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— MEDICAL —
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Our reference: CMY/129/1

Date: 19 April 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

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