Sooper Products

INTRODUCES

SooperMask

Intelligent Protective Gear

**My mask saves you,
your mask saves me! #SooperMasks**

Innovative Hygiene Technology for Maximum Protection.

One virus has completely changed the way we live. Making health and hygiene, everyone's top priority. In today's times, people across the globe are anxious to stay safe from the dreaded Covid-19 virus, and are in search of everyday solutions.

Sooper Products offers a range of solutions that are created using innovative hygiene technology to safeguard people. Whether you want to breathe easy from behind a mask when you step out or disinfect surfaces and objects with UV light, we have you covered. With **Sooper Products** on your side, you can rest assured that your health risk is significantly reduced. And so is your stress.

The **SooperMasks** have 3 layers but it gives 5 levels of protection against SARS-CoV-2, the virus which causes Covid-19. Specially treated textiles along with the filter channels eliminate 99.9% of the virus. **Livinguard Technology is applied to the fabric covering the filter media.**

The **SooperLamp** UV box uses the power of UV light to keep surfaces and objects virus-free for you.

As we go about our daily lives, knowing fully well that the fight with virus is going to be a long drawn one, the best we can do is stay highly protected always with **Sooper Products**.

SooperMask

Intelligent Protective Gear

Destroys Coronavirus*

CE Medical Face Mask Type II
Bacteria Filtration Ecacy (BFE) >98%

Reinventing protection by **destroying SARS-CoV-2**
Livinguard Technology is applied to the fabric covering the filter media.

Reusable
washable up to 30 times and reusable for 6 months.

Sustainable
replaces 210 conventional masks, does not leach.

Protection
fabric destroys bacteria, fungi and viruses and prevents them from spreading.

Style
Available in Vantablack, Bombay Blue. Forest Green, Cosmic Red

Comfort
Silky smooth fabric, odourless, adjustable ear loops for custom fit, high breathability

Safety
High performance filtration & free of toxic metals

Engineered and designed in Switzerland

Standards of Conformity

SooperMask
Intelligent Protective Gear

Proven Antiviral Properties:

Type of Virus	Test Facility	Viral Inactivation %
SARS-CoV-2	Freie Universität Berlin, Germany	99.9%
Human Coronavirus 229E	University of Arizona, Tucson, USA	99.5%
Influenza A	Federal Office for Civil Protection, FOCP, Switzerland	> 99.96%
Yellow Fever	Federal Office for Civil Protection, FOCP, Switzerland	> 99.97%
Bacteriophage MS2	BTS, Mumbai, India	> 99.99%

Antibacterial against a wide range of bacteria,

for example:

Escherichia coli, Staphylococcus aureus, Candida albicans, Multidrug-resistant *Enterococcus faecium* (VRE - ATCC 51559), Methicillin-resistant *Staphylococcus aureus* (MRSA - ATCC 33591), *Mycobacterium tuberculosis* (ATCC 25177), *Klebsiella pneumoniae, Clostridium difficile (C. diff), Mycobacterium terrae, Mycobacterium avium, Salmonella Typhi, Pseudomonas aeruginosa*

Why our mask?

SooperMask
Intelligent Protective Gear

Infinitely better and >25x cheaper masks

		vs. Conventional N95 
Destroys viruses* and bacteria upon contact without leaching poisonous chemicals / metals used in traditional antimicrobial treatments	**Virus & bacteria impact**	Viruses survive and bacteria multiply on the mask, thereby increasing infection risk
210 uses based on daily extended use x 30 weekly washes	**Usable life**	Single use, works for < 8 hours
< $0.12 per use based on $25 per mask	**$ Consumer's cost / use**	Normally $1 per mask and per use, *not accounting for current prices*
N95, can make N99 at slightly additional cost	**Filtration performance**	N95
< 0.5% waste. No leaching. Virus cannot mutate or develop resistance.	**Environmental impact**	> 200x non-biodegradable N95 filters to be disposed. Poisonous leaching if treated with conventional antimicrobials.

