

To: (10)(2e) (10)(2e) @minvws.nl
From: (10)(2e) (10)(2e)
Sent: Mon 5/18/2020 9:05:38 AM
Subject: FW: Decathlon mask PPE - Air Wave.
Received: Mon 5/18/2020 9:05:43 AM
[image002.png](#)

Dag (10)(2e)

Update: Zoals je beneden kunt zien heeft (10)(2e) (10)(2e) (10)(2e) BSI PPE afd) direct gereageerd. Hij zal het oppakken zodra de organisatie de gegevens mbt het (snorkel)maskeer stuurt. De bal ligt bij "Air Wave" om de applicatie in te sturen (10)(2e) zal het oppakken zodra het binnenkomt. We hebben nog niets ontvangen. We wachtren af.

Mvg

(10)(2e)

From: (10)(2e) (10)(2e) <(10)(2e) @bsigroup.com>
Sent: 14 May 2020 17:35
To: (10)(2e) (10)(2e) <(10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) (10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) <(10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) <(10)(2e) @bsigroup.com>
Cc: (10)(2e) <(10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) @bsigroup.com>; (10)(2e) <(10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) @bsigroup.com>
Subject: RE: Decathlon mask PPE

Thanks (10)(2e) for the heads up. If you can provide us with as much product info as possible

(10)(2e) email is below
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Dubbel

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Dubbel

From: (10)(2e) (10)(2e)
Sent: 14 May 2020 15:24
To: (10)(2e) (10)(2e) (10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) <(10)(2e) @bsigroup.com>; (10)(2e) (10)(2e)
 <(10)(2e) @bsigroup.com>; (10)(2e) (10)(2e) <(10)(2e) @bsigroup.com>
Cc: (10)(2e) (10)(2e) @bsigroup.com>
Subject: Decathlon mask PPE

Hi,

(10)(2e) and I have both been contacted by (10)(2e) (10)(2e) (10)(2e) with a request for help. For those who do not know (10)(2e) (10)(2e) (10)(2e) is Director of MOH responsible for the Medicines and Medical Technology (incl Medical Devices) groups within MOH. (10)(2e) had direct contact with (10)(2e) to arrange the designations of BSI NL as Medical Devices NB in Amsterdam for the directives and to discuss the migration of MD Certificates and Staff.

Yesterday (see below mail) (10)(2e) requested help in the Conformity Assessment / Certification of the facemask because it is related to COVID19. The Decathlon facemask is typically used in swimming and with a 3-D printed element manufactured by Royal Dutch Shell it becomes a respiratory device for healthcare professionals (under *EN12941 Respiratory protective devices. Powered filtering devices incorporating a helmet or a hood*). It seems the organisation (*Air wave.org* protector) who (together with Technical University Delft and the Hospital in The Hague) developed this product (demo / promoclip 2 min) was on television a couple of weeks ago and showed their facemask and indicated that it took so long to get the device on the market. This caused a lot of discussions in the Dutch Government (note, a minister of the Government was in the same program). They tried to contact us by phone for some time (2 weeks). After they sent an e-mail this was picked up by (10)(2e) (10)(2e) (yesterday). (10)(2e) explained the process and requested an application. While discussing the product with (10)(2e) (10)(2e) (yesterday), it appeared that the organisation had no idea of the requirements/process of Conformity Assessment and Certification and had a totally wrong

impression of what is needed from them.

Because of the "political discussion on this subject within the government" (10)(2e) (MOH) asked whether we could help and get this device through BSI's "emergency route" = get it on our priority list because its aids in the COVID-19 activities in hospitals.

I informed (10)(2e) about the phone call from (10)(2e) and I called the organisation (10)(2e) (+31 06 (10)(2e) and (10)(2e) to find out the status. They are currently preparing an application which will be picked up by (10)(2e)

In follow up to the phonecall, (10)(2e) sent me the below mail with information

(10)(2e) this is just to give you some early info.

(10)(2e)

From: (10)(2e) <(10)(2e)@minvws.nl>
Sent: 13 May 2020 18:15
To: (10)(2e) <(10)(2e)>
Subject: vraagje snorkelmasker

* This message originated from outside of BSI. Please treat hyperlinks, attachments and instructions in this email with caution. *

Beste (10)(2e)
 Zou jij contact kunnen opnemen met (10)(2e) (06 (10)(2e)). Hij is van Air Wave.org (snorkelmasker). Kennelijk is er al contact geweest met (10)(2e) (10)(2e) van BSI. Zij willen graag tempo maken met dit masker. Ik ken niet alle technische ins en outs en het moet vanzelfsprekend veilig zijn daarom belangrijk dat jullie hier een mening over vormen.
 Alvast dank
 (10)(2e) (10)(2e)

(10)(2e) (10)(2e)
 Ministerie van Volksgezondheid, Welzijn en Sport
 Directie Geneesmiddelen en Medische Technologie
 Postbus 20350, 2500 FJ Den Haag
 070 (10)(2e) / 06 (10)(2e)

(10)(2e)

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