From: David Dickson
Sent: Monday, November 27, 2023 10:16 AM
To: [redacted]@capitalcare.net
Subject: RE: Unapproved/uncertified KN95 found placed in the handrail outside of Jean's room - URGENT

## Good morning Aileen,

We are just following up on last week's communications. Since my last email, I did open one of the KN95 masks we found outside of Jean's room. Further investigation makes this all the more disturbing. Despite the approval request to NIOSH clearly showing these masks have ear loops (and are therefore not an N95 equivalent), this batch appears to have been modified at some point to have head straps without notifying NIOSH of this change.



Note these are welded head straps, not the stapled, elastic type typically found in N95 masks. I have searched the NIOSH certification for these Chinese equivalent GB2626 (N95) respirator equivalents. They are not in the NIOSH approved list. The fact that there is no application nor certification for these modified masks (nor any presence on the manufacturers website) might suggest they are neither certified nor safe. As SanQI has submitted multiple N95 respirators that have been certified by NIOSH (see links below), it is also possible that they maybe counterfeit (which is something that NIOSH warns about regarding KN95 masks).

Under the Health and Safety regulations, Health Canada and NIOSH expectations, KN95 masks are designed as inferior equivalents to the N95 respirator. Anyone using these must therefore follow the expectations of an N95 mask if they are used i.e. FIT testing;

## 1. FIT for Purpose

Has the mask or face covering been proven to be "FIT FOR PURPOSE" i.e. to prevent the spread of an airborne virus?

#### 2. Is the person FIT to wear the mask?

Have you confirmed you (or your staff/customer) will not experience any harmful effects related to the mask or face covering?

#### 3. Is it FIT to the person?

Even if you have moved through the first two processes, any mask or face covering has to be properly FITTED to you to ensure it works for point 1, and doesn't cause issues for point 2.

#### 4. Is it FIT for the environment?

As a mask can be taken off in many circumstances in the same environment i.e. when eating, drinking, regular breaks etc. and there is no separation of atmosphere between the mask wearing and non-mask wearing areas, the risk cannot be environmental, yet it clearly is based on **airborne transmission**.

"SARS-CoV-2, the virus that causes COVID-19, spreads from an infected person to others through respiratory droplets and

## aerosols created when an infected person coughs, sneezes, sings, shouts, or <u>talks</u>."

https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals/main-modes-transmission.html

Point 1 and 4 are something of a concern as they would make the use of any mask (outside of SCBA and SABA respirators) during COVID (as it was during Influenza) moot. Sadly, this is something that was known from the start of COVID but was misrepresented to the point masking became overstated as a protective measure. This is a very dangerous position to have been taken.

So, does this mask FIT the requirements for use? If it was certified for use, then it could only be used by persons properly trained and fit tested. However, this mask is not certified from the documentation I have been able to ascertain.

Below is a list of SanQi NIOSH certified masks (which as N95 masks should never be provided to anyone who does not meet the FIT requirements above). Note that these were all initially certified during the COVID exemption process in 2020. Note that none of these masks appear on the SanQi website.

It is important again to understand that KN95 masks are not approved by NIOSH but are considered N95 type in design so must follow the N95 steps for use. It is probable that anyone using such a mask without the appropriate training/certification and use introduces a liability to the organisation providing it. This is something that should be addressed with a Health and Safety masking expert.

#### https://www.cdc.gov/niosh/npptl/topics/respirators/disp\_part/n95list1sect2-r.html

"A respirator labeled as a KN95 respirator is expected to conform to China's GB2626 standard. NIOSH does not approve KN95 products or any other respiratory protective devices certified to international standards. For more information, view Factors to Consider When Planning to Purchase Respirators from Another Country."

NIOSH Approved devices for SanQI (all listed as N95). SQ100CVb - Carbon Filter https://ia600204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/Rizhao8086.pdf

#### SQ100Sb - Marketed as Not NIOSH but ASTM/N95

https://ia600204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/Rizhao8109.pdf

#### SQ100Cb - Carbon N95

https://ia800204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/Rizhao8110.pdf

#### SQ100Vb - Vented N95

https://ia800204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/Rizhao8111.pdf

#### SQ100D - N95

https://ia800204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/Rizhao9227.pdf

#### SQ100E - N95

https://ia600204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/Rizhao9229.pdf

#### SQ100G - N95

https://ia600204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/9244-Rizhao.pdf

#### SQ100Sc (FDA) - N95

https://ia600204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/9303\_Rizhao.pdf

#### SQ100Gs (FDA) - N95

https://ia800204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/9323\_Rizhoa.pdf

Looking forward to an update.

Thank you again for your time and diligence in this matter.