* See Appendix for virus types and test results

Livinguard patented solution for respirators

Layer 2 (N95) blocks particulate matter

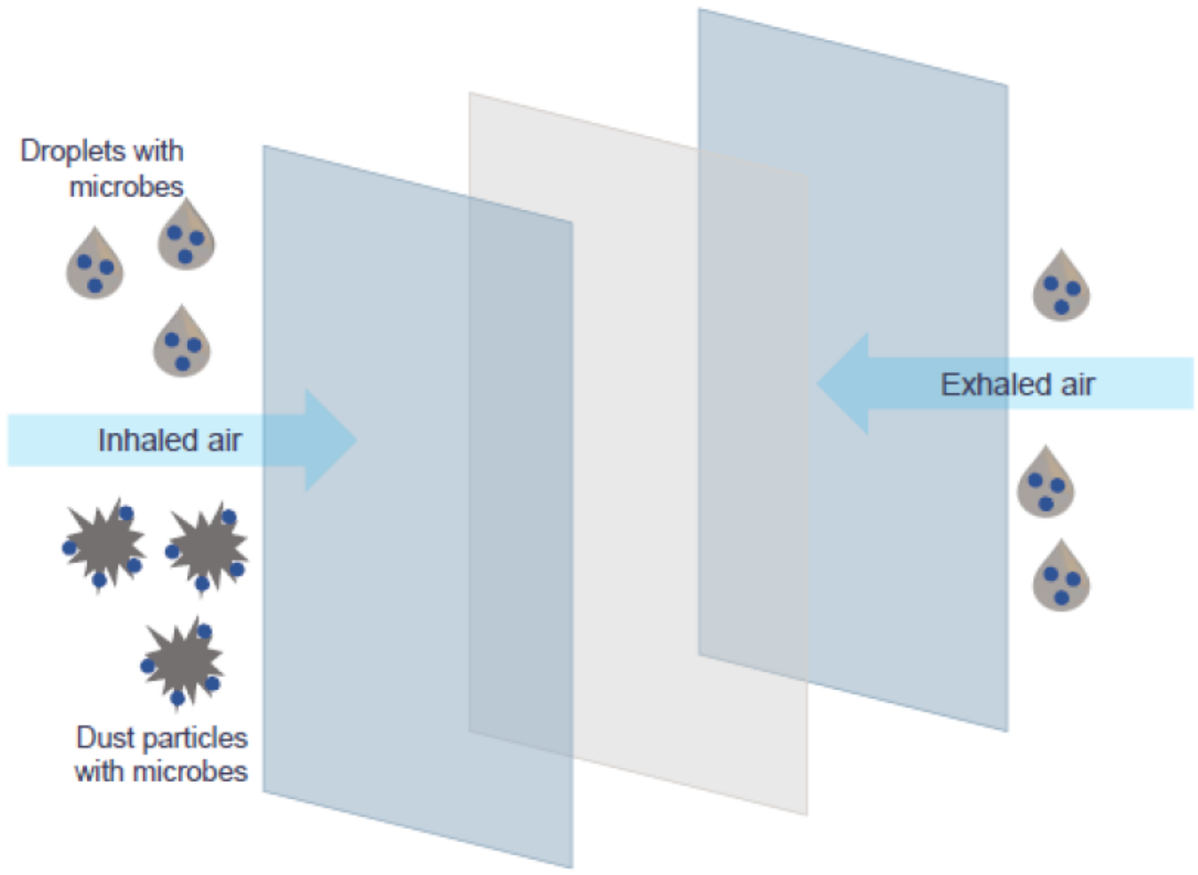
- Nonwoven filtration media blocks most particles in the air and therefore most of the germs contained in dust

Livinguard-charged layers (1 and 3) destroy microbes

- Microbes on dust particles filtered by layers 1 and 3 are partially killed (in contact with textile surface)
- Microbes contained in droplets filtered / absorbed by layer 1 and 3 are killed very effectively
- Microbes accumulating in layer 2 and transferred through respiration to layers 1 and 3 are killed upon contact with the textile surface
- Layers 1 and 3 remain disinfected and show very low contamination levels

Results

- Strongly reduces the transfer of pathogens from infected persons to the environment and from the environment to non-infected persons
- As the outside layers (1 and 3) are permanent disinfectants, **cross-contamination of the person handling the mask is largely reduced**



Why our mask?

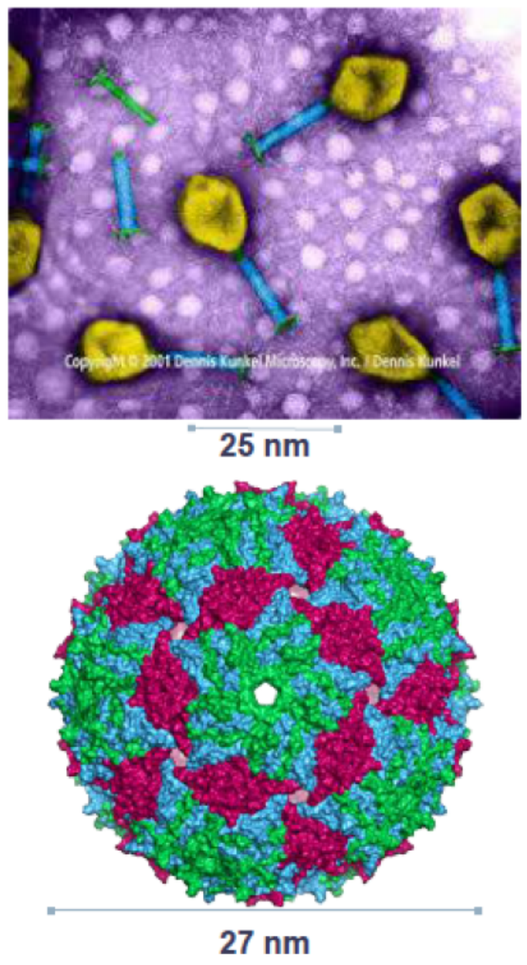
SooperMask
Intelligent Protective Gear

Proven efficacy against other Viruses

NSF International (USA) test report J-00293323
BTS (India ISO & NABL accredited lab) test report 14386/1-3

FR coliphage: 99.999% reduction (5 log)

