

From: Aileen Wong
Sent: Wednesday, November 22, 2023 9:02 AM
To: David Dickson <david.dickson@dksdata.com>
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 <david.dickson@dksdata.com>
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 17th, 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 19th 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.



**PLEASE DO NOT WEAR A MASK IN THIS AREA
THIS PERSON NEEDS TO SEE YOUR FACE
FOR SAFE AND EFFECTIVE CARE**

Effective June 19, 2023



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 17th, 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: 2022-10-14 11:49:55 AM

<p>Mask Procedure with Window ASTM Level 2 MFTW-25-M2</p>		<ul style="list-style-type: none"> • Available from inventory • ASTM Level 1 rated for fluid but passes filtration rates of level 2/3 • Tried by speech language and audiology departments at one sites with positive results • For ordering, contact your local site services staff. Ordering numbers will vary by zone/area
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<p>Mask procedure with window</p>		<ul style="list-style-type: none"> • Available from inventory • Tried by speech language and audiology departments at one site with positive results • For ordering, contact your local site services staff. Ordering numbers will vary by zone/area
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As has been the case throughout COVID, 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

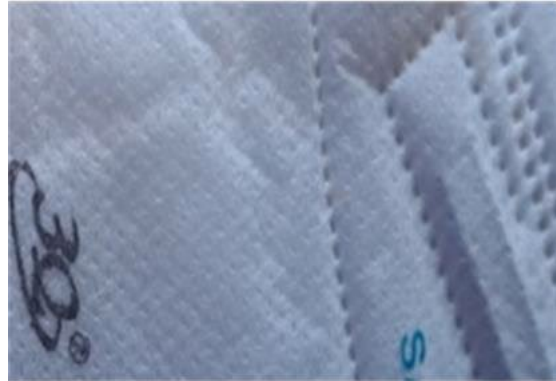
For reference regarding the unapproved and clearly unsafe medical devices by use and design, see the below.
From Health Canada

“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.

https://www.cdc.gov/niosh/nppt/respirators/testing/results/MTT-2020-29.1_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, **this product is an ear loop design.** Currently, **there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands.** Furthermore, **limited assessment of ear loop designs, indicate difficulty achieving a proper fit.** 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.

<http://www.sanqicn.com/>



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-niosh-approved-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/personal-protective-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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