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

RE: Technical File audit- CE 01389

1 message

Vishal Thakker <Vishal.Thakker@bsigroup.com> 23 August 2016 at 14:34
To: Derek Lamb <derek.lamb@viamed.co.uk>
Cc: Daniel Taylor <Daniel.Taylor@bsigroup.com>

Hi Derek,

We have reviewed the documentation you submitted and it is still not clear how you meet the requirements of Annex X of 93/42/EEC. The directive clearly states the following:

1. **General provisions**

'M5

1.1. 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:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:

— there is demonstration of equivalence of the device to the device to which the data relates, and

— the data adequately demonstrate compliance with the relevant essential requirements.

1.1.2. Or a critical evaluation of the results of all clinical investigations made.

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.

From the documentation it is not clear how the requirements are met, you have submitted the data you've analysed but what is the relevance of this. Please also refer to Appendix F of Meddev 2.7.1 rev 3 this gives a guidance on what we are looking for in the final clinical evaluation report.

Any questions do let me know.

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: 23 August 2016 10:52
To: Vishal Thakker <Vishal.Thakker@bsigroup.com>
Subject: Re: Technical File audit- CE 01389

Vishal,

Please find attached all the files we put together to address the 1225836M1 MNC last september.

The main document ID15756 was the end level risk / benefit conclusion statement. which points to other documents in our system.

John Lamb has tidied the document id 15752 up a little. this document is not our 'conclusion document', but a list of references of literature we had been able to find / research.

The Item highlighted in your email I have included the full text, however this is copyright material (PIIS0300957211007337.pdf) , and I don't really like sending it out. point of note the Neopuff is functionally identical to the Tom Thumb.

If need be I'll get John lamb to talk to you directly as he has been involved with the Tom Thumb since its initial release 30 Years ago.

Regards

Derek Lamb

On 22 August 2016 at 16:04, Vishal Thakker <Vishal.Thakker@bsigroup.com> wrote:

> Hi Derek,
>
> As discussed, the evidence for the close out of the Major non conformity is still lacking sufficient information.
>
> I have the following comments from the reviewer which should guide you to get the relevant documentation together, the crux of this is that you need to review Meddev 2.7.1 and base your clinical evaluation this.
>
> *''I see they require further work to be done. There is no proper structure on the clinical evidence being presented and how they have achieved the clinical efficacy and safety claims. Looks like they have not approached a gold standard (Meddev 2.7.1 or EN ISO 14155).*
>
> *I see there are some clinical papers (published, I assume) used Tom Thumb for their study but in the conclusion section of document 'Tom Thumb Clinical Trials Research JSL _ID15752.doc' it states 'there is a need for appropriately designed randomised controlled trials in neonates to high-light the efficacy of one device over another. Until these are performed, healthcare providers should be appropriately trained in the use of the device available in their departments, and be aware of its own limitations.' I am confused; are they talking about their device or others?*
>
> *I am unable to establish if they have done a literature search or clinical investigation or both? If they have done a literature search; they need to provide copies of published literature including cross references and needs to adopt methodology of MEDEV 2.7.1.*

If they have done a clinical trial; then I need to see the following documents;

- *the clinical investigation plan;*
- *clinical investigation plan amendments and the rationale for these changes;*
- *the relevant Ethics Committee(s)' documentation, opinion(s) and comments for each;*
- *investigation site, including a copy of the approved informed consent form(s) and patient information documents;*
- *case report forms, monitoring and audit records;*
- *Regulatory Authority approvals and associated correspondence as required by applicable regulations; and*
- *the signed and dated final report.*

We would also need to verify the credential of authors and importantly, the report must be dated and signed.''

Please can you supply the updated documentation so we can process the renewal ASAP.

Thanks,

Vishal Thakker MEng(Hons) AMIMechE

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389 Chiswick High Road, London, W4 4AL, United Kingdom

From: liquidgands@gmail.com [mailto:liquidgands@gmail.com] **On Behalf Of** Derek Lamb
Sent: 22 August 2016 10:48
To: Vishal Thakker <Vishal.Thakker@bsigroup.com>
Subject: Re: Technical File audit- CE 01389

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

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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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