Gmail **Derek Lamb <liquidgands@gmail.com>**

Re: Technical File audit- CE 01389

1 message

Derek Lamb <derek.lamb@viamed.co.uk> 22 August 2016 at 10:48
To: Vishal Thakker <Vishal.Thakker@bsigroup.com>

See attached requested documents,

On 22 August 2016 at 10:42, Vishal Thakker <Vishal.Thakker@bsigroup.com> wrote:

> Hi Derek,
>
> I'm just finalising the renewal are you able to send through the following documents urgently to close out the major NCR related to the Tom Thumb (the details of the NCR are below as well):
>
> Tom Thumb Clinical Trials Reseach_ID15754
>
> Tom Thumb Clinical Trials Research JSL _ID15753
>
> Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2_ID15732

Major Nonconformities Arising from this Assessment.

Ref	Area/Process	Clause
1225836M1	Clinical Evaluation	Annex X
Scope	CE 01389	
Statement of non conformance:	There is no clinical Evaluation as required by Annex X.	
Requirements:	As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data, hereinafter referred to as 'clinical evaluation', where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:.....	
Objective Evidence:	The elements for the clinical evaluation are all available in different places in the technical file but the requirement for evaluation of this data has not been carried out as required by Annex X of the MDD. There is evidence from 2010 that the device was recommended for use by the NLS and the UK Resuscitation council.	

> If you can send any other information which is related to closing out the major NCR please send that through also.
>
> Thanks,

Vishal Thakker MEng(Hons) AMIMechE

Scheme Manager/Product Specialist

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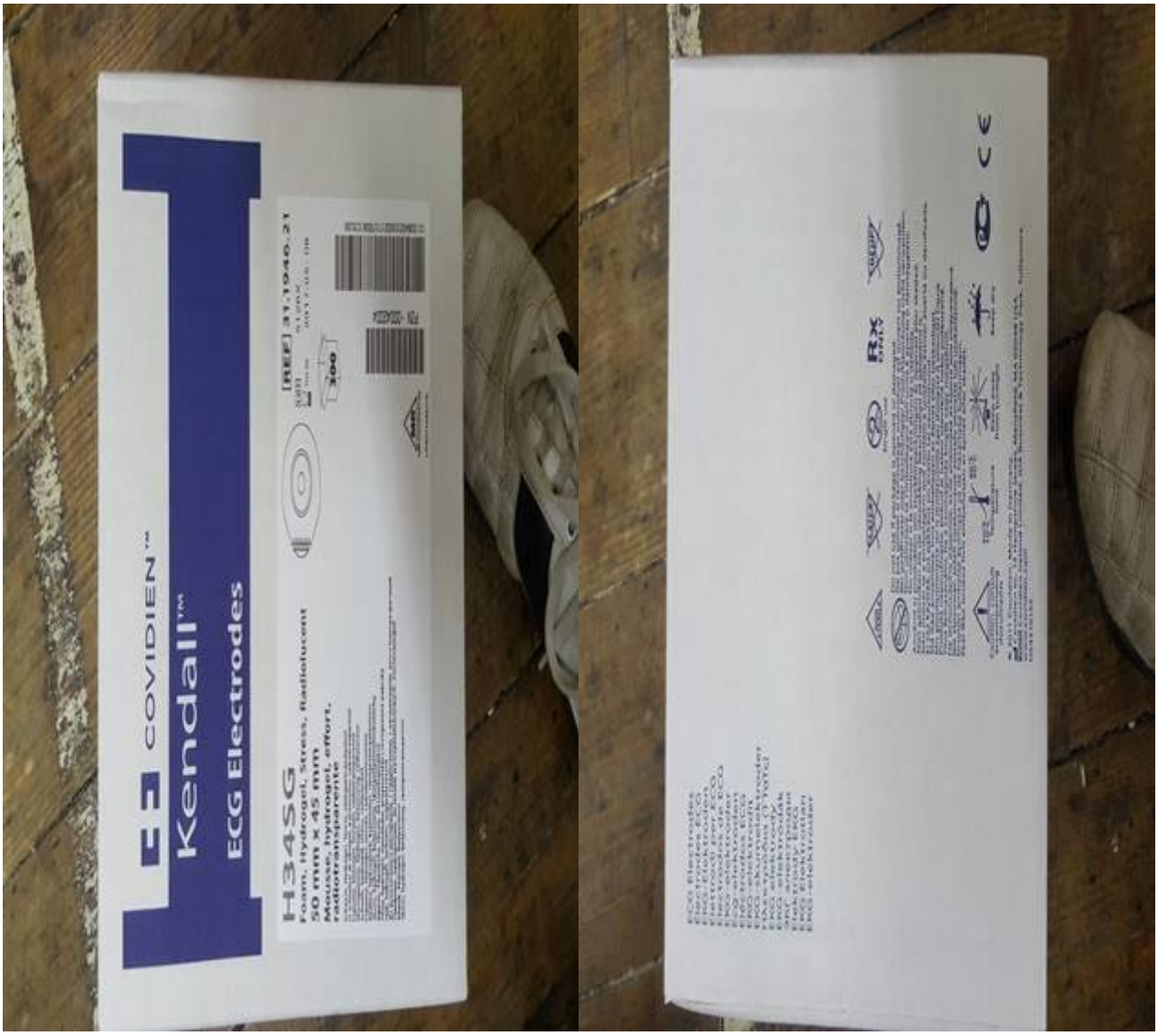
From: liquidgands@gmail.com [mailto:liquidgands@gmail.com] **On Behalf Of** Derek Lamb
Sent: 01 June 2016 11:35
To: Vishal Thakker <Vishal.Thakker@bsigroup.com>
Subject: Re: Technical File audit- CE 01389

