BSI Audit 4135507 2001 July

BSI Client Ref:

9370214

Certificate No:

FS 28344

Report Number:

4135507

Prepared by:

C E Collins

Date:

9th July 01

Continuing Assessment

Viamed Limited
15 Station Road
Crpss Hills
KEIGHLEY
West Yorkshire
BD20 7DT
UK

INTRODUCTION

This report relates to a Continuing Assessment of Viamed Limited held 9th July 01 and includes a strategic review.

During the assessment several pages of hand written notes were taken recording compliance with both the standard and the documented quality management system. As part of this process 2 nonconformities were identified.

9001/2000 TRANSITION

The client is still considering a transition policy. CE marking requires maintenance of ISO9000 and EN46000. Whilst the registered firm certificate will require compliance with 9001/2000 by the end of year 2003. If the client is to use the BSI transition process over two years for 9001/2000 a start will need to be made at the next visit.

CONCLUSIONS

Continued certification is confirmed, however a corrective and preventive action plan is required.

The corrective and preventive actions have been verified for report 4050342 and there are no outstanding NCRs

The nonconformities identified require corrective and preventive action, firstly to correct the identified non-conformance and secondly to examine the underlying cause and implement the changes necessary to prevent recurrence. The investigation and resulting actions may take time, and therefore require the preparation of an action plan.

Please submit a plan to determine action, timescales and responsibilities for review, no later than 9th Aug 01.

The plan should be sent by fax to 0208 996 7988 or by e-mail to caps@bsi.org.uk . Please ensure that your response details each nonconformity and the proposed corrective action with time scales for completions. For administrative reasons please ensure that your response details this report number and your BSI client reference as detailed on page one of this report.

It is confirmed that:

Certificate No:	**Dated**
FS 28344	29th March 01

remain(s) valid for the scope of registration as detailed on the appendix(ces).

ASSESSMENT COMMENTARY

VISIT DETAILS

THE ASSESSMENT TEAM

The assessment was conducted by:

Edward Collins

on behalf of BSI.
The principal staff involved on behalf of the company were:

Mr Lamb - MD

THE MANAGEMENT STANDARD

The management standard used as the basis for this assessment was ISO 9001 and EN46001. The council directive used as the basis for this assessment was MDD 93/42/EEC

THE COMPANY'S DOCUMENTATION

The company's management system documentation forming the basis of assessment was: Issue 2

This visit report forms part of BSI's partnership approach in the assessment of your Management System.
The activities assessed in depth are listed in the 'Areas Assessed this Visit' table attached.
The assessment was based on random samples and therefore nonconformities may exist which have not been identified.
If you wish to distribute copies of this report external to the organisation, then all pages must be included.

Signed for on behalf of BSI

Edward Collins
Client Manager

Date: 9th July 01

Signed for on behalf of the client

Mr Lamb
M.D.

AREAS ASSESSED THIS VISIT

	Management Standard Clause Number																			Nonconformity Summary
Areas Assessed	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20	NCR Ref
QA and strategic review	✓	✓												✓			✓			✓	EC 1
Manufacture of pulse oximeter probes	✓	✓			✓			✓	✓	✓	✓	✓						✓			EC 2

AREAS ASSESSED over the review period

	Management Standard Clause Number																			Nonconformity Summary
Areas Assessed	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20	NCR Ref
EC July 01 - QA, strategic review and manufacture of pulse oximeter probes	✓	✓			✓			✓	✓	1	✓	✓		1			✓			✓	2
EC Dec 00 – QA, design and sales	✓	✓	✓	1										✓		✓	✓	✓			1
MB April 00 – QA, goods inwards	✓	✓			✓		✓	✓				✓	✓	✓	✓	✓	✓				0
MB Oct 99 – QA. Sales, purchasing and repairs	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓		✓		✓	✓		✓		0
Totals				1						1				1							3

Quality Management System Requirements

4.1	Management Responsibility	4.6	Purchasing	4.11	Control of Inspection, Measuring & Test Equipment	4.16	Control of Quality Records
4.2	Quality System	4.7	Control of Customer Supplied Product	4.12	Inspection & Test Status	4.17	Internal Quality Audits
4.3	Contract Review	4.8	Product Identification & Traceability	4.13	Control of NonConforming Product	4.18	Training
4.4	Design Control	4.9	Process Control	4.14	Corrective & Preventive Action	4.19	Servicing
4.5	Document & Data Control	4.10	Inspection & Testing	4.15	Handling, Storage, Packaging, Preservation & Delivery	4.20	Statistical Techniques

NONCONFORMITIES IDENTIFIED DURING THIS VISIT

Area	Ref	Description	ISO Ref
QA Appendix A COP13	EC 1	a) There is no evidence in the management review of Jan 01that the results of any corrective/preventative action have been reported.	4.14.3d
QC12 COP10 QC 11 COP10		b) There is no objective evidence that individual complaints are reviewed against the reporting criteria for vigilance.	An II 3.1
Appendix A COP13		c) VM/COP/18 details complaints, repair file, goods returned and post surveillance enquiry cards as being part of the vigilance process. However there is no formal evidence of a systematic review.	An II 3.1
COP13 QC18 NON-CONFORMANCE		d) Other than for customer complaints no specific procedure exists relating to general corrective and preventative actions.	4.14.1
QA COP30.14	EC 2	The test criteria for pulse oximeter probes was said to be 95 +/- 2%. However this test value and tolerance was not stated in procedures	4.10

