



Ryan Swaine <viamed.ryan.swaine@gmail.com>

RE: Test Report

1 message

Lyes Djennadi <Lyes.Djennadi@sedanamedical.com>
To: "ryan.swaine@viamed.co.uk" <ryan.swaine@viamed.co.uk>
Cc: Peter Fröberg <peter.froberg@sedanamedical.com>

25 February 2021 at 15:22

Hi Ryan,

1. One pack of each is enough for now, thank you.
2. Pending arrival of the sevo, there should be no problem to complete the economical line 24hr test within the next 2 weeks which should be enough to complete the CE mark for that line.

If you require 24hr tests on the premium line then I can't guarantee they will be done in that timeframe but I can hopefully complete some shorter tests (5-8hrs) if that's acceptable? With a plan to eventually complete a continuous 24hr test when we have the time.

Peter will come back to you with some feedback on 3 and 4.

Best regards,

Lyes

From: Main Account <viamedinbox@gmail.com> **On Behalf Of** Ryan Swaine
Sent: 25 February 2021 15:53
To: Lyes Djennadi <Lyes.Djennadi@sedanamedical.com>
Cc: Ryan Swaine <office@viamed.co.uk>; Peter Fröberg <peter.froberg@sedanamedical.com>
Subject: Re: Test Report

Hi Lyes & Peter

It was very nice to speak to you both today. After speaking with my colleagues, I have some additional questions for you.

Q1) With regards to the extra samples you require, I believe I can have another pack (10 lines) of each model sent out to you straight away, would this be enough for the next round of testing?

Q2) Would it be safe to assume that the Sevo test on the economical line and both the Iso and Sevo testing on the premium line can be completed within the next 2 weeks?

If the testing can be completed inside of 2 weeks, then we would be looking at having the CE completed before the end of May.

Q3) How many lines will you need in June for the clinical trial?

Q4) How many lines would you require in total for the clinical trial and over what period?

I look forward to hearing from you.

Best regards

Ryan

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On Thu, 25 Feb 2021 at 12:32, Lyes Djennadi <Lyes.Djennadi@sedanamedical.com> wrote:

Hi Ryan,

As I said on the phone, it would be great if we could get some more samples of both lines so that we can run as many tests as possible over the next few weeks. We're running the tests in Sweden now.

Att: Lyes Djennadi

Add: Sedana Medical AB

[Vendevagen 89](#)

18232 Danderyd

Sweden

VAT: SE556670251901

Best regards,

Lyes

From: Lyes Djennadi

Sent: 09 February 2021 22:17

To: ryan.swaine@viamed.co.uk; Ryan Swaine <office@viamed.co.uk>

Cc: Peter Fröberg <peter.froberg@sedanamedical.com>; James Toland <james.toland@sedanamedical.com>

Subject: Test Report

Hi Ryan,

Sorry for the delay. Please see attached the test report for the 24hr test carried out this weekend on the more economical line provided by Viamed.

We discussed the results briefly before but as you can see in the report, the lines were quite consistent. They weren't identical unfortunately but the difference was quite small between the two lines. I personally don't know the clinical significance of the slight difference but I would assume that a 0.1% reading difference will not affect patient safety. I'm away for the rest of the week but when I return next week, I'll follow up with our clinical team to discuss the findings. It would be good to get their insight as they all have great experience in the ICU as doctors and nurses.

Let me know your thoughts on the test results and report. We will get around to testing the second proposed line but I can't say when we'll have time for another 24hr test. I think it's pretty clear based on the results that the lines remained consistent over 24hrs, there were no obvious changes observed. So I think it would be safe to do some shorter tests (5-8hrs) in the meantime.

Best regards,

Lyes