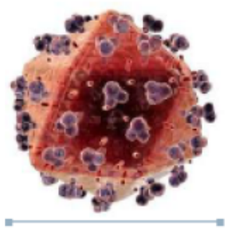
MS2 bacteriophage: > 99.999% reduction (> 5 log) from NSF and > 99.99% (> 4 log) from BTS



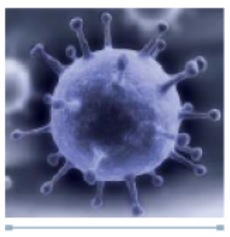
Proven efficacy against other Viruses

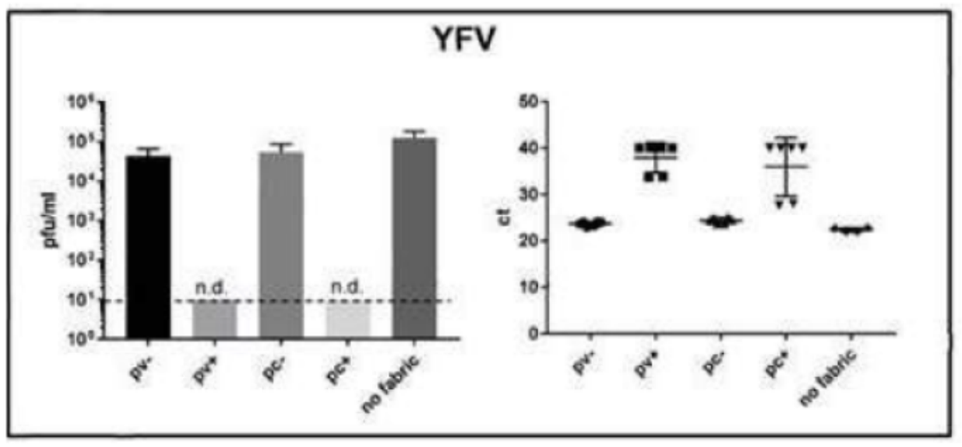
Testing by Swiss Federal Lab ABC Spiez

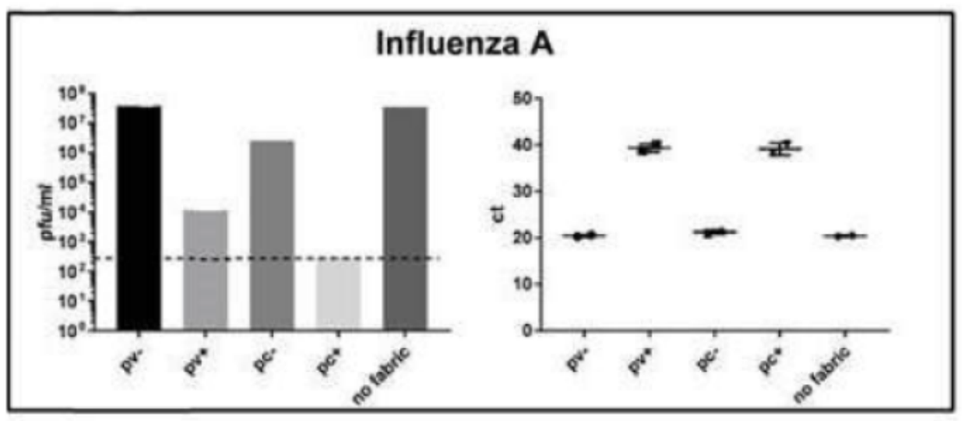
Yellow Fever Virus:
> 99.97% reduction (> 3.6 log)



Influenza A Virus:
>99.96% reduction (> 3.5 log)



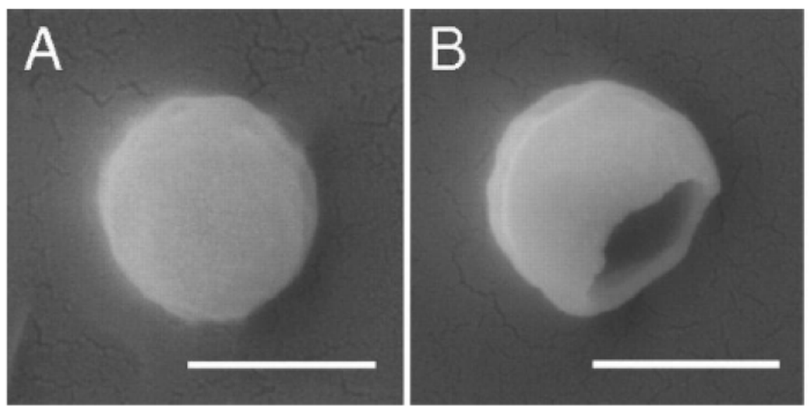




How does Livinguard destroy Viruses?