David & Karen

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From: Aileen Wong
Sent: Wednesday, November 22, 2023 9:02 AM
To: David Dickson <<u>david.dickson@dksdata.com</u>>
Subject: Re: Unapproved/uncertified KN95 found placed in the handrail outside of Jean's room - URGENT

Hi David I am currently in Calgary but hope to have information by friday

## Aileen Wong | Chief Operating Officer | CapitalCare |

[redacted]|Like us on Facebook |Follow us on Twitter | See us on YouTube

Capitalcare respectfully acknowledges that our care homes are situated on Treaty 6 territory, traditional lands of First nations and Metis people, whose history, languages, and cultures enrich our communities

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From: David Dickson <<u>david.dickson@dksdata.com</u>>
 Sent: Wednesday, November 22, 2023 8:09:12 AM
 To: Aileen Wong
 Subject: Unapproved/uncertified KN95 found placed in the handrail outside of Jean's room - URGENT

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Good morning, Aileen.

This is an urgent follow up to our meeting last week, Friday 17<sup>th</sup>, November 2023. In that meeting, we indicated that unapproved KN95 masks were being made available to staff and visitors/DSP's and that these medical devices should be removed from use immediately. However, nothing could have prepared us though for what we saw yesterday evening when we came to pick up Jean (Karen's mum) from CCD to take her for supper.

As Karen left Jean's room, Jean put her foot down to stop the wheelchair and gestured with alarm to the handrail outside her room. She was pointing specifically to a box of KN95 respirators sitting in the handrail outside her room. Note this is the exact same type of KN95 that was on the visitor/DSP cart at the entrance to Unit 3D that we mentioned concerns about in our recent meeting.



This box had clearly been placed there for the use by staff and/or visitors/residents entering Jean's room. Karen and I took a look around the unit and found no other room with masks outside. Considering the recent removal of the no mask sign on Jean's door and the specific mention of these KN95 masks and their danger and requirement for removal in our meeting, it is hard to judge this finding as anything less than malicious on the part of someone at CCD. This is clearly having a detrimental impact to Jean. Kathy, (the unit manager) mentioned she already had to reassure Jean the week before that she would not be restricted in her movement when the cart with KN95 masks (and more) was placed at the

entrance to the unit recently.

This is the laminated mask sign that had been on Jean's door with the approval of the Unit Manager from June 19<sup>th</sup> until recently removed (without notice to us) with the apparent approval of [redacted]. Taking all of these recent events in context, it is impossible to dismiss them as coincidence.



We removed the box of unapproved KN95 respirators and gave it to the RN on duty along with notification that we would be bringing this to your attention. I removed samples from the box for further inspection due to ongoing concerns.

These masks are stamped as GB2626-2019 KN95 respirators. As such, they are classed as a medical device requiring FIT testing/training for safe use. However, they also have ear loops and not elastic straps so cannot be approved for use by NIOSH or Health Canada (see below).

We are now deeply concerned, not only that these devices are being made available at CCD, but also that there appears to have been an additional targeted attack on our family in the placement of this box outside Jean's room. Not to mention the fact that the placement of this box prevents the use of this particular handrail contrary to Health and Safety requirements. As a disabled person who uses a stick to assist me in walking, I am particularly sensitive to these types of breaches of Health and Safety. Note that in all the years at CCD we have never experienced something like this.

Based on the above and below, we would request that these unapproved medical devices be immediately removed from Capital Care. As we discussed in our meeting, (now made more urgent by yesterday's events), we expect signage regarding the requirement for anyone working with Jean to not have their face obscured be reinstated on Jean's door immediately. As discussed and agreed in the meeting, this is in the interest of Health and Safety, as required by AHS, Health Canada and under the Health and Safety Act. We also request further investigation as to who approved the use of these specific masks, who removed the sign from Jean's door and who placed these masks outside of Jean's door post our meeting on Friday 17<sup>th</sup>, November 2023.

Note that this new concern on the placement of masks outside Jean's room is above and beyond Friday's discussion around the uncertified and dangerous, modified KN95 window masks available through AHS as a misguided means to

assist in communication that should also be removed from use. That mask also fails on similar issues to the above but with the added risk of a lack of adequate permeable material to allow for safe use (due to the clear plastic insert). Note that the change in the online AHS document that removed the false ASTM certification happened immediately after I brought the concerns of this mask to the CEO of AHS and others.