Plan for Next Visit

Prepared in accordance with ISO10011-1

Client: Viamed Limited				
Management Standard:	ISO 9001	BSI Team:	Leader:	E Collins - tbc
Opening Meeting Date/Time:	09.00 tbc		Members:	N/a - tbc
Closing Meeting Date/Time:	16.00 tbc			
Company Representative				

Date	Time	Assessor	Business Area
	9.00	**E Collins**	**QA – including reviewing any changes, customer complaints, management review, internal audits and cleardown of any n/c's raised at the previous visit.**
	10.30		**Goods inward**
	13.00		**Purchasing**

Strategic Review

Summary of Previous Assessment Reports

During the review period all of the standard and all of the key business areas have been assessed. However it was not possible to determine from previous visit reports if all the products covered by the EC certificate had been audited. This is a relatively small company with a wide product range and not all product is available at any one time.

There is no obvious trend in either the number or the nature of the nonconformity's raised by BSI in the review period.

Over the review period corrective actions resulting from the nonconformity's raised by BSI have been effectively closed down in a timely manner.

Management Review

Management reviews are carried out every year by the MD and involves senior managers.

The review covers customer complaints and internal audit findings. The objectives of the quality policy are covered but there is no feedback of a general nature such as delivery performance, internal corrective actions or product returns.

Audit results concentrate on progress rather than any specific findings

Actions are not assigned and there is no specific conclusion reached regarding the adequacy of the management system in achieving its objectives.

Internal Quality Audits

Audits are scheduled on the calendar year and are scheduled to cover all of the business in the one year.

Audits are generally thorough, carried out to schedule with prompt closure or any corrective actions identified. There could be more evidence in the planning stage, either in the checklists used or the audit plan to show that the requirements of the directive and EN 46000 are to be covered in the audit. The technical file is subject to a separate audit.

Complaints

Complaints are low in number and are subject to a thorough investigation and are promptly closed out. When not justified the reasons are recorded.

In the review period there have been no complaints made to BSI

Complaints are subject to a monthly analysis by the MD.

There has been no product recall or adverse incident reported in the review period.

Corrective & Preventive Action

The complaints system contains "internal complaints" which use the complaints system and review process. However no formal documented system exists for the systematic review of key data.

The business needs to assess which key data they must measure (vigilance) and which key data it is advisable to measure and review this in a systematic way which demonstrates confidence in their ability to meet specified quality objectives.

Documented Management System

Most of the traditional documentation is now available on the computer system in a read only format. This includes much technical documentation. A back up system is in operation where data is removed from site for additional safety

Additional Items

I have completed the last two assessment visits and these have always been easy to arrange with the client and all members of the organisation have demonstrated a high degree of co-operation. The MD takes a close personal interest in the operation of the management system. With the change of client manager some of the visits have fallen a little later than originally scheduled. However it is intended to catch up over the next cycle and to return to May and Nov as the target months for the visits.

Scope of Registration

There is no proposed change to the scope of registration. However the postcode needs correcting.

There is no change in the T code required by the assessor

Visit Frequency & Duration

There is no proposed change to the visit frequency or duration of 4 days over 2 years, which is in line with EN45012/EAC guidelines and with the IAF interpretation of ISO/IEC Guide 62.

Client Management

There are no issues of impartiality. I have no relatives working in, nor do I have any financial interest in this company. Two different assessors have carried out the last four assessment visits.

Recommendation

Continued registered firm certification is recommended

Plan of Assessment up to and including the next Review

Planned Month Duration	Dec 01 1 day	May 02 1 day	Nov 02 1 day	May 03 1 day
Business Areas * production is spasmodic and the audit plan will need to change to suit the audit sample available.				
Design			✓	
Goods inwards	✓			
Purchasing	✓			
Sales – viamed and vandagraph				✓
* Manufacture of Microstim Nerve Stimulators		✓		
* Manufacture of Tom Thumb Resuscitator		✓		
* Testing of Thermacot		✓		
* Testing of Oxygen monitors (including vandagraph product)				✓
* Manufacture of pulse oximeter, temperature probes and leads				✓
Vigilance	✓	✓	✓	✓
Organisation / Management Review	✓	✓	✓	✓
Quality System & Changes	✓	✓	✓	✓
Internal Audits	✓	✓	✓	✓
Corrective Action inc. Complaints	✓	✓	✓	✓
Strategic Review				✓

Plan subject to change as circumstance demand.

CERTIFICATION DETAILS

REASON FOR ISSUE/REISSUE: Correction to postcode
e.g.: change of address

Client: (as to appear on certificate)

Registered Address: **Correct post code for this location is:** **BD20 7DT**		**Invoice Address:**

Trading name (also to appear on certificate):

Total No of appendices:	

Location Address:	

Approved Site Address:	

Recommended scope of registration (as to appear on appendices):

Accreditation:	Client Tel No:	
Best Fit Code(s):	Client Fax No:	
Certificate Prefix:	Client Contact:	
Visit Frequency:	Alt. Contact:	
Start Month:	Email:	
Location Client Managers:		
Co-ordinating Client Manager:		

Additional Information:

Internal BSI Actions

THE FOLLOWING ACTIONS WILL BE IMPLEMENTED BY BSI.

(include actions detailed in the report).

Reissue certificate with correct post code

VISIT DATA

Number of employees: 22

Certificate Reissue required: yes

Client CAP due: 9th Aug 01