Date: 27/01/2020
From: Derek Lamb <derek.lamb@viamed.co.uk>

To AIC <AIC@mhra.gov.uk>
cc
bcc
Subject RESEND REPORT First Reminder MHRA Ref: 2019/010/022/401/011

From: Derek Lamb <derek.lamb@viamed.co.uk>
Sent: 27 January 2020 10:00
To: AIC <AIC@mhra.gov.uk>
Subject: RESEND REPORT First Reminder MHRA Ref: 2019/010/022/401/011

ref : **MHRA Ref: 2019/010/022/401/011**

This is my first notification of this reference number, I have reviewed the MHRA Field Notifications and have not been able to find anything.
we have not received any emails or post with this reference
can you provide or point me to the Report incident.

Regards

Derek Lamb
Viamed Ltd.

On Fri, 24 Jan 2020 at 14:32, <Grace_Smith/MHRA%MHRA@mca.gsi.gov.uk> wrote:

24/01/2020

MHRA Ref: 2019/010/022/401/011 quote this in any reply

Your Ref:

To date we have not received your final report.

What you need to do now

Send us the final report of your investigation into this incident.

If you can't send the final report, send us a follow-up report.

Fill in 'Expected date of next report' in section 10 of the form. This reduces the number of reminders we send you.

You don't need to re-send correspondence you have already sent us.

Yours sincerely
Patient Safety Communications Team
Devices Information and Operations Group, MHRA

Note: from 01 January 2020 you can only report to us via our Manufacturer's On-line Reporting Environment (MORE) which you can access through our reporting page or on the new Manufacturer's Incident Report (MIR) form. Guidance is available on the EC website under Guidance MEDDEVs 2.12 Post-Market Surveillance.

Use this email address aic@mhra.gov.uk to contact us. We check it regularly.

You can access the Medical Device Safety Officer (MDSO) contact list via MORE in order to copy them in on communications regarding Field Safety Notices (FSNs). This can help you ensure appropriate targeting and prompt action of the FSN within the MDSO's organisation.

We would advise you to familiarise yourself with the new EU Medical Devices Regulation 2017/745 (MDR) and the *in vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR) as they will fully apply in the UK from the 26 May 2020 and 26 May 2022 respectively. The Regulations introduce extensive changes, which you can read about in our guidance. These changes will affect manufacturers, importers, distributors, authorised representatives, as well as health institutions.