BSI Product Services

Maylands Avenue Hemel Hempstead Herts HP2 4SQ

Tel +44 (0)1442 230 442
Fax +44 (0)1442 231 442
www.bsi-global.com

Product Services

Date: 15 September 2003

Mr John Lamb
Viamed
15 Station Road
Crosshill
Keighley
West Yorkshire
BD20 7DT

Dear Mr Lamb

CE Marking for Medical Devices 93/42/EEC – Own Brand/Private Labelling

Thank you for your interest in the services offered by BSI acting as a Notified Body under the Medical Devices Directive. In response to your requests for information regarding the Own Brand/Private Labelling please find enclosed some background information on this subject.

To proceed and obtain a quotation, please would you complete and return the Checklist for my attention. I will be happy to then produce a quotation for you.

When you are ready to make an application, we will also require the following:

- A copy of the technical/quality agreement between the private label company and the original manufacturer.
- Copies of the post market surveillance and vigilance procedures describing the private label manufacturer's responsibilities for these activities.
- Copies of the private label products instructions for use and labels
- A copy of the private label manufactures draft declaration of conformity
- A copy of the original manufacturers declaration of conformity/CE certificate
- Device / product literature, describing the range of devices for which CE Marking is required

I can also confirm that, from a Directive point of view, you do not need to show the country of origin on the packaging.

Should you have any questions regarding the above, please feel free to contact me. In the mean time we look forward to receiving completed checklist and to working with you in the near future.

Yours sincerely

V Gomersall

Vicki Gomersall
Client Relationship Manager
Mobile: +44 (0)7879 435797

shape the future