



Steve Hardaker <viamed.steve.hardaker@gmail.com>

Re: SoR?

1 message

Steve Hardaker <steve.hardaker@viamed.co.uk>

22 September 2021 at 18:50

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

To: "LEE, Peter (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <peter.lee3@nhs.net>

Hi Peter,

I've tracked the package and can see that it has now arrived at the Trust this morning, so hopefully the device has been passed to you by now.

With regards to a talk-through of the device, unfortunately, that's not something that I am able to do, having not had hands-on experience with it myself.

I've spoken to my Director, who has done manufacturer product training, and he is able to speak to the Clinical Educator if needed, however, the information provided should provide enough information to allow clinically trained staff to set up and operate the device.

One of the mandates of the MDR is that *the instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s)*. As this device is intended for use by clinically trained users, if the materials that the manufacturer has provided are not sufficient to allow an understanding of the device and to develop internal competency and training materials, we really need to identify where the shortfalls are and ask the manufacturer to improve and clarify the instructions.

I have attached the key documents that the Clinical Educator will require, can I ask that these are forwarded on with a suggestion that they work through the materials and identify where points of clarification are required?

Please pass on my email address and, if the Clinical Educator is able to advise me of any queries, we can provide answers where we have them or forward the comments to the manufacturer where we do not, thus ensuring that we obtain the manufacturer's response, as opposed to Viamed's interpretation as an intermediary distributor.

I apologise that this is a departure from the way that things were done in the past with company representatives being able to train clinical users directly, but we are being steered away from that model by increasingly stringent regulatory standards.

Regards,

Steve Hardaker
Technical Support Manager
Viamed Ltd.

Please note: Viamed is 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 be answered remotely, but please continue to use email where possible.

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On Tue, 21 Sept 2021 at 16:16, LEE, Peter (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST) <peter.lee3@nhs.net> wrote:

Hi Steve

Just a note that the SoR has yet to turn up

Given that the ITU educator will have to create an internal competency and like staff, will be new to this device, would you be able to do at least a MS Teams-based talk through of the device now, I know last time we spoke that you hadn't had a chance yourself to start gaining more familiarity with?

Kind regards

Peter D. Lee C.Eng MIET MIPEM

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