



Derek Lamb <liquidgands@gmail.com>

RE: Rejection #3 of Corrective Action Plan (CAP) – Report No: 8348484

1 message

Laura Ebbs <Laura.Ebbs@bsigroup.com>

27 March 2019 at 16:37

To: "derek.lamb@viamed.co.uk" <derek.lamb@viamed.co.uk>

Hi Derek,

Thank you very much for getting back to me. I will start the work required to cancel the certificate. This will take some time as there is paperwork to complete and then it needs to go to panel for approval, so I do not believe that this will impact your existing commitments.

Kind regards,

Laura

Laura Ebbs

Scheme Manager and Technical Specialist

M: +00 44 779 545 0832

laura.ebbs@bsigroup.com

-



BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP

bsigroup.com | [Twitter](#) | [LinkedIn](#)

Our [Social Responsibility Code of Conduct](#) provides a foundation of principles from which we expect our suppliers to work.

The British Standards Institution is a member of BSI Group and is incorporated in England under Royal Charter. Its principal address is [389 Chiswick High Road, London, W4 4AL, United Kingdom](#).

Please consider the environment before printing this email.

From: Main Account <viamedinbox@gmail.com> **On Behalf Of** Derek Lamb**Sent:** 22 March 2019 15:38**To:** Laura Ebbs <Laura.Ebbs@bsigroup.com>**Subject:** Re: Rejection #3 of Corrective Action Plan (CAP) – Report No: 8348484

Laura,

We have made some decisions this week.

With regard the cancellation of CE 97289,

We have spent the last couple of weeks in discussion with Envitec, Envitec are now the Manufacturer, and their body number will now be used on the product under there existing certifications.

For almost 2 Years now since the start of the OBL / Virtual Manufacturer changes I've made it clear to BSI CE 97289 and keeping Envitec name from the product was important.

It's a shame it has come to where we are, but it is what it is.

As has also been explained many times, we are / were, running down our own manufacturing and just keeping the Microstim going until stock ran out, and the Tom thumb to keep customer happy. With no intention of upgrading to the newer MDR standards both products had a limited life span.

Moving the Oxygen Sensors onto that certificate would have justified the costs of maintaining the certificate overall. At least until the MDR deadline.

So we have called time on the Microstim and the Tom thumb products.

I still maintain the reason for the non conformity in the BSI report, was the fault of a Single process that produced a PDF of relevant files. But we are finding we keep going round in circles. We supplied the relevant files back in 2017 that would / should have closed of many of the reported non conformance's. But BSI were not interested until a CAP report was done for each NC, and once again BSI have proved we are not getting off the merry go round.

Considering the Tom thumb was BSI reviewed on site in 2015, and then re review remotely in 2017 the number of non conformance's does not make sense.

Also of note, we received a non conformance for paper work in the competitors information folder. Namely BSI reviewed us on "Fisher and Pakel instructions for use" which referenced sterilisation of their accessories. We then had more non conformance's, as the auditor then believed we should have lots of sterilisation documents in the system.

How are we supposed to write up a corrective action plan, when we believe part of the fault was of the auditors?

The end result is we will/can cancel the CE 01389. I have given the date of the 19th of April as the last date, so we can honour any quotes and proformas that are in the system, which I presume you will find acceptable, as without me withholding invoices and complaining further up the BSI chain we would still be in limbo getting no answers from BSI.

Regards

Derek Lamb

Viamed Ltd.

On Tue, 19 Mar 2019 at 15:14, Laura Ebbs <Laura.Ebbs@bsigroup.com> wrote:

Dear Derek,

Rejection #3 of Corrective Action Plan (CAP) – Report No: 8348484

Thank you for the corrective action plan; unfortunately, I am unable to accept this plan.

The reason for the rejection is as follows:

- *The root cause is not specific to each of the nonconformities and does not demonstrate that the non-conformities were fully and individually understood and the reason (root cause) for their occurrence analysed.*
- *The corrective action plan is not specific to each non-conformity and does not detail how each nonconformity has been addressed/ resolved or is intended to be resolved.*
- *There are no specific references to the actions/ documents detailing what has been or will be updated or implemented to resolve each non-conformity.*

Please could you amend the plan and resend by 27/03/2019.

An acceptable Corrective Action Plan must be provided within 7 calendar days. Please note that this is the **final opportunity** to provide an acceptable Corrective Action Plan and failure to do so will lead to certificate suspension.

Kind regards,

Laura

Laura Ebbs

Scheme Manager and Technical Specialist

M: +00 44 779 545 0832

laura.ebbs@bsigroup.com



...making excellence a habit™

BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP

bsigroup.com | [Twitter](#) | [LinkedIn](#)



Our [Social Responsibility Code of Conduct](#) provides a foundation of principles from which we expect our suppliers to work.

The British Standards Institution is a member of BSI Group and is incorporated in England under Royal Charter. Its principal address is [389 Chiswick High Road, London, W4 4AL, United Kingdom](#).

Please consider the environment before printing this email.

Visit the BSI website at www.bsigroup.com

This email may contain confidential information and/or copyright material. This email is intended for the use of the addressee only. Any unauthorised use may be unlawful. If you receive this email by mistake, please advise the sender immediately by using the reply facility in your email software.

The British Standards Institution is incorporated by Royal Charter.

This email has been scanned for all known viruses.

Visit the BSI website at www.bsigroup.com

This email may contain confidential information and/or copyright material. This email is intended for the use of the addressee only. Any unauthorised use may be unlawful. If you receive this email by mistake, please advise the sender immediately by using the reply facility in your email software.

The British Standards Institution is incorporated by Royal Charter.

This email has been scanned for all known viruses.



...making excellence a habit™



image001.png
6K