

To: [redacted] ([redacted]) [redacted]@minvws.nl]
From: [redacted], [redacted] ([redacted])
Sent: Thur 12/3/2020 2:37:44 PM
Subject: FW: Technical documentation review BreathBase
Received: Thur 12/3/2020 2:37:44 PM

Van: [redacted], [redacted] ([redacted])

Verzonden: donderdag 3 december 2020 15:36

Aan: [redacted], [redacted] <[redacted]@bsigroup.com>

Onderwerp: RE: Technical documentation review BreathBase

Dear [redacted]
 Thank you very much!
 [redacted]

[redacted]: [redacted], [redacted] <[redacted]@bsigroup.com>

Verzonden: donderdag 3 december 2020 15:12

Aan: [redacted], [redacted] ([redacted]), [redacted] <[redacted]@minvws.nl>

Onderwerp: RE: Technical documentation review BreathBase

Dear [redacted]

Thank you for the further information.

Just as background we have already worked under COVID 19 derogation in the UK this year for Rapid Manufacture of Ventilator Systems undertaking "reduced core functional & safety" seems and QMS audits in very short time frames. This enabled some 15-18,000 ventilators to reach patients in the spring crisis. In the RMVS case we worked on behalf of the MHRA not the manufacturers and were contracted (at reduced rates) with and paid by UKGOV.

I have requested we follow up on your request with an internal meeting in the next 24 hours and we will respond immediately afterwards. BSI NL of course wishes to support this initiative fully and help in this time of great challenge.

[redacted]

From: [redacted], [redacted] ([redacted]) <[redacted]@minvws.nl>

Sent: 03 December 2020 13:00

To: [redacted], [redacted] <[redacted]@bsigroup.com>; [redacted], [redacted] <[redacted]@bsigroup.com>

Cc: [redacted], [redacted] <[redacted]@igj.nl>; [redacted], [redacted], [redacted] ([redacted]) <[redacted]@minvws.nl>; [redacted], [redacted] <[redacted]@igj.nl>; [redacted], [redacted] ([redacted]) <[redacted]@minvws.nl>

Subject: Technical documentation review BreathBase

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Dear [redacted] and [redacted]

In the context of the COVID 19 crises there is as you know a need in the Netherlands for devices which are able to diagnose COVID patients in a rapid way. One of the devices that could be of importance to the Dutch Covid 19 screening approach is the BreathBase, a device which can be used to test potentially infected individuals to decide whether they can be ruled out of COVID-19 infection based on breath analyses. The device is not CE marked yet and a derogation has been asked for by the manufacturer to make available the product to the Dutch market. As part of the derogation and as rationale for a positive decision the safety of the device has to be reviewed and confirmed to be safe taking into account the requirements of the medical device regulations and/or directives. The technical documentation has been sent to the Ministry of Health as part of the derogation application.

The Ministry of Health is aware that the manufacturer is a client of BSI The Netherlands B.V. and a conformity assessment procedure will be performed to review whether a CE certificate can be issued for the device. Competent personnel is needed to do

an in depth review of this novel device to be able to assure the device fulfills the safety requirements and is meeting its performance claims. As designated Notified Body BSI The Netherlands B.V. has this competence and has as I understand already started the conformity assessment process.

The Dutch Healthcare and Youth Inspectorate is asked to provide an advice on the derogation applied for. The technical documentation sent has been reviewed on completeness as part of this. It is concluded that not all parts of the technical documentation are complete already to be able to do the a full technical dossier review by a Notified Body.

Because of the important role this device could play in the testing-strategy of the Netherlands the Ministry of Health therefore would like to request BSI to perform a review of the technical documentation available already, which will be part of the regular conformity assessment procedure on a short notice. Although this review cannot be complete it could be used for a derogation knowing that the conformity assessment procedure is in progress.

The information coming from the BSI review will be used as an expert review, reviewed and accepted by IGJ, in the derogation review process. The Ministry of Health will be responsible for the decisions taken during the derogation process based on its own reviews. The information from BSI as intermediate outcomes of the conformity assessment activities will be used as supporting evidence only. However BSI The Netherlands B.V. will be responsible for selecting authorized reviewers and auditors for the review activities needed in the conformity assessment process.

The Ministry of Health requests you to:

- to do a review of the technical documentation whether the general safety and performance requirements set in the MDR are fulfilled and which parts or aspects are missing
- special attention is asked to be spent on:
 - o the basic safety requirements applicable to active medical devices
 - o the software validation as this is a core part of the medical device
 - o the risk management file on completeness, review of identified risks and items which are pertinently missing and are a risk for use in practice
 - o the validation of the device performance in relation to the risk of false negative diagnostic outcomes of the device
 - o the completeness of the clinical evaluation (plan) and the quality validation studies performed by the manufacturer to review the performance of the devices
 - o Information to the user including precautions to be taken by healthcare professionals

As this device could be considered to be a borderline product since it includes aspects related the IVDR it might be useful to include IVD competence in the review.

We would appreciate to receive your response in short notice to this request and an indication what would be the estimate review time taking in mind that there is a matter of urgency.

warm regards,

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