

Re: Cetificate of Conformity

1 message

Steve Hardaker <office@viamed.co.uk>

13 October 2020 at 16:59

Reply-To: steve.hardaker@viamed.co.uk

To: Lucian Bizoi <LBizoi@sle.co.uk>

Cc: Farai Manjome <FManjome@sle.co.uk>, Steve Nixon <steve.nixon@viamed.co.uk>

Good Afternoon Lucian,

I have forwarded this on to our Commercial & Technical Director, Steve Nixon, as he will be best placed to provide the information that you need.

Regards,

Steve Hardaker

Technical Support Manager

Viamed Ltd.

Please note: Viamed is now enacting a coronavirus contingency plan to allow sales and admin Staff to work from home, and I am now working remotely. Telephone calls to the main office will not be answered, but emails will. Orders may take longer to process but we aim to continue to operate and serve our customers as best we can.Website: www.viamed.co.ukemail: steve.hardaker@viamed.co.uk

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On Tue, 13 Oct 2020 at 15:14, Lucian Bizoi <LBizoi@sle.co.uk> wrote:

Good afternoon,

In an ISO13485:2016 recertification audit from BSI, a minor NC was raised against process validation for goods received as finished products from our supplier and are not tested nor used as part of production components here at SLE.

The requirement from ISO13485:2016, 7.5.6 is:

The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently.

As a corrective action to the finding, would you be able to provide either:

1. A validation report (IQ, OQ and PQ) for the production process that produces the following products listed below,

OR

2. A copy of the 'Final release' procedure (including any in-process controls procedures) performed on 100% of products supplied to us below as well as a certificate of analysis/ conformity for all batches moving forward

Products

LSPV/0014835	Pulse Oximetry Wrap Sensor Model: W-6500VM 1.2m
LSPV/4410500	Capnograph VM 2500-M
LSPV/4420521/10	IRMA Airway Adapter - Infant (Box of 10)

I look forward to hearing from you

Thank you for your support

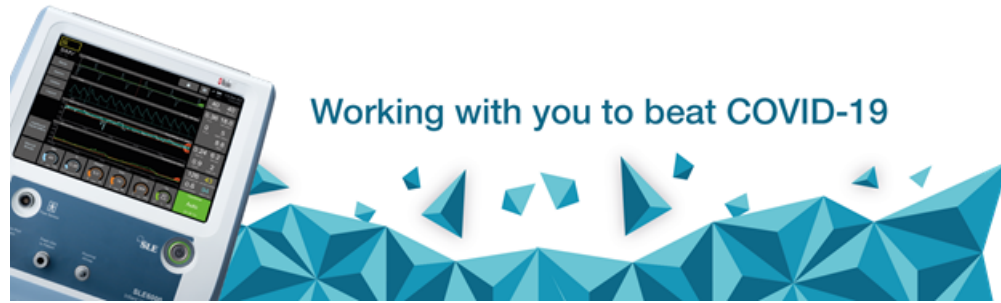
Kind regards,

Lucian Bizoi, *Quality Inspector*



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