- 1 cm^2 of Livinguard treated textiles has an array of 24 billion immobilized cationic charges of different amplitudes

- These positive charges interact with and extract negatively charged compounds from the cell membrane (bacteria) or capsid (viruses), leading to disruption of the integrity and inactivation of the organism, without leaching



Native After exposure

Scale bar represents 100 nm

Image reference of an exploded Virus using cationic charges:
B.B. Hsu, S.Y. Wong, P.T. Hammond, J. Chen, A.M. Klibanov;
PNAS January 4, 2011 108 (1) 61-66

Certifications

SooperMask
Intelligent Protective Gear

China National Accreditation Service for Conformity Assessment
INSPECTION BODY ACCREDITATION CERTIFICATE

(Registration No. CNAS IB0024)

Guangdong Testing Institute of Product Quality Supervision

No.10, Science Avenue, Science City, Huangpu District, Guangzhou, Guangdong, China.

is accredited in accordance with ISO/IEC 17020: 2012 General Criteria for the Operation of Various Types of Bodies Performing Inspection(CNAS-CI01 Accreditation Criteria for the competence of Inspection Bodies) as Type A inspection body for the competence to undertake inspection services as described in the schedule attached to this certificate.

The scope of accreditation is detailed in the attached schedule bearing the same registration number as above. The schedule forms an integral part of this certificate.

Date of Issue: 2018-01-03

Date of Expiry: 2024-01-15

Date of Initial Accreditation: 2004-09-13

Signed on behalf of China National Accreditation Service for Conformity Assessment

China National Accreditation Service for Conformity Assessment(CNAS) is authorized by Certification and Accreditation Administration of the People's Republic of China (CNCA) to operate the national accreditation schemes for conformity assessment. CNAS is a signatory of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) and the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (APLAC MRA).
The validity of the certificate can be checked on CNAS website at http://www.cnas.org.cn/english/findanaccreditedbody/index.shtml

EC declaration of conformity

This is to declare that:

Livinguard AG
Bahnhofstrasse 12
6300 Zug
Switzerland

Product Name:
Livinguard Antibacterial & Antiviral N95/N99 Reusable Face Mask with/without valves

Product model:
FM-95-30-WV-BV: Face mask / N95 / 30 washes / with valve / Antibacterial & Antiviral
FM-95-30-NV-BV: Face mask / N95 / 30 washes / no valve / Antibacterial & Antiviral
FM-99-30-WV-BV: Face mask / N99 / 30 washes / with valve / Antibacterial & Antiviral

Livinguard respiratory face masks Livinguard respiratory face mask can filter >95% droplets, airborne and particles (>0.3 microns). The face masks are hygienic, antibacterial, antiviral, reusable, and washable.

The manufacturer bears the sole responsibility for issuing this declaration of conformity.

Livinguard face masks comply with the Regulation (EU) 2016/425 on personal protective equipment for respiratory protection.

Harmonized standards applied in whole or in part: EN 149:2001+A1:2009 (Reusable FFP2).

EC Declaration of Conformity: As an authorized representative, I declare that the above mentioned products meet the requirements of the applicable directives.

Signed for and on behalf of:

Mr. Sanjeev Swamy CXO

p.a. Wouter Pronk, EVP R&D

CE

Photo verification of the above mentioned object:

Livinguard AG **26.03.2020**

Certifications

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Intelligent Protective Gear

HOHENSTEIN

ERGEBNIS / *RESULT*

- Probe / *Sample* 18.8.5.0138-3

Im Schweißextrakt wurde mit bloßem Auge **keine Verfärbung** beobachtet. Es wurde am Probenmaterial bzw. Schweißextrakt **ein schwach süßlicher Geruch** festgestellt.

*The observation of perspiration extract showed **no discoloration**.*
*In the investigation on odor **a slight sweet smell** was detected.*

Am Schweißextrakt wurde keine Veränderung des pH-Wertes von 5,5 beobachtet.

The pH-value in the perspiration extract was still 5.5.

Rel. Proteingehalt / *Rel. protein content* OD [570nm]	X	±	s	Wachstumshemmung / *growth inhibition* in %	
Leerwert / *blank*:	0,1894				
Positivkontrolle / *positive control*:	0,3719	±	0,0079	88	
Negativkontrolle / *negative control*:	1,9360	±	0,0832	0	
Lösungsmittelkontrolle / *solvent control*:	1,6762	±	0,0041	0	
Prüfgegenstand / *test sample*:					Limit
33,30%	1,4613	±	0,0625	14	≤ 30%
22,20%	1,5517	±	0,0361	8	
14,80%	1,6224	±	0,0586	4	
9,90%	1,6163	±	0,0206	4	

X entspricht Mittelwert aus Mehrfachmessungen
s entspricht der Standardabweichung
Versuchsdurchführung: hec, nka

X *is the average of multiple measurements*
s *is the standard deviation*
Test performance: hec, nka

Unter den angegebenen Bedingungen zeigte der Schweißextrakt der Probe eine Wachstumshemmung von 14 % im Zytotoxizitätstest.

Under the mentioned test conditions, the perspiration extract of the test material showed a growth inhibition of 14 % in the cytotoxicity test.

Ausgehend vom Prüfmaterial konnte eine dosisabhängige Wachstumshemmung der L929 Zellen beobachtet werden, jedoch wurde die Signifikanzgrenze von 30 % nicht überschritten.

A dose-dependent growth inhibition of L929 cells could be observed, which derived from the test material, but the significant limit of 30 % was not exceeded.

