



John Lamb &lt;viamed.john.lamb@gmail.com&gt;

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**Phototherapy eye masks Project 29 44701**

4 messages

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**John Lamb** <john.lamb@viamed.co.uk>  
To: Alexander Yin <alexander99@yahoo.com>

Mon, Sep 2, 2013 at 11:42 AM

Dear Alexander,  
We have found a discrepancy in your paperwork

Page 3 Technical File you quote MDD93/42/EEC/MDD2007/47/EEC Amending Annex VII

On your declaration of Conformity you quote Annex VIII 93/47/EEC

As you have ISO13485 I believe you should be quoting Annex II

Kind regards

John

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**Alexander Yin** <alexander99@yahoo.com>  
Reply-To: Alexander Yin <alexander99@yahoo.com>  
To: John Lamb <john.lamb@viamed.co.uk>  
Cc: "Derek@lamb.uk.net" <Derek@lamb.uk.net>

Tue, Sep 3, 2013 at 10:49 AM

Dear Mr.John,

It should be Annex **VIII** of Directive 93/42/EEC as amended by 2007/47/EEC.

Thanks&Best regards,

Alexander

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**From:** John Lamb <[john.lamb@viamed.co.uk](mailto:john.lamb@viamed.co.uk)>  
**To:** Alexander Yin <[alexander99@yahoo.com](mailto:alexander99@yahoo.com)>  
**Sent:** Monday, September 2, 2013 6:42 PM  
**Subject:** Phototherapy eye masks Project 29 44701

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**John Lamb** <[john.lamb@viamed.co.uk](mailto:john.lamb@viamed.co.uk)>  
To: Alexander Yin <[alexander99@yahoo.com](mailto:alexander99@yahoo.com)>

Tue, Sep 3, 2013 at 12:44 PM

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**John Lamb** <[john.lamb@viamed.co.uk](mailto:john.lamb@viamed.co.uk)>  
To: Alexander Yin <[alexander99@yahoo.com](mailto:alexander99@yahoo.com)>

Tue, Sep 3, 2013 at 12:51 PM

Dear Alexander,  
Sorry to be so pedantic but our MHRA (equivalent to your SFDA) and Notified bodies have become so strict it is unbelievable.  
My copy of 93/42/EEC Amended April 2002 defines Annex viii as  
"Statement concerning devices for special purposes"  
These tend to be custom made devices.

I will check when Derek returns that we do not have yet another later version.

Kind regards

John

PS Many thanks for the swift and detailed replies  
John

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