Subject : FWD: RE: CE Mark Questions
Date : Fri, 4 Feb 2005 09:37:00 +0000
Linked to : Wade M Abraham
From : HELEN (Helen J Lamb) <GoldMine User>
To : JSLAMB (John Lamb) <GoldMine User>

---------- **Forwarded Message** ----------

From: "Wade Abraham" <wade@novahealthsystems.com>
To: "'John Lamb'" <jsl@viamed.co.uk>
Date: Thu, 3 Feb 2005 14:16:24 -0500
Subject: **RE: CE Mark Questions**

Dear John,

I have inserted responses to your questions below each individual question. I have used a blue color font for my response, but don't know if your email supports it.
Please let me know if these response are adaquate, or if you need me to fax a more formal response on letterhead. Also, let me know which answers may require more details or information.

Thanks,

Wade

1.Have there been any product changes.
a. To improve the product
b.Rectify any problems
If Yes to b
i Describe problem
ii Describe the cure

There have been no changes to the product since Nova acquired the product line in August of 1998.

2. Have you had
a. Any customer complaints
b. Suggestions for improving the product

We are required by the FDA to maintain customer complaint files, but have received no complaints.

3. Location of responsibilities. You signed this without filling it in. Who is responsible for
a. Design
b. procurement of parts and/or materials or finished product.

c. QA

I, Wade Abraham, am responsible for all Design, procurement and QA.

4. Manufacturing route. Who manufactures for you. Do they have ISO9000

Our products are manufactured by Happy Manufacturing in Taiwan. Khan's Enterprise Co., Ltd. in Taoyuan acts as our broker and representative. To the best of my knowledge neither is ISO certified.

5. Work Instructions. Where are they held and are they followed

Our work instructions are contained in manuals in our document room. These are used for training and as our standards for manufacturing process. All changes are documented.

6. Copy of your 510K and FDA registration, Product liability insurance

I have both and will fax over to you. However, even though we have a 510k for oxygen hoods, the product has since been recatagorized as "exempt" and the FDA no longer requires a 510k for oxygen hoods.

7. Have you had any packaging problems

No packaging problems have arisen.

8. Does Nova have ISO9000 if not do you have a quality plan and quality proceedures. Can I have a copy

Nova does not have ISO9000. We are in the process of a complete update of our quality plan. I should be able to send or fax you a copy by the end of the month.

9. Are there any accessories

The only accessory we offer for our oxygen hoods is our disposable, self adhesive, temperature strips. However, very few customers request this product. It does not need to be offered.

10. Specifications of the materials .Plastic metals and glues. Are they all biocompatible? We need MSDS and Biocompatible statement from manufacturer of the materials.

I have specifications of our materials and will fax over to you. I will have to contact Khan's to determine how to obtain MSDS and other material statements for you. This will probably take a few weeks at best. Taiwan is celebrating New Years until Feb 14.

11. Do you have any literature containing product reviews or do you have any clinical trials

We do not have any literature or reviews of our standard products at this time. There is some information regarding special uses of double tents, but is very old and equipment specific.