HOHENSTEIN

ZUSAMMENFASSUNG / *CONCLUSION*

BEURTEILUNGSKRITERIEN / *ASSESSMENT CRITERIA*

Nach DIN EN ISO 10993-5 wird eine Wachstumshemmung von **mehr als 30 %** im Vergleich zur Lösungsmittelkontrolle als eine zytotoxische Wirkung angesehen.

*According to DIN EN ISO 10993-5 a growth inhibition of **more than 30 %** in comparison to the solvent control is considered as a clear cell-toxic effect.*

BEURTEILUNG / *ASSESSMENT*

- Probe / *Sample* 18.8.5.0138-3

Extrakt von Reusable cotton hand towel roll scoured treated (1 x washed by Hohenstein Institute)

Extract of Reusable cotton hand towel roll scoured treated (1 x washed by Hohenstein Institute)

Die ermittelte Wachstumshemmung von unter 30 % zeigt, dass aus dem Prüfgegenstand keine zelltoxischen Substanzen freigesetzt werden.

The detected growth inhibition of less than 30 % shows that no cytotoxic substances are released.

Schloss Hohenstein, 23. Februar 2018

Deputy Director
Life Science & Care

Dr. Anja Gerhardts

Hohenstein Laboratories · Schloss Hohenstein ·

Product Manager Biomedicine
Life Science & Care

Dipl.-Ing. (FH) Anne Schopfer

"The translation was carried out to the best of a non-native speaker's knowledge. Liability cannot be taken."

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

M4 Medical Pty Ltd

for approval to supply

M4 Medical Pty Ltd - Mask, surgical, reusable

ARTG Identifier	335554
ARTG Start Date	1/05/2020
Product Category	Medical Device Included Class 1
GMDN	37713
GMDN Term	Mask, surgical, reusable
Intended Purpose	An N95 reusable mask placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed.

Manufacturer Details	Address	Certificate number(s)
FINE HYGIENIC PAPER FZE	PLOT NO EWRA 56 JEBAL ALAI FREE ZONE PO BOX 16927 , DUBAI , United Arab Emirates	

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, reusable

Product Specific Conditions

No specific conditions have been recorded against this entry.

Certifications

SooperMask

Intelligent Protective Gear

DMT - Prüf- und Ergebnisprotokoll

DMT

Prüfung Corona SARS-Cov-2-Virus Pandemie Atemschutzmasken

auf Grundlage Prüfgrundsatz Rev. 1 vom 26.03.2020 - erstellt von der DEKRA Testing and Certification GmbH und dem Institut für Arbeitsschutz (IFA) der Deutschen gesetzlichen Unfallversicherung

Allgemeines

Berichts Nr.:	Prüfzeitraum:	Datum Prüfungsannahme:
800 301 9204 - 1	13.05. - 15.05.2020	08.05.2020

Prüfung beauftragt durch:	Endkunde:	Unterschrift Prüfer:	Unterschrift Leiter Prüflabor:
TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen	Medivid GmbH Billwerder Neuer Deich 70 20539 Hamburg	25.05.2020 (Gläser)	25.05.2020 (Schamberg)

Angaben zum Prüfling

Modell/Typbezeichnung (*):	KN95
Ausführung:	Nasenbügel, Ohrenschlaufen
Hersteller:	Anhui Tiankang Medical Technology Ltd.
Modellbezeichnung:	High-Performance Virus-Eliminating Mask
Ident.-Nr./Artikelnummer:	k. A.

Lieferumfang

Verpackungsart:	Papier-/Kunststoffbeutel
Verpackungseinheit:	1 Stück
Informationsbroschüre:	auf Verpackung gedruckt

Prüfungen und Test-Ergebnisse

1. Sichtprüfung

Kriterium	Bewertung
Verpackungsart:	Papier-/Kunststoffbeutel
Verpackungseinheit:	1 Stück
Verpackung stoßsicher:	i. O.
Verpackung staubdicht:	i. O.
Zustand CPA:	i. O.
Beurteilung:	bestanden

2. Anlegeprüfung

Kriterium	Bewertung
CPA leicht anzulegen	i. O.
CPA leicht abzulegen	i. O.
Komfort der Kopfbänderung	i. O.
Gesichtsfeld	i. O.
offensichtliche Undichtigkeiten:	nein
wahrnehmbare Luftströmung:	nein
Beurteilung:	bestanden

3. Zustand nach Temperaturkondtionierung (24 h bei 70°C)

Zustand CPA:	formstabil, Zustand unbeschadet
Beurteilung:	bestanden

4. Zustand nach Gebrauchssimulation

Zustand CPA:	formstabil, Zustand unbeschadet
Beurteilung:	bestanden

5. Durchlass-Prüfung (Max.-Wert Prüflinge 1-3)

Paraffinöl-Konzentration nach Maske - Reingas C_2 [mg/m³]:	0,82
Paraffinöl-Konzentration vor Filter - Rohgas C_1 [mg/m³]:	21,07
Durchlassgrad P [%]:	3,9
Sollwertabgleich:	Pmax ≤ 6%
Beurteilung:	bestanden

Beurteilung: bestanden

6. Prüfung CPA mit Ausatemventil

Prüfung:	Ergebnis:	Beurteilung:
Ergebnis Zugversuch am Ventil mit 10 N:	hier nicht anwendbar	-
Funktionsprüfung nach Belastung bei 300 l/min:	hier nicht anwendbar	-

