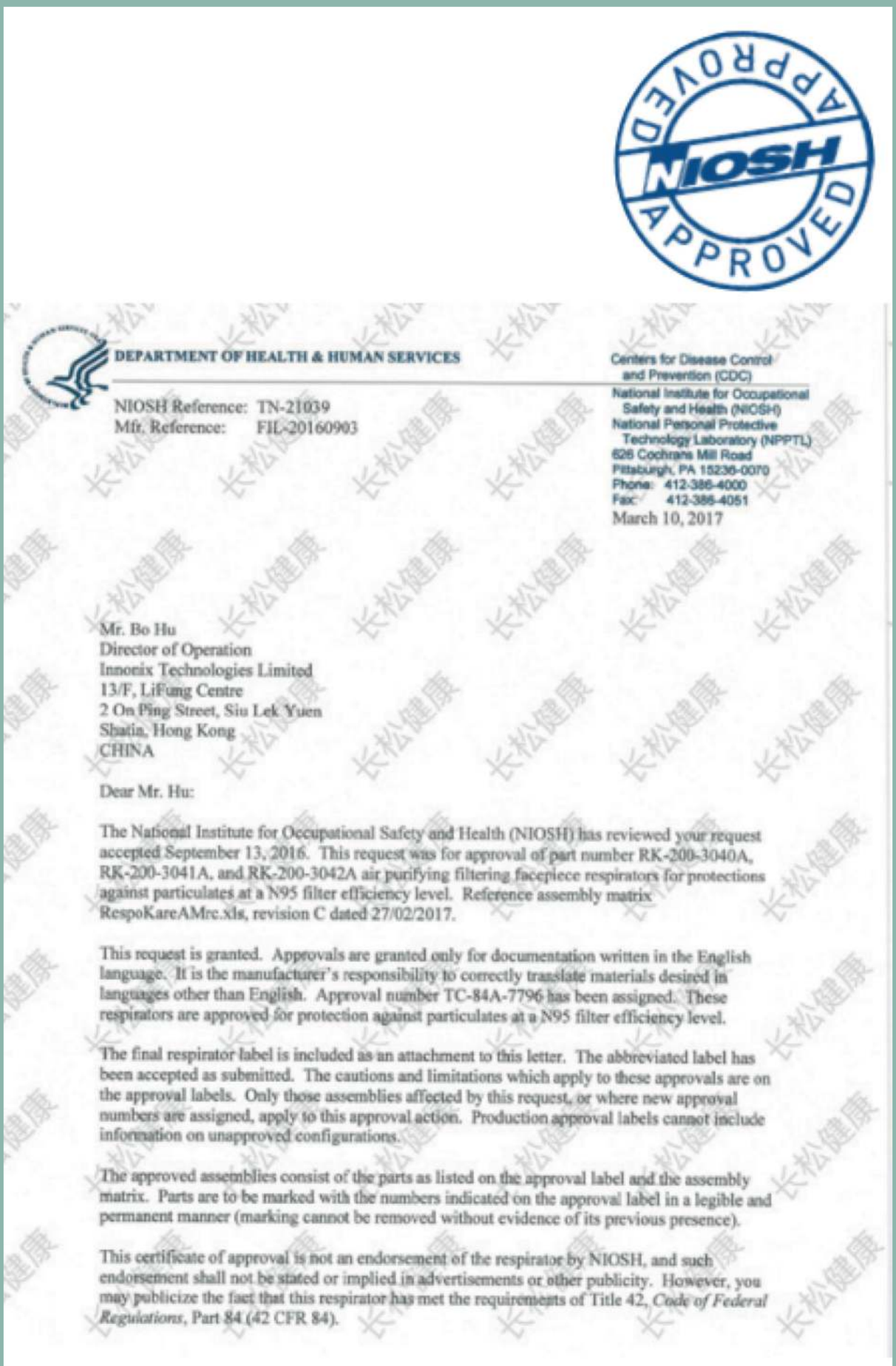
This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-7641 has been assigned. These respirators are approved for protection against particulates at a N95 filter efficiency level.

NIOSH has also reviewed the quality manual presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, *Code of Federal Regulations* (CFR), Section 84.41(a) and, on the basis of that review, the quality manual is accepted.

The final respirator label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to these approvals are on the approval labels. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

FDA Approved

APPLICABLE STANDARD



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-21039
Mfr. Reference: FIL-20160903

March 10, 2017

Mr. Bo Hu
Director of Operation
Innonix Technologies Limited
13/F, LiFung Centre
2 On Ping Street, Siu Lek Yuen
Shatin, Hong Kong
CHINA

Dear Mr. Hu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 13, 2016. This request was for approval of part number RK-200-3040A, RK-200-3041A, and RK-200-3042A air purifying filtering facepiece respirators for protections against particulates at a N95 filter efficiency level. Reference assembly matrix RespoKareAMrc.xls, revision C dated 27/02/2017.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-7796 has been assigned. These respirators are approved for protection against particulates at a N95 filter efficiency level.

The final respirator label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to these approvals are on the approval labels. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assemblies consist of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

NIOSH Approved

APPLICABLE STANDARD

13/06/11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Filligent (HK) Limited
C/O Mr. Ian Gordon
Emergo Group, Incorporated
611 West 5th Street Third Floor
Austin, Texas 78701

MAY 26 2011

Re: K101128
Trade/Device Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: OUK
Dated: May 20, 2011
Received: May 23, 2011

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

APPLICABLE STANDARD

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPLICABLE STANDARD

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Anthony D. Watson

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPLICABLE STANDARD

K101128

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007,A/Wisconsin/67/2005.), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

Prescription Use _____ AND/OR Over-The Counter Use ___X___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K101128

APPLICABLE STANDARD

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of microorganisms, body fluids and particulate material.

