Derek Lamb <liquidgands@gmail.com>

MHRA Ref: 2013/005/020/401/001 - SpiroTrue A flow sensors

1 message

Emma.Rooke@mhra.gsi.gov.uk <Emma.Rooke@mhra.gsi.gov.uk> 1 August 2013 11:13
Reply-To: Emma.Rooke@mhra.gsi.gov.uk
To: liquidgands@gmail.com

Dear Mr Lamb,

Thank you for your report.

Please could you clarify whether this is a single patient use device or re-useable device. From your report it would appear to be a single patient use device, but the e-mail sent to Mr Williams (who reported this incident) on 13/05/2013 states that they are not single patient use devices. In addition, I cannot see any indication on the instructions for use that these are single use devices rather than re-useable devices.

Please can you also confirm the date that flow sensors made from ABS from the alternative supplier went into production, and the dates that Viamed started and ceased supplying devices manufactured from this alternative material.

Kind regards,
Emma

Emma Rooke
Medical Device Specialist - MHRA
Tel: 0203 080 6609

Date: 31/07/2013 17:04:00

From: liquidgands@gmail.com On Behalf Of
Derek Lamb

ToAIC,

cc

bcc

SubjectFINAL Third Reminder to Manufacturer MHRA
Ref: 2013/005/020/401/001

Attachments: <<*see below*>>

From: liquidgands@gmail.com [mailto:liquidgands@gmail.com] **On Behalf Of** Derek Lamb
Sent: 31 July 2013 17:04