The Electrodes are supplied by Covidien, under htere CE marking - see images 20160601_110554.jpg and 20160601_110601.jpg



Own Brand Label Envitec Sensors

1225837M1
see the attached envitec labels,

The other documentation I believe was sent directly to richard tully, from Envitec.

This is an own brand product and the information requested was confidential from us.

1225837N1
See comments in Expected life of product

Tom Thumb Report

1225836M1

See the final statement Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits_ID16043

and

Tom Thumb Clinical Trials Reseach_ID15754

Tom Thumb Clinical Trials Research JSL _ID15753

Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2_ID15732

1225836N1

The replacement end print of the ER Checklist.

The actualy checklist has moved from paper to a computer system so is no longer a generic road map pointing to documents,

1225836N2

We added the statement to the file Tom Thumb Packaging Trials and validation _ID15461

Also see : ID2245 , ID7724 and ID7726

1225836N4

We added a statement to the technical file

No risks disposal_ID15183

"The disposal of the device is not discussed in the ifu" (n) precautions to be taken against any special, unusual risks related to the disposal of the device;

As there are not precautions to be taken (it is at the end of the day a solid brass block).

Sorry the email has taken a while to put together,

Regards

Derek Lamb

On 1 June 2016 at 10:41, Vishal Thakker <Vishal.Thakker@bsigroup.com> wrote:

> Hi Derek,

I have started the audit of the Microstim MKIII, and I have a couple of urgent questions:

#1 Is Viamed CE marking associated electrodes? If so where in the technical file can I find details of any accessories associated with the device e.g. electrodes that fall within the scope of the certificate CE 01389?

#2 The non-conformities (NC's) from report 8164150 dated 11/08/2015 need to be formally closed, please forward documentary evidence the demonstrates closure.

I may have more questions as part of the assessment however these are the 2 questions I need answering urgently.

Thanks,

Vishal Thakker MEng(Hons) AMIMechE

Scheme Manager/Product Specialist

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3 attachments

Tom Thumb Clinical Trials Research JSL _ID15752.doc
68K

Tom Thumb Clinical Trials Reseach_ID15754.pdf
95K

Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2_ ID15732.pdf
108K