APPLICABLE STANDARD

Certificate of Registration

In accordance with European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states.

We hereby declare that:

- An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.
- The EU Authorised Representative contract has been fulfilled.
- Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.

Therefore, these devices have met the requirements of the council directive and the CE mark may be applied to the products listed below.

Certificate No: CE/HKG/2008/12/03	Issue Date: 01st January 2020	Expiry Date: * 31st December 2020

**Please note, due to the implementation date of the new medical device regulation (EU 2017/745) this certificate is subject to a review of the client's technical documentation before the 26th May 2020, whereupon a new Certificate of Registration is issued once compliance to the medical device regulation has been achieved.*

Legal Manufacturer	EU Authorised Representative (EC REP)
Innonix Technologies Limited 13/F, LiFung Centre, 2 On Ping Street, Siu Lek Yuen, Shatin Hong Kong	Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names	MCCAA Device Registration Reference(s)
RespoKare Anti-Viral Face Mask	DVC-MT-19-04-000117

Competent Authority
Malta Competition and Consumer Affairs Authority (MCCAA) Mizzi House, National Road, Blata l-Bajda, HMR 9010 Malta. Tel: +356 2395 2000 Email: info@mccaa.org.mt

This certificate is issued by:	Authorised Signature:
Advena Limited Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta. Tel: +44 1926 800153 Email: info@advenamedical.com Registered in Malta No. C 76865	Anthony Kirby – Managing Director (Malta)

This certificate is subject to the organisation maintaining their documentation in compliance with the directive stated in this certificate.

This certificate is for the exclusive use of Advena Ltd's client and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

APPLICABLE STANDARD

Innonix Technologies Limited
13/F, LiFung Centre, 2 On Ping Street, Siu Lek Yuen, Shatin, Hong Kong
T: 852 2300 3601 F: 852 2300 3858

Declaration of Conformity

for RespoKare Anti-Viral Face mask

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Anti-Viral Face mask
Legal Manufacturer: (Name on Label)	Innonix Technologies Limited 13/F, LiFung Centre, 2 On Ping Street, Siu Lek Yuen, Shatin, Hong Kong
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	This is a fluid-resistant, single use, disposable face mask that actively inactivates 99.99% of the tested viruses. It helps reduce exposure to bodily fluids and particulate materials. It breaths well and provides all-day comfort.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Hu Bo **Position** Director of Operations-Asia

Signed **Date** 22/02/2019

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

APPLICABLE STANDARD

Innonix Technologies Limited
13/F, LiFung Centre, 2 On Ping Street, Sio Lek Yuen, Shatin, Hong Kong
T : 852 2300 3601 F : 852 2300 3858

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
RK-200-2001A	Anti-Viral face mask	35177

Version History

Version	Compiled by	Date	Description
1.0	Benson Lau	22-02-2019	First issue

LABORATORY TEST DATA

Anti-Viral Mask is highly effective against 18 common Seasonal & Pandemic Influenza

Viruses	Inactivates
INFLUENZA A >99.99% within 5 minutes	
H1N1	
#A/California/04/2009	99.99%
#A/Brisbane/59/2007	99.99%
#A/Wisconsin/10/1998	99.99%
#A/NewJersey/8/1976	99.99%
#A/PuertoRico/8/1934	99.99%
#A/Swine/1976/1931	99.99%
H2N2	
#A/2/Japan/305/1957	99.99%
H3N2	
#A/Brisbane/10/2007	99.99%
#A/Wisconsin/67/2005	99.99%
A/HongKong/8/1968	99.99%
A/Victoria/3/1975	99.99%

Viruses	Inactivates
INFLUENZA A >99.99% within 5 minutes	
H5N1	
NIBRG-14	99.99%
H5N2	
#A/Duck/PA/10218/84	99.99%
H9N2	
#A/Turkey/Wisconsin/1966	99.99%
H3N8	
#A/Equine/2/Miami/63	99.99%
INFLUENZA B >99.99% within 5 minutes	
B	
B/Brisbane/60/2008	99.99%
#B/Florida/4/2006	99.99%
#B/Lee/1940	99.99%

In addition to influenza viruses, RespoKare® inactivates a wide range of other pathogens, bacteria and fungi listed below:

Germs (Pathogens)	Inactivates
Coronavirus (SARS and MERS)* within 1 minute	≥99.99%
Rhinovirus (Type 16) within 1 minute	96.61%
MRSA within 30 minutes	99.93%
Measles (Paramyxovirus) within 1 minute	≥99.99%
T.B. (Mycobacterium Tuberculosis) within 10 minutes	88.97%
Streptococcus Pneumoniae within 30 minutes	89.22%
Haemophilus influenzae within 60 minutes	90.15%
Herpes Simplex Virus (HSV Type 1) within 1 minute	≥99.41%
Staphylococcus epidermidis within 8hrs	≥99.99%
Respiratory Syncytial Virus (RSV) within 5 minutes	≥99.99%
Human Immunodeficiency Virus type (HIV type 1)	≥99.99%
Feline Calcivirus within 5 minutes	99.9%

APPLICABLE STANDARD

Anti-Viral N95 Respirator Plus

Niosh approved N95

Subjected to rigorous testing, this mask blocks 95% of very small (0.3 micron) particles. FDA Approved. CDC approval #84A-7796.