7. Prüfung des Atemwiderstandes CPA

Max.-Wert Ausatemwiderstand bei 160 l/min (Sollwert ≤ 3 mbar)

Blickrichtung:	Druckverlust	Beurteilung
gerade aus	297 Pa	bestanden
nach links	-	-
nach rechts	-	-
nach oben	-	-
nach unten	-	-

Max.-Wert Einatemwiderstand bei 95 l/min (Sollwert ≤ 3 mbar)

Blickrichtung:	Druckverlust	Beurteilung
gerade aus	298 Pa	bestanden

8 Prüfung der Kennzeichnung

Kriterium	Prüfung	Bewertung
Herstelleridentifikation:	Anhui Tiankang Medical Technology Ltd.	o. k.
Warenidentifikation:	KN95	o. k.
Informationsschrift:	auf Verpackung gedruckt	o. k.
Aufsetzanleitung	auf Verpackung gedruckt	o. k.
Hinweise zur Verwendung:	auf Verpackung gedruckt	o. k.

Beurteilung: bestanden

Gesamtbeurteilung der geprüften CPA: bestanden

DMT GmbH & Co. KG
Am TÜV 1
45307 Essen / Germany
TÜV NORD GROUP

RESEARCH, DISCOVERY & INNOVATION

Water & Energy Sustainable Technology Center

Study Conclusions

The FM-7 Test Fabric was the most efficacious against Human Coronavirus 229E, achieving a reduction of 99.5% (2.30 $\log_{10}$) given two hours of exposure relative to the Control Fabric (Table 1). Test Fabric FM-26 reduced levels of the test virus by 98.4%, while reductions were minimal for Test Fabric FM-14 at 13.8%.

With regard to cytotoxicity effects on the MRC-5 cell line, the level of toxicity observed for test fabrics FM-7 and FM-26 was similar to that of the Control Fabric (Table 2). Toxicity levels on MRC-5 host cell monolayers were slightly greater for the FM-14 test fabric. However, the sensitivity of MRC-5's, an internal human lung fibroblast cell line, should not necessarily be extrapolated assume any effects on the protective and resilient cells comprising the external cell layers of human skin.

Neutralization was validated for each of the Control and Test Fabrics beyond the level of cytotoxicity, with < 0.5 $\log_{10}$ difference in viral titer observed between the Control and Test fabrics (Table 3).

References

1. Sturman, L.S., Holmes, K.V. and Behnke, J., 1980. Isolation of coronavirus envelope glycoproteins and interaction with the viral nucleocapsid. *Journal of virology*, *33*(1), pp.449-462.
2. Chen, D., Luo, W., Hoffman, J., Huang, L., Sandefur, S., Hall, T., Murphy, M. and O'Donnell, S., 2019. Insights into Virus Inactivation by Polysorbate 80 (PS80) in the Absence of Solvent. *Biotechnology Progress*.
3. Colavita, F., Quartu, S., Lalle, E., Bordi, L., Lapa, D., Meschi, S., Vulcano, A., Toffoletti, A., Bordi, E., Paglia, M.G. and Di Caro, A., 2017. Evaluation of the inactivation effect of Triton X-100 on Ebola virus infectivity. *Journal of Clinical Virology*, *86*, pp.27-30.

Nelson Labs
A Sotera Health company

Biocompatibility of Mask Material
Prepared For: Livinguard, Inc.
22 April, 2020

Livinguard Self-Disinfecting Textile for Emergency Use in N95 Facemasks: Statement of Biocompatibility

Background
COVID-19 is an infectious disease caused by the SARS-COV-2 virus that has been declared a global pandemic by the World Health Organization. The spread of SARS-COV-2 has resulted in immense stress on global healthcare systems and produced a shortage of lifesaving medical devices and personal protective equipment used by medical professionals, including face masks. Livinguard, Inc. manufactures a range of self-disinfecting materials including textiles that are fabricated through the integration of disinfectants directly into the material. Livinguard wishes to use their self-disinfecting textile in the fabrication of an N95 facemask. This use would classify the device as an N95 Respirator with Antimicrobial/Antiviral Agent (product code ONT) regulated by 21CFR878.4040 which specifies that "the user contacting components of the device must be demonstrated to be biocompatible." The FDA has raised a specific question on the point of biocompatibility of the treated textile when used as a mask.

The textile in question is treated with polyhexamethylene biguanide (PHMB, Manufactured by Arch UK Biocides as Vantocil IB). This active agent is bonded to the textile fibers, with effectiveness that persists after multiple washes (data on file with Livinguard). This document summarizes what is known about the biocompatibility of the Livinguard self-disinfecting textile in question, and evaluates the appropriateness of its use in N95 masks from the perspective of biocompatibility.

Summary of Biocompatibility Testing Completed on MED610
A suite of biocompatibility tests have been conducted on a worst-case version of the textile that contains PHMB among other ingredients at a concentration 250% above normal.

