MHRA Ref: 2013/005/020/401/001

5 messages

By way of info@viamed.co.uk <Emmanuel.Scott@mhra.gsi.gov.uk> 20 May 2013 15:53
To: Derek Lamb <derek@viamed.co.uk>
Cc: John Lamb <jsl@viamed.co.uk>

20/05/2013

Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT
UK

MHRA Ref 2013/005/020/401/001

MHRA ADVERSE INCIDENT CENTRE (Direct Tel: 020 3080 7080 / Fax : 020 3118 9814)

Dear Mr Lamb

Thank you for your report in connection with the following device:

Device Lung Ventilators
Item Ventilator
Model SpiroTrue A
Batch number 7001131B

The information provided in your report will now be subject to a triage assessment conducted by our medical device specialists and clinical advisers. In the meantime, could you please keep us informed of the progress of your investigation, any conclusions you may reach and any actions you propose to take.

If the report is relevant to a CE-marked device, and your investigation reveals that the incident led to, or could have led to, a death or serious deterioration in health then it will be dealt with under the requirements for medical devices vigilance.

If the report relates to a product recall, please could you keep us informed of the progress of the recall and any further actions you propose to take. We would be grateful if you could inform us when the recall has been completed.

Yours sincerely

EScott

PP Mr R Saunders
Head of Adverse Incident Centre, MHRA

PLEASE QUOTE OUR REFERENCE IN ANY REPLY

IMPORTANT:

1. Any email reply to this correspondence should be addressed to: **aic@mhra.gsi.gov.uk** Replies sent to personal email addresses may be delayed because of staff absence.

2. Do not send medical devices to the MHRA unless you have been specifically requested to do so. If responding to such a request, you must ensure that the device has been appropriately decontaminated, securely packaged, and clearly labelled (including the MHRA reference number)

Draper, Sandra <Sandra.Draper@mhra.gsi.gov.uk> 22 May 2013 13:17
To: Derek Lamb <derek@viamed.co.uk>
Cc: John Lamb <jsl@viamed.co.uk>

Viamed

Please see the attached extra information in relation to the incident forwarded to you yesterday along with the incident report.

Please note that the reporter (Mr Williams) also sent us a photograph and it looks as if this was omitted from our initial letter. I have therefore attached it to this email - please accept our apologies for this omission.

Regards

Sandra Draper
Administrative Team Leader
MHRA Adverse Incident Centre
4Y
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 0203 080 7222
Email: Sandra.draper@mhra.gsi.gov.uk

From: Williams, Frank [mailto:Frank.Williams@dchft.nhs.uk]
Sent: 22 May 2013 10:35
To: AIC
Subject: RE: MHRA Ref: 2013/005/020/401/001

Hi Mark

Thanks for the response, we have approximate 20 units quarantined and available for inspection.

Regards

Frank Williams

Chief Technician

Medical Engineering Department

Dorset County Hospital

NHS Foundation Trust

Dorchester

DT1 2JY

Tel No. 01305 254118

frank.williams@dchft.nhs.uk

From: Mark.Smethurst@mhra.gsi.gov.uk [mailto:Mark.Smethurst@mhra.gsi.gov.uk]
Sent: 21 May 2013 18:00
To: Williams, Frank
Subject: MHRA Ref: 2013/005/020/401/001

21/05/2013

Frank Williams
Medical Engineer
Dorset County Hospital
Dorset County Hospital
Williams Avenue
Dorchester
DT1 2JY

Your ref W17054
MHRA ref 2013/005/020/401/001

MHRA ADVERSE INCIDENT CENTRE (Direct Tel : 020 3080 7080 / Fax : 020 3118 9814)

Dear Frank Williams

Thank you again for your report in connection with the following device:

Device Lung Ventilators
Manufacturer Viamed Ltd
Supplier Viamed Ltd

Further to my earlier letter, I can now confirm that after initial assessment of your report we have decided to pursue this matter directly with the manufacturer, requiring them to investigate the incident under our supervision, and to report back to us as soon as possible. When we are satisfied with the manufacturer's response and any action taken, we will provide you with details from the investigation report and outcome. The manufacturer's role in this may involve a review of their manufacturing processes and quality control systems, and may also include detailed analysis of the device itself, or the instructions for use.. For this reason, you may, if requested, release the device to the manufacturer.

If you have any comments or queries about the progress of this investigation please do not hesitate to contact the MHRA Adverse Incident Centre on 020 3080 7080 or by email:

aic@mhra.gsi.gov.uk

Thank you again for bringing this matter to our attention. Every incident report contributes to the MHRA's

knowledge about medical devices and their usage, and helps us to develop suitable safety guidance and take appropriate action to protect the safety of patients, carers, healthcare workers and other medical device users.

Yours sincerely

Mark Smethurst

PP ROY SAUNDERS
Head of Adverse Incident Centre, MHRA

PLEASE QUOTE OUR REFERENCE IN ANY REPLY

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Viamed Spiro True A Flowsensors.jpg
1675K

Derek Lamb <liquidgands@gmail.com> 30 May 2013 13:18
To: "By way of info@viamed.co.uk" <Emmanuel.Scott@mhra.gsi.gov.uk>, aic@mhra.gsi.gov.uk

Dear Emmanuel Scott,

I apologise for the untimely response, Unfortunately your email got caught in my email spam box, Normally I would pick these up but due to the bank holiday its taken a little longer than normal to find the Emails dated 20/05/2013, and subsequent email dated 22/05/2013.

This is the first I know of the incident, so will give you a fuller reply this afternoon when I have investigated further.

Regards

Derek Lamb
30/05/2013
Viamed Ltd.
[Quoted text hidden]

Derek Lamb <derek@lamb.uk.net> 30 May 2013 13:25
To: Steve Nixon <steve.nixon@viamed.co.uk>

[Quoted text hidden]

Derek Lamb <liquidgands@gmail.com> 30 May 2013 14:11
To: Ben Wall <Ben.Wall@bsigroup.com>

Dear Ben,

I have just found the following email from the MHRA in my spam box. It relates to Own Brand Labeling Certificate CE 565618.

I am now opening up an Investigation and will keep you informed of any progress,

Please supply me with any reference numbers you allocated so I can tie them together. At this point in time it appears I've not had any report from the customer themselves,

A quick check of any returns of the product over the 3-4 Years they have been on sale have been Incorrect Orders. and the Single Incident number 2012/001/018/401/002 Which was a cleaning Issue.

I have not received back the current faulty units so can only base my initial risk assessment on the photographs provided.

The photos clearly show broken Tee-Pieces so the Issue is NOT related to 2012/001/018/401/002.

I'll keep you up to date with my findings.

Regards

Derek Lamb
Viamed Ltd.

---------- Forwarded message ----------
From: **By way of info@viamed.co.uk** <Emmanuel.Scott@mhra.gsi.gov.uk>
Date: 20 May 2013 15:53
Subject: MHRA Ref: 2013/005/020/401/001
To: Derek Lamb <derek@viamed.co.uk>
Cc: John Lamb <jsl@viamed.co.uk>

[Quoted text hidden]