Nelson labs tested

Validation tests were conducted in compliance with GLP regulation. Approved according to 42 CFR Part 84.

U.S. patented antiviral tech

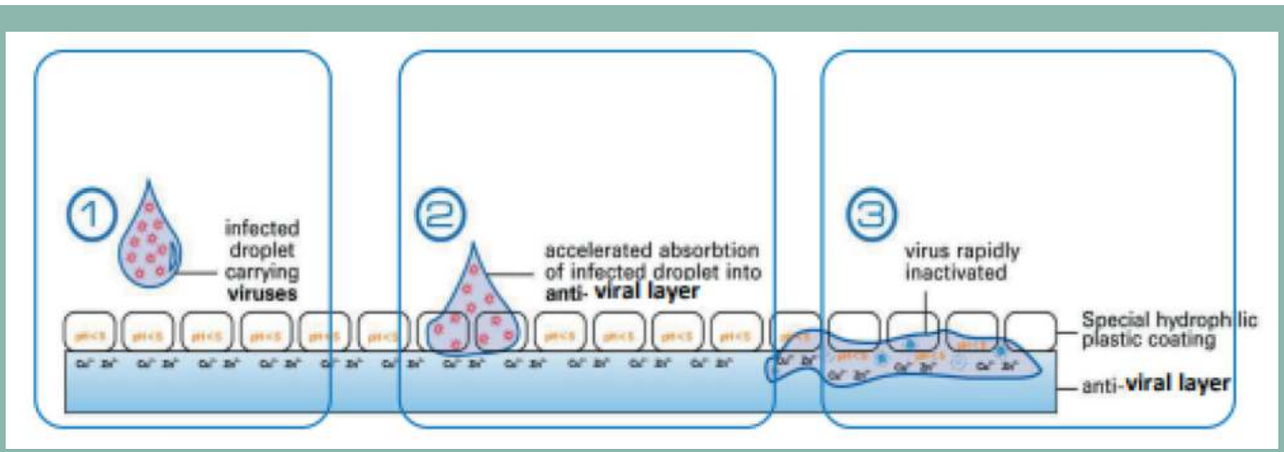
Revolutionary Innonix design decreases the transmission of one (or more than one) human pathogen by antibacterial, anti-fungal, and antiviral activity.

The technology

Our patented multilayer, anti-viral technology has proven effective in the inactivation of 99.9% of flu viruses and other airborne health hazards.

Same Anti-Viral Technology Inside

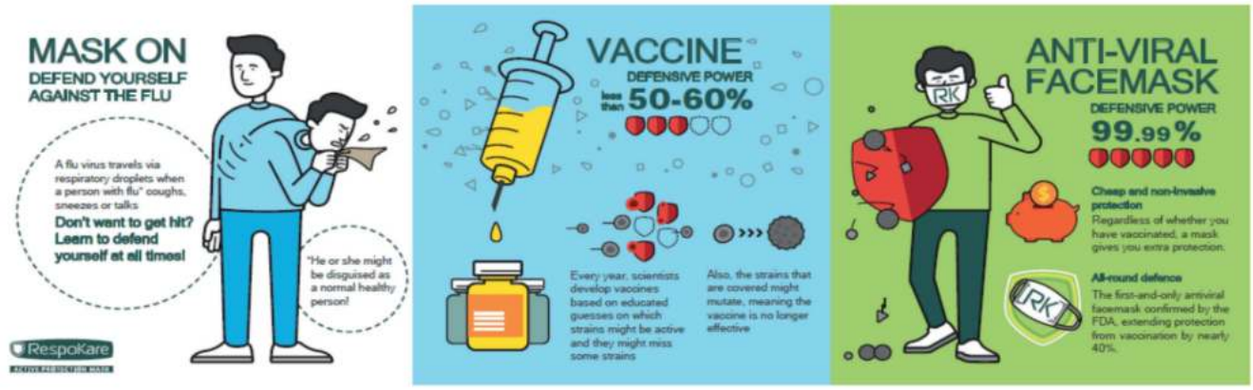
ACTIVE PROTECTION - HOW IT WORKS



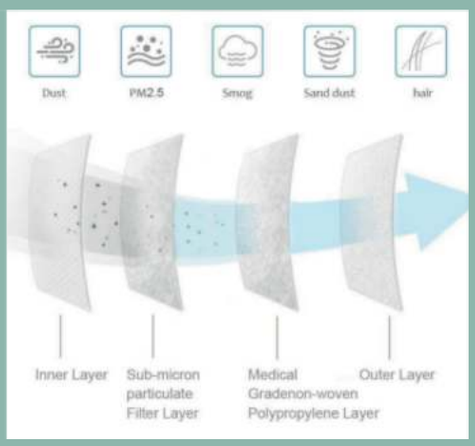
1 **Virus Trapping**
The Outer Layer of the mask not only helps to trap airborne particles but is coated with a special hydrophilic plastic that increases permeation of liquids.

2 **Virus Inactivation**
The coating of the outer layer is acidic, creating a low pH environment which destabilizes the virus proteins and effectively inactivate the virus functioning.

3 **Virus Destruction**
Infect droplets are quickly wicked away from the outer surface into the Anti-viral layer where the viruses are trapped and inactivated.



UNIQUE FEATURE



99.99% virus and bacteria inactivation within 5 minutes.