# Options and Adaptations for Healthcare Providers to Address Patient Communication Challenges in Acute Care, Ambulatory Care and Community Settings

	Created:	2022-10-14 11:03:02 AM	Modified	d: 2022	2-10-	14 11:49:55 AM		
Mask Procedure with Window					•	Available from	inventory	
ASTM Level 2 N					•		STM Level 1 rated for fluid but passes filtration tes of level 2/3	
					•	Trialed by speech language and audiology departments at one sites with positive results		
					•		contact your local site services g numbers will vary by zone/area	
Created: 2023-02-22 3:08:12 PM Modified: 2023-02-28 2:02:35 PM								
Mask procedure with window				<ul> <li>Available from inventory</li> <li>Trialed by speech language and audiology departments at one site with positive results</li> </ul>				

As has been the case throughout COVD, the concerns regarding the improper use of masks continues to be a significant concern to our family in relation to the Health and Safety of staff, resident and visitors/DSP's to all facilities.

We would appreciate your urgent attention and response to these matters, Aileen.

Many thanks,

David & Karen

For reference regarding the unapproved and clearly unsafe medical devices by use and design, see the below. From Health Canada

"Respirators can be tested to different international standards. These standards include the:

- Canadian CAN/CSA Z94.4.1
- U.S. NIOSH standard for N95s
- European EN 149 standard (FFP2 or FFP3)
- GB 19083 for Chinese medical respirators
- GB2626 for Chinese KN95s

In Canada, it is the **labelling**, indications for use and claims that contribute to the **classification of a product as a medical device**."





These specific KN95 respirators were tested by the CDC in April 2020 as part of the emergency approval for KN95 Medical Devices in place due to an expected shortage of N95 respirators. Note that this device failed the NIOSH approval (and therefore the Health Canada importation and use approval) in a number of areas. <u>https://www.cdc.gov/niosh/npptl/respirators/testing/results/MTT-2020-</u> 29.1 International 3Q9505 TestReport Redacted-508.pdf

*"Manufacturer: Rizhao Sanqi Medical & Health Articles Co., Ltd. Model Tested: 3Q 9505 Date Tested: April 16, 2020* 

These findings pertain to the Rizhao Sanqi Medical & Health Articles Co., Ltd., 3Q 9505. The packaging indicates that this product meets GB2626-2006, the Chinese standard for Respiratory Protective Equipment Non-Powered Air-Purifying Particle Respirator...

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, <mark>this product is an ear loop design.</mark> Currently, <mark>there are no NIOSH-approved products with ear loops</mark>; NIOSH-approved N95s have head bands. Furthermore, <mark>limited assessment of ear loop designs, indicate difficulty achieving a proper fit</mark>. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved."

Note that the manufacturer's website does not list this KN95 respirator as a product for sale. <u>http://www.sangicn.com/</u>

# Manufacturer: RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO.,LTD Add: No.137, Rizhao North Road, High-tech Zone, Rizhao City, Shandong Prov, China 276800 Tel: +86 633-7663737 Fax: +86 633-7653718 Email: 3qmedical@3qcn.cc Web: www.sanqicn.com See the Information Supplied by the Manufacturer

MADE IN CHINA

All emergency use authorizations for this type of medical device/respirator were revoked in on June 30, 2021 by NIOSH, the FDA and as such, Health Canada (who relies on NIOSH/FDA approval/certification).

Note that this particular device, due to numerous failures, never received approval even under the emergency use authorisation at the start of COVID.

https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-nioshapproved-disposable-filtering-facepiece-respirators#imported https://www.fda.gov/media/136403/download

Also note that the emergency authorization for KN95 respirators in Canada was repealed.

"Repeal

28 The Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020 and published in the Canada Gazette, Part I, on March 28, 2020, is repealed." At this time, the only location that appears to sell this particular medical device is a grocery distributor based on Quebec. https://www.deliver-grocery.ca/en/pharmacy/2640-3q-kn95-disposable-face-mask-10-counts.html

#### Health Canada References.

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators/health-professionals.html

https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-

devices/amendments-regulations-continue-importation-sale-notice.html

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-

information/guidance-documents/use-relation-covid-19.html

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personalprotective-equipment/medical-masks-respirators/authorization.html

David & Karen

## David T. Dickson

Disabled Police Officer (retired - injury on duty) C.E.O. DKS DATA (www.dksdata.com) Consulting C.I.O. Management/Legal Consultant Privacy and Cybersecurity Expert. Cell: [redacted] Fax: [redacted] Email: david.dickson@dksdata.com COVID 19 Information: https://dksdata.com/COVID19



Microsoft Partner "The darkest places in hell are reserved for those who maintain their neutrality in times of moral crisis." Dante Alighieri "So whoever knows the right thing to do and fails to do it, for him it is sin." James 4:17

#### Some rules to live by:

Always do the best you can by your family. Go to work every day. Always speak your mind. Never hurt anyone that doesn't deserve it. And never take anything from the bad guys. (Mel Gibson: Edge of Darkness 2010)



#### https://avoidabledeathawareness.com

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