

McKenna, Neil

From: Kim, Sabrina
Sent: Sunday, July 12, 2020 12:56 PM
To: Stickney, Matt
Subject: Fwd: Med Device Check

Sabrina Kim
Issues Advisor
Office of the Prime Minister
613-795-7803

Begin forwarded message:

From: "Gordon2, Travis (HC/SC)" <travis.gordon2@canada.ca>
Date: July 12, 2020 at 12:05:01 PM EDT
To: "sabrina.kim@pmo-cpm.gc.ca" <sabrina.kim@pmo-cpm.gc.ca>
Subject: **FW: Med Device Check**

Yo - looks like their face shield is licensed. Should be good to go.

More to come on whether they have MDEL but is not required for this if separately approved.

TG

--
Travis Gordon
Senior Policy Advisor
613-410-2938

----- Original message -----

From: "Wen, Vanessa (HC/SC)" <vanessa.wen@canada.ca>
Date: 2020-07-12 12:01 PM (GMT-05:00)
To: "Gordon2, Travis (HC/SC)" <travis.gordon2@canada.ca>
Subject: Re: Med Device Check

They would not need one. We are checking anyway...

On Jul 12, 2020, at 11:39 AM, Gordon2, Travis (HC/SC)
<travis.gordon2@canada.ca> wrote:

Thanks - confirming they dont need an MDEL if they have IO auth?

--

Travis Gordon
Senior Policy Advisor
613-410-2938

----- Original message -----

From: "Wen, Vanessa (HC/SC)" <vanessa.wen@canada.ca>
Date: 2020-07-12 11:29 AM (GMT-05:00)
To: "Gordon2, Travis (HC/SC)" <travis.gordon2@canada.ca>
Subject: Re: Med Device Check

Hey Travis, here is the info we have. I'm still waiting to hear on the MDEL side but this may be enough for you. Sorry for weird font.

Sinix PPE received IO authorization (314031) for the Sinix PPE Full Face Splash Shield on April 22 (the IO authorization was amended on June 17 – date shown on the website).

This device is included the List of authorized medical devices other than testing.

On Jul 12, 2020, at 8:38 AM, Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca> wrote:

Hey friend,
.sorry about this but hoping to get a signal by noon as folks will need to plan for a visit/find a new location in either outcome.

Cheers,
Travis

--

Travis Gordon
Senior Policy Advisor
613-410-2938

----- Original message -----

From: "Wen, Vanessa (HC/SC)" <vanessa.wen@canada.ca>
Date: 2020-07-11 7:10 PM (GMT-05:00)
To: "Gordon2, Travis (HC/SC)" <travis.gordon2@canada.ca>
Subject: Re: Med Device Check

Ok. Will ask.

> On Jul 11, 2020, at 6:39 PM, Gordon2, Travis (HC/SC)
> <travis.gordon2@canada.ca> wrote:
>
>
> Hi Vanessa,
>
> Sorry to ask on a Saturday evening. PMO is planning a visit to Ottawa Print
Services/Sinix PPE on Monday.
>
> I was given a website for one of their products. If not for medical use it would
be fine but they claim IO Approval on the webpage at
<https://www.sinixppe.com/product/faceshield> and I was not able to match their
name or ID/Approval # on any of our public lists (IOs, MDELL, MDALL).
>
> Can we please have MDD/ROEB take a look and confirm/deny whether this
business' device is actively licensed (if required) or whether they have an MDEL
or device/IO approval.
>
> Ottawa Print Services' website: <https://ottawaprintservices.com/page/covid-19-essentials>
>
> This is for a tentative PM Visit on Monday so the sooner we can confirm/deny
that they're compliant with MDR/FDA the better.
>
> Again, I apologize for sending this Saturday PM.
>
> Best,
> TG
>
>
>
> --
> Travis Gordon
> Senior Policy Advisor
> 613-410-2938
>