Tight-fitting to face as proven by various quantitative and qualitative fit tests.

Inactivates SARS, MERS, Bird Flu, Swine Flu, T.B., Measles, Chickenpox and more.

Very soft and comfortable material on the inside, High breath ability and filterability achieve.

Vertical seam and malleable aluminum nose piece ensure a good seal.

ANTI-VIRAL N95 MASK

Other N95 Anti-Viral Respirator

Almost all N95 masks only filter airborne particulates

VS

RespoKare® Anti-Viral N95 Respirator

- **Highest-level barrier against fluid/blood penetration**
- **4-layer construction**
- **Active anti-viral protection**
- **8 hours life-time**

1 Facial mask = 2 Surgical N95 masks

RespoKare® Anti-Viral N95 Respirator does more than filtering it "inactivates" pathogens with the same technology as the Anti-Viral Mask.

DETAILED SIZE DESCRIPTION - SIZE GUIDE

- NIOSH approved fitting
- Convex mask for comfort
- S - M - L for correct fit
- Fit-test must be performed for medical professionals
- Please follow instructions for correct wearing and removal

SMALL

RK-200-3040A

- Small size
- 133 mm

MEDIUM

RK-200-3041A

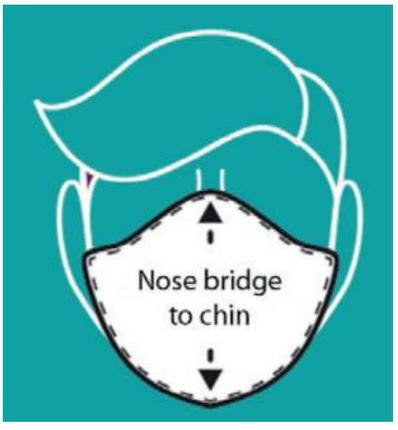
- Medium size
- 146 mm

LARGE

RK-200-3042A

- Large size
- 175 mm

* **Length measurement nose bridge to chin.**



PACKAGE COMPONENTS

Various types of packaging satisfy various business demands.

5 pics/box

Size(mm):
140 x 45 x 225

10 pics/box

Size(mm):
140 x 90 x 225

30 pics/box

Size(mm):
285 x 105 x 140

Size(mm):
585 x 435 x 445

SIZE	Small	Medium	Large
PCS / BOX	5 pcs/box	10 pcs/box	30 pcs/box
BOX / CARTON	72 boxes/carton	36 boxes/carton	24 boxes/carton

Storage Instructions

Keep masks in the package away from direct sunlight or contamination until use. Ambient temperature between -20° C to +40° C, and relative humidity <80%, no corrosive gas, good ventilation. During transportation, keep away from moisture, light and heat.

Important

1. Never alter or modify this mask in any way.
2. Discard the product as a medical product.
3. Children under three years old are not recommended to use the product because of their low vital capacity.
4. The masks must be stored and transpoted in their original package and protected by the storage temperature and humidity as suggested by the manufacturer.

Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Mask, surgical, single use

ARTG Identifier	297583
ARTG Start date	15/12/2017
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	The device is a single use, disposable N95 face mask with a hydrophilic plastic coating on the outer layer, and a second inner layer treated with metal ions. The outer layer absorbs pathogen aerosol droplets into the inner antiviral layer where pathogens are inactivated. It helps to reduce risk of exposure to body fluids, particulate matter and both viruses and bacteria.

Manufacturer Details	Address	Certificate number(s)
Innonix Technologies Limited	13/F LiFung Centre 2 On Ping Street Siu Lek Yuen , Shatin, Hong Kong - SAR of 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. Mask, surgical, single use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

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  - 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. Mask, surgical, single use

Product Specific Conditions

No specific conditions have been recorded against this entry.

FDA Standards for Antiviral Activity of Medical Devices

Antiviral activity of medical protective devices such as facemasks must meet rigorous standards for FDA approval. Within a brief contact time, there must be a 4 log (10,000 fold or 99.99%) reduction in the amount of infectious virus on a mask compared to a control mask made from identical physical materials without the antiviral agents. Furthermore, this degree of activity must be demonstrated with number of different viral strains.

The Innonix Anti-Viral RespoKare Facemask ("Innonix RespoKare mask" thereafter) is the only available protective surgical mask or N95 respirator with antiviral activity claims approved by the US FDA. Competitor masks that make antiviral claims have not demonstrated adequate activity to meet the standards required for FSA approval when tested in head-to-head comparisons with the Innonix RespoKare mask.

All antiviral testing for validation of the Innonix RespoKare mask was performed at accredited third-party laboratories with extensive experience testing medical devices under GLP (Good Laboratory Practice) conditions for conducting and documenting studies for submission to regulatory agencies. The laboratories used for validation of the Innonix RespoKare mask include Nelson Laboratories for physical properties (particle filtration), WuXi AppTec for safety testing, and MicroBioTest for antiviral and antibacterial activity testing.

Antiviral Testing Procedure

A summary of the antiviral testing procedure is as follows:

1. 0.4 mL viral inoculum containing at least 10^7 viable virus particles per mL is applied to test mask fabric samples (2.5×2.5 cm) as a mist, simulating airborne aerosol droplets.

2. Appropriate controls including mask samples without antiviral modifications, and liquid controls are tested concurrently.

3. After a specific selected contact time, the mask fabric samples are placed in a neutralization buffer that immediately counteracts the virucidal agents in the mask. Viable viruses remaining after the specific contact time are extracted from the material in a "stomaching" device.

