



1 message

2 June 2016 at 13:10

If that is the case you need to spate out the different models as the intended use would have changed to act as an oxygen hood as well.

Thanks,

Vishal Thakker MEng(Hons) AMIMechE
Scheme Manager/Product Specialist

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Vishal.Thakker@bsigroup.com



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From: liquidgands@gmail.com [mailto:liquidgands@gmail.com] **On Behalf Of** Derek Lamb
Sent: 02 June 2016 11:35
To: Vishal Thakker <Vishal.Thakker@bsigroup.com>
Subject: Re: Attachment

Hi Vishal,

Please see 2 Documents attached.

The light shields can be made as a complete Oxygen Hood so falls under the same classification as the Oxygen Hood.

John has also pointed out I need to add the Class 1 plastic products (Tube holder and Cot Lid) to your spreadsheet.

We used to have a Single Plastics / Acrylic Technical file which had everything from all the products in 1 file.

When we computerised the file it was easier for use to separate the products into groups.

This does cause us to have some 'grey' areas of what classification the product falls into. I've added to the indications of use of the light shield stating it can be made as a photo therapy oxygen hood.

Regards

Derek Lamb

On 2 June 2016 at 08:34, Vishal Thakker <Vishal.Thakker@bsigroup.com> wrote:

Hi Derek,

Thanks for the classification documents, can you send through the updated spreadsheet as well.

However the classification for the light shields is incorrect, I believe rule 9 would not be applicable as the device is not an active device. Please have a look at the definition of an active device in the MDD as well as the med dev guidance document.

Thanks,

Can you please have a look at the 2 marked in red, for the light shields can you please look at the rule you are using again as the product is not an active device. For the Heat shields I agree with the rule but not the classification.

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 15:13

To: Vishal Thakker <Vishal.Thakker@bsigroup.com>

Subject: Attachment

Think I missed the attachment as I hit send

11

Regards

Derek Lamb

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Regards

Derek Lamb

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Regards

Derek Lamb