Table 1. Biocompatibility Tests Performed on Livinguard's Self-Disinfecting Textile

Biological Endpoint	Testing Standard	Result
Sensitization	EPA P328 Buehler Method	Pass
Irritation	EPA P326 Primary Skin Irritation	Pass
Acute Dermal Toxicity	EPA P322 Acute Dermal Toxicity	Pass

Gap Assessment, Testing Conducted, and Regulatory Expectations for Mask Applications
Testing was conducted on the textile per EPA protocols assuming household use, not necessarily as a mask. For masks that are marketed as a medical device, a biocompatibility evaluation should be conducted per ISO 10993-1. According to this standard, N95 masks would be categorized as surface devices with a cumulative contact to intact skin possibly greater than 30 days. The biological endpoints for evaluation of this contact type are cytotoxicity, sensitization, and irritation.

Based on the passing results of sensitization and irritation per EPA standards, it is likely that the material would pass these tests when tested per ISO 10993-1, and the risks associated with these endpoints are acceptable. Cytotoxicity testing was not conducted. This test would not be a good indicator of biocompatibility for the textile in question, as it is designed to be anti-microbial and is expected to be cytotoxic. Cytotoxicity testing should be considered on the same textile not treated with the active agent. Nevertheless, the absence of these test results should not prevent the material from being used in PPE during the COVID-19 pandemic.

FDA Feedback Regarding Use
In preliminary conversations, the FDA indicated to Livinguard a concern that the charged fibers of the textile could act as a cationic surfactant that may damage respiratory tissue.

Nelson Labs
A Sotera Health company

Biocompatibility of Mask Material
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22 April, 2020

Vantocil IB is an aqueous solution of PHMB, which is applied to the textile and then fully dried. PHMB is a polymer, typically with 10-40 repeating units and a molecular weight in excess of 700 g/mol. Therefore, it is expected to be non-volatile and has a reported vapour pressure of 4.11×10^{-7} Pa at 25 °C and not able to vaporize for inhalation at any appreciable amounts (see CLH Monograph on PHMB). Because the active agent on the treated textiles is permanently applied, persisting over several washes, and non-volatile they are not available to be inhaled and interact with respiratory tissues.

Potential Risks Associated with VOCs and Particulates: While VOCs released from the textile were not explicitly measured, the non-volatile nature of active agents and their persistence on the textile mitigate this concern. Therefore, any risks potentially associated with VOCs and particulates from the textile are considered acceptable in emergency situations associated with the COVID-19 pandemic.

Limits and Recommendations
The risks related to use of Livinguard's self-disinfecting textile in masks is considered minimal. It is recommended that representative samples of material are fabricated into masks and tested per the most current FDA recommendations to explicitly demonstrate compliance to the standards and to completely mitigate risk. It is however acceptable to proceed with use in applications related to the COVID-19 pandemic ahead of the conclusion of this testing.

Conclusion
The minimal biocompatibility risks associated with use of Livinguard self-disinfecting textile is masks are acceptable in emergency situations associated with the COVID-19 pandemic.

Document Prepared By:

2020.05.02 10:14:59 -06'00'

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NELSON LABORATORIES, LLC
A Sotera Health Company

Important Information: *This document is not equivalent to regulatory approval by any regulatory body. It is a third-party expert evaluation of the potential risks of the material when used described and in accordance with Emergency Use Authorization (EUA) being issued in response to concerns relating to insufficient supply and availability of FDA-cleared PPE for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic. For more information visit US FDA at: https://www.fda.gov/media/136423/download.*

Certifications

SooperMask
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Supplementary Information about Chinese Mask Test Report (FZ2011002)

27.04.2020, Zug

Livinguard Respiratory Face Mask was tested by Chinese lab GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION, the test results show Livinguard Respiratory Face Mask is compliant with Chinese Standard GB 2626 2006 KN95 (Respiratory protective equipment. Non-powered air-purifying particle respirator), based on the comparison below, it is reasonable to consider China KN95 as "equivalent" to US NIOSH N95 and European FFP2 respirators.

Certification/Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLWNotification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

Livinguard AG
Bahnhofstrasse 12, 6300 Zug, Switzerland

Livinguard AG
Bahnhofstrasse 12, 6300 Zug, Switzerland

Berlin, 16.06.2020

Report-Antiviral Activity of textile products from Livinguard

Tested by: Prof. Uwe Rösler and Dr. Anika Friese

Freie Universitaet Berlin, Institute for Animal Hygiene and Environmental Health

Tested textile product

- reference textile: Baumwolle (Co) unbehandelt 11.04.2020, lab number: C1
- antiviral textile: HEFM47.CO.01, 13.05.2020, LIVINGUARD, lab number: C2-neu

Method

- based on ISO 18184 (First edition 2014-09-01)
  - ➢ washing of all tested textiles with deionized water 10 times at **40°C**, drying
  - ➢ cutting pieces of approximately 20x20mm and making up a mass of 0,4g with several pieces
  - ➢ sterilization at 121°C for 15 min, drying
  - ➢ before starting the test **conditioning the textiles overnight** in a humid environment (incubator 37°C)
  - ➢ controls: Verification of cytotoxic effect and cell sensitivity to virus/inactivation of antiviral activity
  - ➢ test: inoculation of 0,4g textile **with 1ml virus suspension** (at least 10^7 $TCID_{50}$/ml)
    washing out using 19 ml **cell culture medium** auf (MEM Eagle EBSS + 10% FKS + 1% nicht-essentielle AS, +1 % Penicillin (10.000 U/ml) / Streptomycin (10 mg/ml))
    titration in 96-well plate and titer calculation with method of **Spearman and Karber in TCID/ml**
  - ➢ comparison of titer from untreated textile (reference) and treated textile for the specific time points