4. Extracted infectious viruses are quantified in a standardized TCID (Tissue Culture Infective Dose) assay, in which viruses are measured by their ability to kill susceptible cells in culture.

While simple in principle, standardization of the assay to meet GLP requirements for reproducibility, quality, and documentation is a complex process. The cover page, table of contents and summary result table from a testing report submitted to the FDA is appended; the full report may be made available upon request.

Antiviral Activity of the Innonix Anti-Viral RespoKare Facemask

The antiviral activity of the mask against influenza was used for initial FDA approval. 18 different strains, including both Influenza A and Influenza B were tested

A summary of results against all 18 strains is presented in the table below. In all cases a difference between the active Innonix RespoKare mask and a physically identical mask (without antiviral modifications) of more than 4 logs was observed, a 10,000-fold difference in infectious virus survival and recovery. In most cases, no infectious virus was detectable after contact with the mask for 5 minutes. The lower limit of detection of the assay was 2.4 logs of virus, below the threshold for infection of the cells used in the assay, so this value rather than zero was used, so >4 log virus inactivation was the most conservative estimate of antiviral activity.

Table 1 Viral Reduction of the Innonix Anti-Viral RespoKare Facemask on 5 Minutes Surface Contact based on Control Mask (Initial Load)

Subtype	Isolate	Initial Load (Log_{10} $TCID_{50}$)	Output Load (Log_{10} $TCID_{50}$)	Log_{10} Reduction
H1N1	A/California/04/2009	7.45 ± 0.34	≤3.43*	≥4.02 ± 0.34
	A/Brisbane/59/2007	7.51 ± 0.26	2.57 ± 0.25	4.94 ± 0.36
	A/Wisconsin/10/98	6.45 ± 0.39	≤2.32 ± 0.43*	≥4.13 ± 0.58
	A/New Jersey/8/76	6.76 ± 0.33	2.40 ± 0.29	4.36 ± 0.44
	A/PR/8/34	7.78 ± 0.29	≤3.30 ± 0.49*	≥4.48 ± 0.57
	A/Swine/1976/31	6.45 ± 0.30	≤2.31± 0.30*	≥4.14 ± 0.43
H2N2	A/2/Japan/305/57	7.03 ± 0.14	≤2.40*	≥4.63 ± 0.14
H3N2	A/Brisbane/10/2007	6.74 ± 0.30	≤2.40*	≥4.34 ± 0.30
	A/Wisconsin/67/2005	6.53 ± 0.36	≤2.40*	≥4.13 ± 0.36
	A/Hong Kong/8/1968	7.35 ± 0.41	≤3.30 ± 0.49*	≥4.05 ± 0.64
	A/Victoria/3/1975	8.78 ± 0.26	4.70 ± 0.28	4.08 ± 0.38
H5N1	NIBRG-14	6.95 ± 0.20	≤2.40*	≥4.55 ± 0.20
H5N2	A/Duck/PA/10218/84	7.96 ± 0.27	≤3.08 ± 0.44*	≥4.89 ± 0.51
H9N2	turkey/Wisconsin/66	6.70 ± 0.30	2.66 ± 0.22	4.04 ± 0.37
H3N8	A/Equine/2/Miami/63	7.95 ± 0.20	≤3.45 ± 0.49*	≥4.50 ± 0.53
B	B/Brisbane/60/2008 (Victoria Lineage)	6.37 ± 0.33	≤2.40*	≥3.97 ± 0.33
	B/Florida/4/2006 (Yamagata Lineage)	6.40 ± 0.36	≤2.40*	≥4.00 ± 0.36
	B/Lee/40	6.45 ± 0.36	≤2.40*	≥4.05 ± 0.36

* No virus was detected; the theoretical titer was determined based on the Poisson distribution.

Results presented average of three replicates

Activity against other viruses

The Innonix RespoKare mask exploits 4 different, complementary mechanisms of action against viruses and other pathogens, including low pH, a surfactant to disrupt lipid envelopes on some viruses, and a high local concentrations of zinc and copper ions, which damage viruses via ionic and redox effects. The mechanisms of action provide broad antiviral activity against the major classes of airborne pathogenic viruses.

Testing in some cases was conducted with established surrogate viruses, for example when highly pathogenic viruses have not been released to accredited testing labs by the US Center for Disease Control. SARS and MERS are coronaviruses, so the standard surrogate for testing disinfectants is a closely related virus, Human Coronavirus 229E, which has equivalent susceptibility to a range of disinfectants. Similarly, Ebola virus is not available for testing in validated assays at commercial laboratories. The CDC and EPA (Environmental Protection Agency) recommend in formal guidelines that one of a set of non-enveloped viruses be used as a surrogate for validating activity of disinfectants against Ebola, since Ebola, and enveloped virus, is known to be more susceptible to disinfectants than the non-enveloped surrogates.

