



Derek Lamb <liquidgands@gmail.com>

Re: BSI ISO 13485 Scheme Management change - Viamed Ltd - MD 78787

1 message

Derek Lamb <derek.lamb@viamed.co.uk>
Reply-To: derek.lamb@viamed.co.uk

To: Juliana Pérez De Marziani <Juliana.Perez@bsigroup.com>, Christopher Serna <Christopher.Serna@bsigroup.com>

11 November 2024 at 12:54

Dear Juliana Pérez,

Please find attached my correction plan for the minor issue noted in our last audit.

Regarding our current scope, we are no longer manufacturing medical products. Production of our own devices ceased in 2017/2018, and they have effectively reached their end of life. We are still providing service on a limited number of units in the field and continue to perform the yearly PMS report. However, the time is right for us to update our ISO scope accordingly.

Our current scope includes:

"Service of Supra-Maximal Peripheral Nerve Stimulators, Simulation Equipment, Infant T-Piece Resuscitators, Apgar Timer, and Resuscitation Cabinets. Distribution and Service of electromedical devices."

We would like to update this to:

"Distribution and Service of Medical Devices and Products."

Although we still produce a small number of V1000 simulators, they are not classified as medical devices. We continue to service approximately 30 Infant T-Piece Resuscitators annually, which could be covered under "Service of Medical Devices and Products."

Our primary focus now is distributing equipment from other manufacturers and managing their customer returns — whether through servicing, repair, or coordinating returns to the supplier, along with providing them feedback.

On another note, our ISO system is somewhat unique in how it complies with regulations, which can take an auditor some time to fully understand. I am looking to transition Michael Lamb into a role where he can actively engage with ISO auditors and demonstrate our system. Michael has already completed a 13485 auditing course and is capable of performing internal audits. I would like him to take on a more prominent role in running our BSI audits. For this reason, would it be possible to have one of the auditors we have worked with recently for the next audit? Their familiarity with our system would provide an ideal environment for Michael to step into hosting the audit, while I remain available as needed.

I discussed this with Christopher Serna, who suggested I reach out to you.

Kind regards,

Derek Lamb
Viamed Ltd.On Tue, 1 Oct 2024 at 18:01, Juliana Pérez De Marziani <Juliana.Perez@bsigroup.com> wrote:

Dear Derek,

Thank you for your email.

There has been no update to the audit scheduling, it continues to be booked for the next 30th – 31st of October with BSI assessor Christopher Serna (in cc), as confirmed in the attached email back in April.

Mr Serna will contact you in the following weeks regarding the audit plan.

I remain at your disposal in the meantime.

Kind Regards / Saludos cordiales,

Juliana Pérez

Certification Specialist

Regulatory Services – Medical Devices

Juliana.Perez@bsigroup.com

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From: Derek Lamb <derek.lamb@viamed.co.uk>
Sent: Wednesday, September 25, 2024 1:24 PM
To: Juliana Pérez De Marziani <Juliana.Perez@bsigroup.com>
Subject: Re: BSI ISO 13485 Scheme Management change - Viamed Ltd - MD 78787

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

Can you please confirm the BSI visit date in october,

Regards
Derek Lamb
Viamed Ltd.

On Fri, 12 Apr 2024 at 13:35, Juliana Pérez De Marziani <Juliana.Perez@bsigroup.com> wrote:

Confidential

Dear Mr. Lamb,

I trust my email finds you well.

Please allow me to introduce myself. My name is Juliana Pérez and I am a Certification Specialist with BSI based in Spain.

I have recently taken over the management of your ISO 13485 certification and will be your primary contact going forwards for certification matters. I operate in the same team as your previous scheme manager Nathan Bevis and will work closely with him to ensure a smooth transition of certification management.

I will be then taking care of the renewal of your certificate and I'm aware of your next recertification audit is already scheduled end-October of current year 2024. Until then, I remain at your disposal for any doubt or comment.

Looking forward to working with you in the future.

Kind Regards / Saludos cordiales,

Juliana Pérez

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