TÜV NORD Zertifizierung

Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Revision 1
Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks revision 1

Berichtsnummer *Report number*	8003019204-1
Prüfgegenstand *Test subject*	Partikelfiltrierende Halbmaske ohne Ventil
Modell *Type*	High-Performance Virus-Eliminating Mask
Importeur *Importer*	Medivid GmbH Billwerder Neuer Deich 70 20539 Hamburg
Hersteller *Manufacturer*	Anhui Tiankang Medical Technology Co. Ltd. 228 Weiyi Road, Economic Development Zone, Tianchang City, 239300 Anhui, China

Die Anforderungen des Prüfgrundsatzes sind mit Paraffin Öl *The requirements of the test principle with paraffine oil are*	Erfüllt *Fulfilled*

Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Empfehlung (EU) 2020/403 der Europäischen Kommission vom 13. März 2020 über Konformitätsbewertungs- und Marktüberwachungsverfahren im Kontext der COVID-19 Bedrohung zu vermuten.
The technical efficiency of the above-mentioned product is to be presumed within the framework of the European Commission Recommendation (EU) 2020/403 of 13th March 2020 on conformity assessments and market surveillance procedures in the context of the COVID-19 risk.

Der Prüfgrundsatz kann unter dem folgenden Link eingesehen werden:
The test principle can be accessed under the following link:
http://www.zls-muenchen.de/Corona/Atemschutzmasken/index.htm

Dieses Bewertungsschreiben bezieht sich nur auf die geprüften Masken und verliert bei Produktänderungen seine Gültigkeit.
This confirmation letter only refers to the tested masks and loses its validity if the product changes.

Diese Bewertung ist gültig ab dem 26.05.2020.
This evaluation of conformity is valid as of 2020-05-26.

TÜV NORD CERT GmbH
Essen, 26.05.2020

TÜV NORD Digital unterschrieben von Eck, Michael Datum: 2020.05.30 09:38:00 +02'00'

Zertifizierungsstelle *Certification Body*

TÜV NORD CERT GmbH, Langemarckstraße 20, 45141 Essen
Telefon +49 201 825 0, Fax +49 201 825 2517, info@tuev-nord.de

Certifications

SooperMask
Intelligent Protective Gear

HygCen Austria GmbH | Werksgelände 28 | 5500 Bischofshofen

HYGCEN AUSTRIA

Akkreditierte Prüfstelle nach EN ISO 17025

Certificate

Livinguard AG
Bahnhofstrasse 12
6300 Zug
Switzerland

Street Mask
can be certified, that it fulfills the biocompatibility according to ISO 10993-1:2018 .

The conformity with these requirements is confirmed by the test report number: B 24462a

Identification Number: 2024462a/078

Bischofshofen, 2020-06-22

Prof. Dr. med. H.-P. Werner
Managing Director
Medical Specialist for Hygiene & Microbiology

HygCen Austria GmbH | Werksgelände 28 | 5500 Bischofshofen

HYGCEN AUSTRIA

Akkreditierte Prüfstelle nach EN ISO 17025

Certificate

Livinguard AG
Bahnhofstrasse 12
6300 Zug
Switzerland

Pro Mask, Typ I
had been **tested** according to
EN 14683:2019
„Medical face masks - Requirements and test methods "
inclusive appendix B, appendix C

The conformity with these requirements is confirmed by the test report number: B 24508

Identification Number: 2024508/074

Bischofshofen, 2020-06-22

Prof. Dr. med. H.-P. Werner
Managing Director
Medical Specialist for Hygiene & Microbiology

HygCen Austria GmbH | Werksgelände 28 | 5500 Bischofshofen

HYGCEN AUSTRIA

Akkreditierte Prüfstelle nach EN ISO 17025

Certificate

Livinguard AG
Bahnhofstrasse 12
6300 Zug
Switzerland

Ultra Mask, Typ II
had been **tested** according to
EN 14683:2019
„Medical face masks - Requirements and test methods "
inclusive appendix B, appendix C

The conformity with these requirements is confirmed by the test report number: B 24507

Identification Number: 2024507/073

Bischofshofen, 2020-06-22

Prof. Dr. med. H.-P. Werner
Managing Director
Medical Specialist for Hygiene & Microbiology

SooperMask

Intelligent Protective Gear

Suitable for daily personal use.
Medical Face Mask Type II

- Conforms to EN14683 Medical Mask Type II (Bacteria Filtration Efficacy (BFE) >98%)
- CE Medical device class I
- Choice of 4 solid colours

Destroys 99.9% Coronavirus

Also available for kids:

SooperMask JUNIOR

Intelligent Protective Gear

Contact us for more details.

SOOPER PRODUCTS

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