RNA Viruses

1. Measles (Inhalation of airborne virus is a most common route of measles transmission; infectious measles can stay suspended in air even after an infected person has left the vicinity)

- The Innonix RespoKare mask material inactivated measles virus by >99.99% within 1 minute of contact **(no viable infectious virus was detectable)**

2. Human Coronavirus 229E (Surrogate for **SARS** and **MERS**, both of which are coronaviruses)

- The Innonix RespoKare mask material inactivated Human Coronavirus 229E by >99.99% within 1 minute of contact **(no viable infectious virus was detectable)**

3. FCV (Feline Calicivirus), a non-enveloped RNA virus closely related to norovirus. Non-enveloped viruses are more resistant to disinfectants than are enveloped viruses like influenza or measles. The CDC and EPA in the US accept FCV as a surrogate for demonstrating activity of disinfectants against **noroviruses** in general (which cause gastroenteritis in humans; they are often culprits in cruise ship infections), and also against **Ebola**. EPA also considers activity against an established surrogate non-enveloped virus such as FCV sufficient to broadly claim activity against enveloped viruses, which are more susceptible to disinfectants as a class.

- The Innonix RespoKare mask material inactivated FCV by >99.9% within 5 minute of contact **(no viable infectious virus was detectable)**. 5 minutes was the shortest contact time tested.

DNA Virus

1. HSV1 (Herpes Simplex Virus 1), a surrogate for **Chicken Pox** (varicella zoster virus; VZV; Human Herpes Virus Type 3) and other herpes viruses. Chicken pox, like measles is often transmitted by the airborne route.

- The Innonix RespoKare mask material inactivated HSV1 virus by >99.4% within 1 minute of contact **(no viable infectious virus was detectable)**

Duration of Protection

The active virucidal and antimicrobial agents in the Innonix RespoKare masks were selected for their stability as well as their activity and safety. In formal shelf-life tests using the same protocols and accredited testing laboratory used for the activity studies described above, the Innonix RespoKare mask has been shown to retain full antiviral activity after storage for more than 3 years at elevated temperatures and humidity.

Evaluation of the Extended Influenza Virus Inactivation Efficacy

As part of the application for FDA clearance, the mask was tested in an extended-use study involving overloading the mask with repeated application of simulated saliva, exceeding the amounts to which the mask could be exposed during actual use. Under these conditions, the mask retained full antiviral activity for up to 8 hours of simulated use.

The virucidal efficacy results show that the 4-layer Innonix Antiviral Face Mask material surgical facemask was capable of inactivating ≥4-log of influenza virus (versus untreated control textiles as a baseline) at all tested time points after prolonged exposure, representing excessive, supraphysiological saliva/nasal secretion conditions.

Table 2: Influenza A inactivation at time points during exposure of Innonix Antiviral Mask to simulated saliva/nasal fluids (Table 6 from Test Report "Assessment of Virucidal Effectiveness of Treated Face mask Under Simulated Use Conditions -Influenza A Virus Misting Study")

Table 6
Viral Reduction - based on (Control Mask)

Test Article	Timepoint	Input Load* ($Log_{10}TCID_{50}$)	Output Load* ($Log_{10}TCID_{50}$)	Log10 Reduction*
RK-200-3015A	0 hour	7.40	2.92	4.48
	2 hours	7.30	3.09	4.21
	4 hours	7.23	3.09	4.14
	6 hours	7.23	3.09	4.14
	8 hours	7.23	3.21	4.02

* Results represent the average of three replicates.
Note: the test and control mask was challenged with artificial nasal fluid (ANF) to the inside of the mask every hour, until one hour prior to the viral challenge, which was applied onto the outside of the mask. After the viral challenge, the mask was held for 5 minutes, and then neutralized and recovered for virus.

Evaluation of the Influenza Virus Inactivation Efficacy after extended wear by subjects

The mask was also tested in an extended wear by subjects continuously for 4 hrs and 8 hrs period, and the subjects were asked to store the mask in a paper bag every time they remove it (for toilet breaks, tea/lunch breaks and at the end of the treatment period). Under these conditions, the mask retained full antiviral activity for up to 8 hours of extended wear.

Table 3: Influenza A inactivation at time points after extended wear of Innonix Anti-viral mask by subjects (Table 6 from Test Report "Assessment of Virucidal Effectiveness of Treated Face mask after extended wear by subjects – Human Influenza A Virus")

Table 6
Viral Reduction - based on Neutral Control (BF-200-3013 CCX)

Test Agent	Test Subjects	Extended Wearing Time	Initial Viral Load* ($Log_{10}TCID_{50}$)	Output Viral Load ($Log_{10}TCID_{50}$)	Log_{10} Reduction
BioFriend™ Biomask™ BF-200-3013CC	Subject 1	4 hours	5.78	≤ 1.10	≥ 4.68
	Subject 2			≤ 1.10	≥ 4.68
	Subject 3			≤ 1.10	≥ 4.68
	Subject 4			1.22	4.56
	Subject 5			≤ 1.10	≥ 4.68
	Subject 6			1.22	4.56
	Subject 7	8 hours	5.78	1.22	4.56
	Subject 8			1.22	4.56
	Subject 9			≤ 1.10	≥ 4.68
	Subject 10			≤ 1.10	≥ 4.68
	Subject 11			1.22	4.56
	Subject 12			1.22	4.56

* Results represent the average of three replicates.

Other Antiviral Masks

Other than the Innonix Anti-Viral RespoKare Facemask, no disposable masks or respirators currently on the market have been demonstrated to display contact-inactivation of pathogenic viruses sufficient to meet requirements for FDA approval. When tested head to head in the validated assays used for the Innonix RespoKare mask, competitors' masks claimed to have antiviral activity have consistently displayed 100× less activity than the Innonix RespoKare mask, producing only a 0 to 2 log reduction in infectious influenza virus titer, versus the >4 logs (10,000 fold reduction) achieved with the RespoKare mask.

