

Steve Nixon <steve.nixon.viamed@googlemail.com>

RE: Self certify MDD extension?

1 message

Narasimhan, Vasu P (US) <Vasu.Narasimhan@teledyne.com>
To: "steve.nixon@viamed.co.uk" <steve.nixon@viamed.co.uk>
Cc: "Khan, Mohammad (US)" <Mohammad.Khan@teledyne.com>

5 July 2023 at 21:22

Steve,

We have signed the Proposal from Intertek and expect a letter from them before the CE certification expiration. They are still asking for the SRN, but seem to have processed our application on the strength of the email that you had sent.

Meaning, we will be changing our Notified Body from BSI to Intertek and will eventually be transfer to MDR from MDD with Intertek as the NB.

The ISO 13485 certificate will remain with BSI until the recertification audit that is scheduled for later this year. After securing the recertification, we plan to convert that over to Intertek as well.

With a copy, I request Mohammad Khan to check with Intertek on the issuance of MDD extension letter.

Thanks,

Vasu

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From: Main Account <viamedinbox@gmail.com> On Behalf Of Steve Nixon

Sent: Wednesday, July 5, 2023 1:14 PM

To: Narasimhan, Vasu P (US) < Vasu. Narasimhan@Teledyne.com>

Subject: Re: Self certify MDD extension?

External Email

Hi Vasu

Do you have any news regarding the MDD extension or MDR CE certification?

I will need to update an extension letter or new certificate on the MHRA portal on the 8th July.

Regards

Steve

On Wed, 14 Jun 2023 at 17:40, Steve Nixon <steve.nixon@viamed.co.uk> wrote:

Hi Vasu

What are your thoughts on the attached, can Teledyne self certify an MDD extension?

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Steve Nixon

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Steve

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