To: 5.1.2e, 5.1.2e.[5.1.2e @igj.nl]; 5.1.2e, 5.1.2e. 5.1.2e (5.1.2e)[5.1.2e @minvws.nl]
Cc: 5.1.2e, 5.1.2e.[5.1.2e @igj.nl]; 5.1.2e, 5.1.2e.(5.1.2e)[5.1.2e @igj.nl]; 5.1.2e, 5.1.2e. (5.1.2e)[5.1.2e @igj.nl]
From: 5.1.2e, 5.1.2e. 5.1.2e 5.1.2e (5.1.2e)
Sent: Tue 12/8/2020 2:53:51 PM
Subject: FW: Technical documentation review BreathBase
Received: Tue 12/8/2020 2:53:52 PM

Beste 5.1.2e en 5.1.2e

Zie net de mail die we van BSI hebben gekregen. De fabrikant lijkt (nog steeds) geen vaart te maken met het contract met BSI. Dat maakt deze situatie nu ingewikkeld, want ik vraag me af of wij een opdracht aan BSI willen geven voor een versnelde beoordeling op onderdelen voor een ontheffing zolang het contract met de fabrikant en BSI nog niet getekend is. Zijn wij (IGJ danwel VWS) bereid hiervoor te betalen? Ik vraag me sowieso af of er een titel is om dat door te berekenen aan de fabrikant, zeker niet zolang er nog geen contract is tussen de fabrikant en BSI.

Ik denk dat er een duidelijk statement nodig is richting de fabrikant dat een contract een absolute voorwaarde is om de beoordeling van de ontheffing te kunnen doorzetten. Vraag is even wie dat statement afgeeft: IGJ of VWS. Ik vind het prima om ze daarover te bellen, maar om ruis te voorkomen leg ik dat even aan jullie voor.

Groet, 5.1.2e

Van: 5.1.2e 5.1.2e < 5.1.2e @bsigroup.com>
Verzonden: dinsdag 8 december 2020 14:33
Aan: 5.1.2e, 5.1.2e. 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>
CC: 5.1.2e, 5.1.2e. < 5.1.2e @igj.nl>; 5.1.2e, 5.1.2e. 5.1.2e 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e. < 5.1.2e @igj.nl>; 5.1.2e, 5.1.2e. 5.1.2e (5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e 5.1.2e < 5.1.2e @bsigroup.com>; BSIMedDev.NB2797 < 5.1.2e @bsigroup.com>
Onderwerp: RE: Technical documentation review BreathBase

Dear 5.1.2e

Thank you for your e mail requesting that BSI support the derogation procedure for the BreathBase® product. BSI understands the acute urgency of the request and we would of course like to support this process fully.

Contractual Status between BSI Group the Netherlands B.V. & Breathomix: Breathomix has still not returned a signed quotation and the company has not submitted any Technical Documentation. Therefore, BSI cannot commence any direct conformity assessment on behalf of Breathomix as no contract exists.

Derogation Request: BSI's understanding is that Breathomix's BreathBase platform and the eNose Device is seen to potentially play an important role in the COVID19 diagnostic testing. Also, that normal full product conformity assessment to EU MDR [(EU) 2017/745] is seen to likely take too much time even when given priority. As a result, VWS/IGJ would like to make the device available on the Dutch market based on "derogation", if possible. We understand 5.1.2e has informed Breathomix that BSI has been asked to support in the derogation process by providing assessment service under derogation on behalf of VWS.

Next Steps:

Contract: Since BSI's activities in the Derogation Process are on behalf of VWS and not conducted under the umbrella of BSI's regular Conformity Assessment Process for which BSI is designated as a Notified Body, BSI will require VWS to issue a formal Contract in which BSI is requested to provide a service to VWS/IGJ within a defined derogation process.

The contract should specify:

- *The Parties VWS and BSI Group the Netherlands B.V.*
- *The contract purpose, i.e., relating to Technical and / or QMS assessment for the product specific derogation request.*
- *The derogation procedure will only be applied as extraordinary measures during the COVID19 pandemic.*
- *VWS to provide guidance to BSI what exactly is expected (timing, priorities, abridged assessment conformity route to be applied (e.g. Annex IX), reporting of the assessment).*
- *VWS to specify what elements/aspects should be assessed for this device, General Safety and Performance Requirements (per MDR Annex I) (incl. Review of Clinical data, accuracy), post market surveillance aspects, QMS aspects to be reviewed (to be*

specified).

- *VWS to clearly indicate that the derogation is a temporary measure applied by VWS to temporarily allow this product to be used in the NL without CE marking and without the NB Identification Number.*
- *Confirm the Post Market Surveillance is the responsibility of VWS*
- *Confirm VWS accepts the Legal responsibility / Liability for the device/platform within derogation.*
- *Confirm acceptance of BSI's agreed fee structure for the assessment services provided.*

We hope this helps clarify the next steps, so we can move forward quickly and support this acute need within the Netherlands during the current pandemic.

5.1.2e 5.1.2e, 5.1.2e – Global Medical Devices
5.1.2e 5.1.2e, 5.1.2e

BSI Group The Netherlands B.V.
Medical Devices Notified Body (NB 2797)
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Van: 5.1.2e, 5.1.2e. 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>
Verzonden: 03 December 2020 14:00
Aan: 5.1.2e 5.1.2e <5.1.2e @bsigroup.com>; 5.1.2e 5.1.2e <5.1.2e @bsigroup.com>
CC: 5.1.2e, 5.1.2e. <5.1.2e @igj.nl>; 5.1.2e, 5.1.2e. 5.1.2e 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e, 5.1.2e. <5.1.2e @igj.nl>; 5.1.2e, 5.1.2e. 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>
Onderwerp: Technical documentation review BreathBase

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

Dear 5.1.2e and 5.1.2e

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:
    - the basic safety requirements applicable to active medical devices
    - the software validation as this is a core part of the medical device
    - the risk management file on completeness, review of identified risks and items which are pertinently missing and are a risk for use in practice
    - the validation of the device performance in relation to the risk of false negative diagnostic outcomes of the device
    - the completeness of the clinical evaluation (plan) and the quality validation studies performed by the manufacturer to review the performance of the devices
    - 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,

5.1.2e

5.1.2e 5.1.2e 5.1.2e
Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie
Postbus 20350, 2500 EJ Den Haag
070 5.1.2e / 06 5.1.2e