Appendix

MICROBIOTEST
A Division of Microbac Laboratories, Inc.
105-B Carpenter Drive
Sterling, VA 20164

FINAL REPORT

ASSESSMENT OF VIRUCIDAL EFFECTIVENESS BY DIRECT CONTACT KILL OF TREATED FACE MASK MATERIAL AGAINST MULTIPLE TYPES OF INFLUENZA VIRUSES

Misting Study – 12 Influenza viruses

Test Agent
BioMask BF-200-3013

Author
S. Steve Zhou, Ph.D.

Performing Laboratory
MICROBIOTEST
105 Carpenter Drive
Sterling, Virginia 20164

Laboratory Project Identification Number
639-137

Sponsor
Filligent, Ltd.
7th Floor
09 Jervois Street
Sheung Wan, Hong Kong

703.925.0100 (phone) • www.microbiotest.com • 703.925.9366 (fax)
www.microbac.com

RESULTS (continued)

Table 1
Summary
Viral Reduction - based on Neutral Control Mask

Test Agent	Challenge Organism(s)	Initial Viral Load* ($Log_{10}TCID_{50}$)	Output Viral Load* ($Log_{10}TCID_{50}$)	Log_{10} Reduction *
BioMask BF-300-3013	Human Influenza A Virus (H1N1), A/New Jersey/8/76	6.76 ± 0.33	2.40 ± 0.29	4.36 ± 0.44
	Human Influenza A Virus (H1N1), A/Wisconsin/1/88	6.45 ± 0.39	≤ 2.32 ± 0.43	≥ 4.13 ± 0.58
	Human Influenza A Virus (H3N2), A/Victoria/3/75	8.78 ± 0.26	4.70 ± 0.28	4.08 ± 0.38
	Human Influenza A Virus (H3N2), A/Hong Kong/8/68	7.35 ± 0.41	≤ 3.30 ± 0.49	≥ 4.05 ± 0.64
	Human Influenza A2 Virus (H2N2), A/Japan/305/57	7.62 ± 0.14	≤ 2.40	≥ 5.23 ± 0.14
	Human Influenza B Virus, B/Brisbane/60/2008	6.37 ± 0.33	≤ 2.40	≥ 3.97 ± 0.33
	Human Influenza B Virus, B/Florida/4/2006	6.40 ± 0.58	≤ 2.40	≥ 4.00 ± 0.58
	Human Influenza B Virus, B/Lee/40	6.45 ± 0.36	≤ 2.40	≥ 4.05 ± 0.35
	Avian Influenza Virus (H9N2), Turkey/Wis/68	6.70 ± 0.30	2.66 ± 0.22	4.04 ± 0.37
	Duck Influenza Virus (H5N2), A/Duck/PA/10218/84	7.86 ± 0.27	≤ 3.06 ± 0.44	≥ 4.80 ± 0.51
	Equine Influenza Virus (H3N8), A/Equine/2/Miami/63	7.85 ± 0.20	≤ 3.40 ± 0.43	≥ 4.50 ± 0.48
	Swine Influenza Virus (H1N1), A/Swine/1976/31	6.45 ± 0.30	≤ 2.31 ± 0.20	≥ 4.14 ± 0.43

* Results represent the average of three replicates.

* "RespoKare Anti-Viral Face Mask" formerly commercialized as "BioMask"

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-21039 Reference No.: CFR 84.180
Test: Exhalation Resistance Test STP No.: 3
Manufacturer: Innonix Technologies Limited

Filter Type: Filter Only

Item Tested: RK-200-3040A/RK-200-3041A

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	13.2	PASS
2	25	12.7	PASS
3	25	12.9	PASS
4	25	9.3	PASS
5	25	10.2	PASS
6	25	10.2	PASS

Overall Result: PASS

Comments:
Samples were tested on manometer 000283 1-3: RK-200-3040A 4-6: RK-200-3041A

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta Date: 1/12/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-21039
Test: Inhalation Resistance Test
Manufacturer: Innonix Technologies Limited
Item Tested: RK-200-3040A/-RK-200-3041A

Reference No.: CFR 84.180
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	16.7	PASS
2	35	16.7	PASS
3	35	15.5	PASS
4	35	9.9	PASS
5	35	14.3	PASS
6	35	12.3	PASS

Overall Result: PASS

Signature: Nicole L. Petitta

Date: 1/12/2017

Engineering Technician

Task Number: TN-21039
Test: Inhalation Resistance Test
Manufacturer: Innovix Technologies Limited
Item Tested: RK-200-3040A/-RK-200-3041A

Reference No.: CFR 84.180
STP No.: 7

Comments:
Samples were tested on manometer 000285. 1-3: RK-200-3040A 4-6: RK-200-3041A

Was all equipment verified to be in calibration throughout all testing?	(•) Yes	( ) No

Signature: Nicole L. Petitta

Date: 1/12/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-21039 Reference No.: CFR 84.181
Test: Sodium Chloride (NaCl) - N95 STP No.: 59
Manufacturer: Innonix Technologies Limited
Item Tested: RK-200-3040

