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Derek Lamb <liquidgands@gmail.com>

Re: Annual review of Own Brand Labelling certificates No: CE 565618, CE 565620, CE 97289

1 message

Derek Lamb <derek.lamb@viamed.co.uk> 20 March 2014 10:25
To: Lena Gourmelon <Lena.Gourmelon@bsigroup.com>

Dear Gourmelon,

The own brand certificates CE 565618 and CE565620, are in the process of being cancelled as they have just been replaced by a single own brand certificate:ce540537

With regard to CE 97289,
The scope is still correct, and the products are the same.
No labels have changed,
Same technical Agreement,
No vigilance reports to report.
The requested certificates are attached,

Regards

Derek Lamb
Viamed Ltd.

On 18 March 2014 15:37, Lena Gourmelon <Lena.Gourmelon@bsigroup.com> wrote:

> Dear Mr Lamb,
>
> As part of your continuing approval under the 'Own Brand Labelling' (OBL) or Private Label (PL) scheme, and to ensure that your certification remains valid and up-to-date, this request will be sent annually to verify that all required elements of this process remain in place.
>
> We require confirmation of the following information for our records:-
>
> - Please confirm that you are still OBL the devices detailed on your BSI OBL / PL Certificate, and that the wording of the scope is still correct
> - Please supply a copy of the latest CE Certificate (from the Notified Body that originally CE marked these devices), which includes all devices listed in your OBL certificate
> - Please confirm whether any devices have been added to or removed from the OBL certificate within the current scope
> - If any changes have been made to the device labelling, please provide details
> - Please confirm, whether there have been any significant changes to the Technical Agreement. If there have been any significant changes since the last submission please supply a new copy of the agreement
> - Have there been any vigilance reports on the devices covered by the OBL certificates above? Please provide details

- Finally, please confirm whether you intend to OBL any devices not detailed in the certificates above

Once I have reviewed the documents sent I will contact you again, if the information is incomplete or if any other action is required. If you do not hear from me you can assume that there are no problems with the above certification and that no further action is required.

In the meantime, I would again draw your attention to the Conditions of Approval at the foot of your certificate: "The validity of this certificate is conditional on the continuing validity of the Original Equipment Manufacturers certification under the above Directive and maintenance of the relevant controls exercised by the Own Brand labeller" Please contact me if you have any questions.

Kind Regards,

-

Lena Gourmelon

Scheme Manager, Medical Devices

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By Royal Charter

UK Superbrands 2014

3 attachments

OEM CE.pdf
171K

Viamed CE 97289.pdf
850K

OEM 13485.pdf
332K