Gmail **Derek Lamb <liquidgands@gmail.com>**

RE: CE 01389

1 message

Varun Sukumaran <Varun.Sukumaran@bsigroup.com> 1 September 2016 at 18:58
To: "derek@viamed.co.uk" <derek@viamed.co.uk>, Vishal Thakker <Vishal.Thakker@bsigroup.com>

Hi Derek,

Fairly simple paper work exercise is what is needed from your end to close this NC. Your responses as below, as it appears to be a substantial claim, if evidence is suitably documented. I concur with you views there is no enforced template on how the clinical evaluation report must be presented to NB but it is manufacturers responsibility to present the data in consolidated form on how you perceive that the requirements of Annex X sec 1.1 d are met. Perhaps, it is the evidence(could be read: consolidated report) for us to assess on how you claim to have met the requirements of Annex X section 1.1d is what we are after.

As soon as this NC is close your certificate will be issued. Unfortunately we cannot re-issue the certificate with this NC still open. I totally understand your plight and we would do anything in our power to avoid any further delays from our side. At this juncture, I would recommend you submit the report(as requested above) and we could try closing this NC. A fee will be charged on every occasion we re-issue the certificate, so downsizing the certificate scope will not be a viable option if you are thinking it as an alternative. I believe with a simple paperwork exercise this NC could be closed and hence hassle of amending the scope is not something I would recommend.

I am willing to follow this up a phone call if you seek further clarification.

Best regards,

Varun

From: Derek Lamb [mailto:liquidgands@gmail.com]
Sent: 01 September 2016 15:40
To: Varun Sukumaran; Vishal Thakker
Subject: Re: CE 01389

Dear Varun,

I think we're/I'm going round in circles a little,

Maybe I'm missing what your requiring here, are you after a report repeating the information contained within our technical files - including all the data for Annex 1.1d, or are we able to reference files within our existing Technical File?

Demonstrating safety and performance, we have in the system all Q.A. records for all Tom Thumb Units, not batch tested, and records of all the units we have had returned / serviced.

This gets reviewed in the Yearly post market surveillance (ID15747).

All Issues within the company relating to Tom Thumb units - even down to orders picked are reviewed in the Yearly post market surveillance (ID15747) so any safety concerns would be brought to the surface.

We have a residual risk reports(ID2182/ID15751), risk benefit analysis report(ID15756) contained within the technical file.

The subject of Clinical Investigation - the method of PPV (positive pressure ventilation) has been established since before CE Marking/Formal Clinical trials so there are no clinical trials of using PPV. We have found however some reports on comparing different types of PPV equipment.

We do have an Article written by Sam Oddie, Jonathan Wyllie, Andrew Scally, Comparing Self inflating bag PPV against our Tom Thumb unit - published May 2005, It also refers to the Neo Puff resusitator as an equivalent system (ID11656).

A more recent article "Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review" Colin Patrick Hawkes a,b, C. Anthony Ryana,b, Eugene Michael Dempseya,b (ID17306) - also compares T-Piece resusitators with manual ventilation. Again they are not Evaluating 'PPV' but which equipment should be used. So we do not have any Clinical Investigations/Literature review routes for PPV. We only have the safety of the device route Annex X 1.1d.

"State of the Art" is subjective and a conversation we have had with our last auditor a T-Piece Resusitator is simply a T piece and a blow-off valve there is very little to it, we have Tom Thumb units which are still being used and serviced which are now 20+ years old and still performing to the required specifications. We see no reason why these same Tom Thumb units and future units will still not be performing to the required specifications in another 20 Years time. Subject to regular servicing as per the servicing manual (ID 15677).

"There also needs to be comprehensive analysis of your complaint and vigilance data, including key failure modes, any corrective actions that you might have taken and any other inputs that have influenced the evolving design of the product"

This is addressed in the Post market surveillance reports where returns data is reviewed - there have been no evolving design changes for at least the last 12 years.

So while documents are spread out in our files we believe we have the documentation to justify Annex X 1.1d. As noted by

Richard Tully: "The elements for the clinical evaluation are all available in different places in the technical file " and yourself

"All the elements are there".

Originally in August 2015, when I went over the Visit report with a Richard Tully I was left with the impression the only actually document we had missing from our files was the clinical re-evaluation of the risks against benefits report(now ID15756). Its possible I misunderstood the verbal conversation. As at the time BSI double booked me and sent in Richard Tully (report 8164150) to review the technical Files and Both Malcolm Goodall and Edward Collins to review the ISO 13485 management systems on the same 2 days so I was getting bounced around a little.

(I didn't realise the double booking as an appointment with BSI is an appointment with BSI).

I was asked to send the corrective documentation before the 1st October 2015 which I did on September 30th 2015.

I heard nothing more regarding non conformance 1225836M1 until 22nd August 2016, where I was asked explicitly for some documentation references 15754/15753/15732.

I now find myself in a position due to having multiple products on the one certificate having to hold orders until I get a new certificate as the current one has now gone out of date.

I need to know if this is going to hold up our certificate much longer, and do I need to consider reducing the scope removing the Tom thumb from the certificate for the benefit of our other product lines.

If I do remove the Tom thumb will I be charged when it comes around to getting it added it back into the scope?

Regards

Derek Lamb

Viamed Ltd.

01/09/2016

See Attached John Lambs notes on your email

On 1 September 2016 at 11:15, Varun Sukumaran <Varun.Sukumaran@bsigroup.com> wrote:

Hello Derek,

I have reviewed the documents and have following comments;

- Reference needs to change to Annex X 1.1d instead of 'Annex X 1.1b'
- Your justification is "clinical data is not appropriate as the product was originally designed and manufactured in the 1990's before the introduction of the CE mark and associated procedures". MDD states that you need to comply with all current applicable standards and regulations so this justification is not acceptable. If you are not taking the clinical investigation or literature review routes, you need to make a stronger case, focussing on demonstrating safety and performance.
- "Viamed has been unable to locate any references to formal clinical investigation" – there is a reference to clinical literature as you have not initiated a clinical investigation. Also you talk about not being able to locate any references but then go on to talk about references comparing T-occluders and hand bag mask ventilation. A more

systematic review would at least address "state of the art" and safety. This coupled with a more detailed equivalence comparison between your device and competitor products must be presented.

· There are no elaborate references to bench testing or other pre-clinical testing that has been carried out – you claim that this is covered in technical file(faintly) but Annex sec1.1d requires you to demonstrate conformity of ER's by reference to such elements.

· You talk residual risks but not about risk benefit analysis

· There also needs to be comprehensive analysis of your complaint and vigilance data, including key failure modes, any corrective actions that you might have taken and any other inputs that have influenced the evolving design of the product – this is kind of there but not presented very well

All the elements are there but it still needs some work. I would suggest you work on above so that we can get rid of the N/C completely.

Best regards,

Varun

From: Vishal Thakker
Sent: 31 August 2016 14:17
To: Varun Sukumaran
Subject: FW: CE 01389

Come through from Viamed.

Thanks,

Vishal Thakker MEng(Hons) AMIMechE

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From: liquidgands@gmail.com [mailto:liquidgands@gmail.com] **On Behalf Of** Derek Lamb
Sent: 31 August 2016 12:09
To: Vishal Thakker <Vishal.Thakker@bsigroup.com>
Subject: CE 01389

Please find attached,

John has created a Tom Thumb summation document embodying the main points of the report.

DOCID17353

Please also find Document ID 9358 created 24 May 2009, which after talking to you yesterday I pulled out of our files.

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Regards

Derek Lamb