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	19.5	5.00	3.020	3.020	PASS
2	85	20.8	5.00	2.770	2.770	PASS
3	85	18.8	5.00	2.630	2.630	PASS
4	85	18.4	5.00	1.980	1.980	PASS
5	85	17.4	5.00	1.760	1.760	PASS
6	85	19.2	5.00	2.880	2.880	PASS
7	85	17.9	5.00	1.710	1.710	PASS
8	85	20.9	5.00	2.130	2.130	PASS
9	85	19.0	5.00	2.070	2.070	PASS
10	85	19.6	5.00	1.860	1.860	PASS
11	85	17.9	5.00	2.340	2.340	PASS
12	85	17.7	5.00	2.040	2.050	PASS
13	85	16.6	5.00	2.250	2.250	PASS
14	85	18.7	5.00	2.610	2.610	PASS
15	85	17.3	5.00	1.750	1.750	PASS
16	85	16.2	5.00	1.770	1.770	PASS
17	85	19.2	5.00	2.340	2.340	PASS
18	85	17.5	5.00	2.360	2.360	PASS
19	85	17.3	5.00	2.080	2.080	PASS
20	85	18.4	5.00	1.890	1.890	PASS

Overall Result: PASS

Signature: Nicole L. Petitta Date: 1/12/2017

Engineering Technician

Task Number: TN-21039 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Innonix Technologies Limited
Item Tested: RK-200-3040

Comments:

Samples 1-11 were tested on TSI 8130 machine 000334 using timer 000217. Samples 12-17 were tested on TSI 8130 machine 000333. Samples 18-20 were tested on TSI 8130 machine 000332.

Was all equipment verified to be in calibration throughout all testing?	(•) Yes	( ) No

Signature: Nicole L. Petitte **Date:** 1/12/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-21039 Reference No.: CFR 84.181
Test: Sodium Chloride (NaCl) - N95 STP No.: 59
Manufacturer: Innonix Technologies Limited
Item Tested: RK-200-3041A

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	12.7	5.00	2.280	2.280	PASS
2	85	13.6	5.00	2.830	2.830	PASS
3	85	13.5	5.00	3.510	3.510	PASS
4	85	13.4	5.00	1.980	1.980	PASS
5	85	13.9	5.00	2.040	2.040	PASS
6	85	14.2	5.00	2.360	2.360	PASS
7	85	15.4	5.00	2.260	2.260	PASS
8	85	14.5	5.00	4.180	4.180	PASS
9	85	14.2	5.00	2.290	2.320	PASS
10	85	13.8	5.00	2.310	2.350	PASS
11	85	15.2	5.00	2.270	2.270	PASS
12	85	13.3	5.00	2.500	2.500	PASS
13	85	15.3	5.00	2.660	2.680	PASS
14	85	13.4	5.00	2.890	2.930	PASS
15	85	13.9	5.00	2.420	2.420	PASS
16	85	14.5	5.00	1.740	1.740	PASS
17	85	14.7	5.00	2.210	2.210	PASS
18	85	15.4	5.00	2.620	2.620	PASS
19	85	14.2	5.00	2.640	2.640	PASS
20	85	13.3	5.00	1.790	1.790	PASS

Overall Result: PASS

Signature: Nicole L. Petitta Date: 1/11/2017

Engineering Technician

Task Number: TN-21039 **Reference No.:** CFR 84.181

Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59

Manufacturer: Innonix Technologies Limited

Item Tested: RK-200-3041A

Comments:

Samples 1-8 were tested on TSI 8130 machine 000332 using timer 000213. Samples 9-14 were tested on TSI 8130 machine 000333. Samples 15-20 were tested on TSI 8130 machine 000334.

Was all equipment verified to be in calibration throughout all testing?	(•) Yes	( ) No

Signature: Nicole L. Petitta **Date:** 1/11/2017

Engineering Technician

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2013

Kai Deusch, M.D., Ph.D.
Chief Executive Officer
Filligent (HK) Limited
7th Floor 69 Jervois Street
Sheung Wan, Hong Kong

Re: K122702
Trade/Device Name: BioFriend™ BioMask™ N95 Surgical Respirator
Model: Professional BF-200-3013AN
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: ONT
Dated: January 14, 2013
Received: February 28, 2013

Dear Dr. Deusch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(K) Number (if known): K122702

Device Name:

BioFriend™ BioMask™ N95 Surgical Respirator
Model: Professional BF-200-3013AN

Indications for Use:

The BioFriend™ BioMask™ N95 surgical respirator is a single use NIOSH-approved, disposable N95 surgical respirator with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH-lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ N95 surgical respirator inactivates 99.99% of tested influenza viruses on five minutes contact with the surface of the respirator in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses. Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/04/2009, A/Brisbane/59/2007, A/Wisconsin/18/1988, A/New Jersey/8/1976, A/PuertoRico/8/1934), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/Japan/305/1957); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1968), H6N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/1981); the equine flu subtype: H3N8 (A/Equine/2/Miami/1963); and Influenza B strains: (B/Florida/4/2006, B/Lee/1940), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

The BioFriend™ BioMask™ N95 surgical respirator, Model: Professional BF-200-3013AN is flat-folded and expands into a convex-shaped mask with polyamide/spandex elastic head-loops to secure the mask to the user's face, and a malleable aluminum strip positioned above the nose for a tighter seal around the nose and face. The device is intended to be worn during seasonal Influenza A or Influenza B, and an Influenza A or Influenza B pandemic. It is intended for occupational use, to help reduce wearer exposure to pathogenic biological airborne particulates, and to protect against the transfer of micro-organisms, body fluids, and particulate material.

filligent

BioFitend™ BioMask™ N95 Surgical Respirator

Prescription Use _____ AND/OR Over-The Counter Use ___X___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Elizabeth F. Claverie
2013.03.18 15:14:51 -04'00'

FDA

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123702

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thank you!