BSI Audit 4201631 - 2002 Feb.

BSI Client Ref:

9370214

Certificate No:

FS 28344
CE 01389

Report Number:

4201631

Prepared by:

C E Collins

Date:

21st Feb. 02

Continuing Assessment

Medical Devices

BSI action required: **None**

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

4201631C1

INTRODUCTION

This report relates to the Continuing Assessment for Viamed Limited held 21st Feb. 02.

The assessment was based upon the Client's Management System, reference Issue 3.

As part of the assessment process several pages of conformance notes were recorded showing that key processes were in line with the requirements of the standard. As part of this process no nonconformities were identified.

CONCLUSIONS

Continued certification is confirmed.

The corrective actions have been verified for report 4135507 and there are no outstanding nonconformities.

It is confirmed that:

Certificate No:

FS 28344
remain(s) valid.

The recommendation to the BSI Medical Devices Notified Body is that certificate

Certificate No:

CE 01389
remain(s) valid.

ASSESSMENT COMMENTARY

A new software system (goldmine) is being implemented which will simplify and modernise the whole purchasing system. It also affords the opportunity to introduce a re-evaluation process. A more specific requirement for the re-evaluation of suppliers does not necessarily mean repeating the initial approval process by repeating the questionnaire, unless this would be of value to the organisation. It is more likely that a review of supplier performance from internal data would be more appropriate and be of greater benefit to the organisation

VISIT DETAILS

THE ASSESSMENT TEAM

The assessment was conducted by:

C E Collins

on behalf of BSI.

The principal staff involved on behalf of the company were:

Mr Lamb - MD

Mr Rush - QA Manager

THE MANAGEMENT STANDARD

The management standard used as the basis for this assessment was, ISO 9001:1994 and EN 46001

Special scheme requirements: Council Directive 94/42/EEC Annex II

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

C E Collins
Client Manager

Signed for on behalf of the client

Mr Lamb
MD

Date: 21st Feb. 02

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	✓	✓												✓			✓				
Goods Inwards	✓	✓							✓	✓		✓	✓		✓	✓					
Purchasing	✓	✓				✓										✓					

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& Data Control

Quality Management System Requirements

4.6 Purchasing
4.7 Control of Customer Supplied Product
4.8 Product Identification & Traceability
4.9 Process Control
4.10 Inspection & Testing
4.11 Control of Inspection, Measuring & Test Equipment
4.12 Inspection & Test Status
4.13 Control of NonConforming Product
4.14 Corrective & Preventive Action
4.15 Handling, Storage, Packaging, Preservation & Delivery
4.16 Control of Quality Records
4.17 Internal Quality Audits
4.18 Training
4.19 Servicing
4.20 Statistical Techniques

THE FOLLOWING ACTIONS WILL BE IMPLEMENTED BY BSI.

(include actions detailed in the report).

None

VISIT DATA

Number of employees: 28

Certificate Reissue required: n/a

Client CAP due: n/a

Assessment duration: 1 day

Use of BSI / accreditation symbols checked: Yes

ISO 9001:2000 Transition Progress					
					Enter ✓
Not applicable to this Client. Enter reason:					
The Client has transferred and is registered to ISO 9001:2000					
The Client is planning a full transfer assessment Planned date:					
The client is progressing with the transition route. Progress is notes below Started (date):					
QMS	PR	MAI	MR	RM	Issue to close out
(Tick the boxes to indicate the Client's progress as appropriate.)					

Additional Comments:

In order to support the CE marking certificate the client is reminded of the need to maintain ISO9001 + EN46001 for the foreseeable future until ISO 13485 is revised.

The client is also reminded that ISO 9002 will be obsolete by the end of Dec 03 and that transition to ISO9001/2000 will be required before that date to support the Registered Firm Certificate.

The client commented that they might choose to loose Registered Firm status rather than switch to ISO 9001/2000 and have a CE certificate only.

Plan for Next Visit

Prepared in accordance with ISO10011-1

Client: Viamed Limited				
Management Standard:	ISO 9001:1994ISO 900	BSI Team:	Leader:	C E Collins - tbc
Opening Meeting Date/Time:	09.00		Members:	tbc
Closing Meeting Date/Time:	16.00			
Company Representative				

Date	Time	Assessor	Business Area / Process
Oct 02 1 day	**09.00**	**C 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.**
			Vigilance + Post market surveillance
	10.00		**Manufacture of medical devices - Microstim Nerve Stimulators, Tom Thumb Resuscitator, Thermacot testing.**
			Ps if production is not available we can sample from another business area

Management System Assessment Report

BSI Client Ref:

9370214

Certificate No:

FS 28344
CE 01389

Report Number:

4201631

Prepared by:

C E Collins

Date:

21st Feb. 02

Continuing Assessment

Medical Devices

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15 Station Road
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KEIGHLEY
West Yorkshire
BD20 7DT
UK

4201631C1

P222

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Goods Inwards	✓	✓							✓	✓		✓	✓		✓	✓					
Purchasing	✓	✓				✓										✓					

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
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