— MEDICAL —
DEVICES
DIRECTORATE

Medical Devices Directorate
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Tel: 071 972 8308
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Your reference:

Our reference: CMY/129/1

Date: 28 March 1994

Mr John S Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT

Re: Your letter of 7 March 1994 to Mr Kent

Dear Mr Lamb

I have examined the btrochures that you provided and it is our opinion that those listed are either Class I or Class IIa:

... headboxes, light shield, heat shields, and oxygen therapy chair are Class I;
... Anaestim II and Microstim are Class IIa.

Article 11 of the Directive gives the various methods available to manufacturers in order to CE mark their products.

Since none of your Class I products appear to be supplied sterile or contain a measuring function, they would not require intervention by a Notified Body in order to be CE marked. Manufacturers of such Class I devices are required to draw up a declaration of conformity, the procedure for which is given in Annex VII of the Directive. MDD is producing guidance for manufacturers of Class I devices which should be available this summer.

Regarding Class IIa products, a manufacturer must draw up a declaration of conformity as above combined with one of four options:

1. EC Verification (Annex IV): Notified Body tests each product.
2. Production Quality Assurance (Annex V): roughly, BS 5750: Part II.
3. Product Quality Assurance (Annex VI): roughly, BS 5750: Part III, which appears to be the path you are already following in seeking Stockist accreditation.
4. Full Quality Assurance (Annex II): roughly, BS 5750: Part I.

It is strongly recommended that you obtain a copy of the MDD (DIRECTIVE 93/42/EEC) if you have not already done so. Copies can be purchased from Her Majesty's Stationery Office by telephoning 071-873-9090, quoting the Official Journal of the European Communities (OJ No. L169) and the date of publication, 12 July 1993.

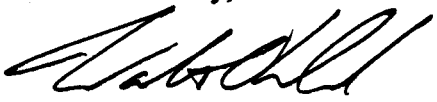
Under the Directive, it is the responsibility of the Manufacturer to determine the classification of his products in light of the claims that he makes for them and the rules of Annex IX. The Medical Devices Directorate will of course give advice when interpretation is unclear. Clearly we are not in a position,

nor have we the resources, to classify all products for all manufacturers. We do however try to assist manufacturers in making their decisions. In the first instance, you should determine if a device actually falls within the scope of the Directive in light of your claims for it. Next, all applicable devices should be classified in light of Annex IX of the Directive. Some will be easy to classify but others not so.

If you are still experiencing difficulties either in respect of determining classifications or indeed whether a product is considered to be a medical device, please write again explaining where the difficulty lies, and we will try to assist you. Where products are not covered by the medical device directives, there may be other directives which apply, such as the Measuring Instruments Directive; DTI should be contacted in such cases if advice is required.

We are happy to help you by giving you our views and comments but you must appreciate we are unable to give you any legal advice.

Yours sincerely,



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Your reference:

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Date: 19 April 1994

Mr John S Lamb
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15 Station Road
Cross Hills
Keighley
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BD20 7DT

Re: Your letter of 7 March 1994 to Mr Kent

Dear Mr Lamb

It has come to my attention that one item in my reply of 28 March 1994 to the above letter may have been misleading. The section concerning conformity assessment of Class IIa products should read as follows:

Regarding Class IIa products, a manufacturer must draw up a declaration of conformity as above combined with one of three options:

1. EC Verification (Annex IV): Notified Body tests each product.
2. Production Quality Assurance (Annex V): roughly, BS 5750: Part II.
3. Product Quality Assurance (Annex VI): roughly, BS 5750: Part III, which appears to be the path you are already following in seeking Stockist accreditation.

Alternatively, the manufacturer may choose to take the Full Quality Assurance route (Annex II): which is roughly, BS 5750: Part I.

Yours sincerely,

WJ O'Dowd
Room 617A