Assessment Report

Viamed Ltd

Report Author

Edward Collins

Visit Start Date

24/11/2011

Introduction

This report has been compiled by Edward Collins and relates to the assessment activity detailed below:

Visit ref/Type/Date/Duration	Certificate/Standard	Site address
7638671 Continuing Assessment (Surveillance) 24/11/2011 0.5 day(s) No. Employees: 14	FS 28344 ISO 9001:2008	Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom
7640177 Continuing Assessment (Surveillance) 24/11/2011 0.5 day(s) No. Employees: 14	CONTRACT 200483566 CE 01389 Healthcare 93/42/EEC Annex II, Section 3.2 CE MARKING John Howlett MD 78787 Healthcare ISO 13485: 2003 N/A Stewart Brain FM 540797 ISO 13485: 2003 CMDCAS CMDCAS Paul Brooks	Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of this assessment was to evaluate the continuing implementation of the clients management system as it includes ISO 9001, ISO13485 Part 1 of the Canadian Medical Device Regulations (GD210 will be used), the assessment requirements of 93/42/EEC Annex II 3.2, BSI Conditions of Contract and the companies own policies and procedures.

Management Summary

The objectives of the assessment were met. The management system continues to be effectively implemented. BSI Conditions of Contract and the companies own policies and procedures are effectively addressed by the management system. The client continues to implement ISO 13485 as it incorporates both the assessment requirements of 93/42/EEC Annex II 3.2 and Part 1 of the Canadian Medical Device Regulations.

There were no outstanding nonconformities to review from previous assessments.

No new nonconformities were identified during the assessment. Enhanced detail relating to the overall assessment findings is contained within subsequent sections of the report.

Areas Assessed & Findings

Overview and assessment rationale

The client has 3 management certificates with different expiry dates. A reassessment visit has been scheduled for Oct 2012 as the ISO 9001 certificate expires on the 28th Nov 2012 some two months before the MD and FM certificates.
The client has moved office premises into a new adjacent building, freeing up warehouse space. The impact on the management system is minimal as core processes and staff are unchanged. The focus of the business remains as a stockists, virtual manufacturer and small scale manufacture of legacy products.
There has been no change in the one Canadian licence held for one class 2 Microstim device. The scope for cmdcas remains appropriate for this product.

Core QA processes and objectives for quality and improvement

Internal audits: Audits are scheduled to the calendar year. Records show completion of the audit schedule where no issues were raised.
Management review: A rolling review is demonstrated on the integrated electronic management system with frequent reviews, typically monthly. These reviews include a review of key performance indicators that includes reported product faults, returns and service.
Complaints, corrective action and vigilance: No vigilance issues have been identified. A review of the complaints log showed no complaints which relate to the clients own products. Complaints, corrective action and vigilance procedures are unchanged with no recently completed corrective action forms.
Post market surveillance: Procedures identify a range of information sources and a rolling review is demonstrated as part of the integrated management system.
Preventive action: The top level manual and 8.5.3 gives a link to the analysis of data process. A proactive approach is demonstrated in the analysis of data and the statistical techniques used to predict trends.

Manufacture and testing of pulse oximeter probes

An overview of the manufacturing process was provided for the manufacture and testing of pulse oximeter probes. Production levels are relatively low utilising a small manufacturing cell. Environmental conditions were seen to be appropriate for the nature of the product being manufactured. Clear manufacturing information was available in the area in the form of engineering drawings. Clear final inspection and pass fail criteria is documented and calibrated simulators are available to test finished product to defined oxygen levels and pulse count. No complete manufacture was available at the time of the visit, however finished product was traced back to manufacturing records which demonstrated appropriate traceability and test status. Packaging, product labelling and instructions for use were seen to meet Annex 1 13.1. Technical files were also seen for this product with appropriate headings. A project is currently underway to review and transfer older legacy products, such as the pulse oximeter which have paper records into the integrated electronic management system. No issues were raised

During the course of the visit logos were found to be used incorrectly.

An older version of the logo is in use on letter heads and the client is asked to make use of the current version at the first opportunity.

Assessment Participants

On behalf of the organisation:

Name	Position
Mr Lamb	MD

The assessment was conducted on behalf of BSI by:

Name	Position
Edward Collins	Team leader

Continuing Assessment

The programme of continuing assessment is detailed below.

Site Address	Certificate Reference/Visit Cycle	
Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom	FS 28344	
	Visit interval:	12 months
	Visit duration:	3.5 hours
	Next re-certification:	01/11/2010

Site Address	Certificate Reference/Visit Cycle	
Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom	CONTRACT 200483566	
	Visit interval:	12 months
	Visit duration:	3.5 hours
	Next re-certification:	01/11/2010

Re-certification will be conducted on completion of the cycle, or sooner as required. An entire system re-assessment visit will be required.

Certification Assessment Plan

		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Business area/Location	Date (mm/yy):	11/09	11/10	10/11	10/12		
	Duration (days):	1	1	1	2		
Core QA processes - Including: The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, corrective action processes, and complaints.		✓	✓	✓	✓		
General objectives for quality and improvement		✓	✓	✓	✓		
Discussion with Top Management		✓			✓		
Strategic Review of MD and 9001 certificates		✓					
Scheme requirements for vigilance and feedback		✓	✓	✓	✓		
Manufacture and test:			✓	✓	✓		

Tom Thumb resuscitator		✓				
Head boxes and phototherapy shields		✓				
Pulse oximeter probes			✓			
Nerve stimulators				✓		
Sales and order processing				✓		
Design				✓		
Purchasing and supplier controls				✓		
Reassessment visit				✓		
.						
Technical visits are to be carried out by a technical expert to a separate schedule						

Next Visit Plan

Visit objectives:

To carry out a two day reassessment visit in line with the next visit and strategic plans

Visit scope:

ISO 9001
ISO 13485 as it incorporates part 1 of the Canadian Medical Device Regulations
GD210
93/42/EEC Annex II 3.2
BSi contract terms
The clients own documented management system

Date	Assessor	Time	Area/Process	Clause
		09.00	Opening Meeting – review of changes since the previous assessment visit – changes to quality system, product range or key processes.	
		09.15	Review of visits carried out since the previous certification decision.	
		10.00	QA, incorporating a discussion with Top Management – including objectives for quality and improvement The use of BSI and UKAS logos, internal audits, management review, corrective action, preventive action, complaints, customer satisfaction, vigilance and post market surveillance.	
		12.00	Lunch	

		13.00	Design	
		14.00	Material control and purchasing	
		15.30	Report preparation	
		16.00	Closing meeting	
		09.00	Virtual manufacture - nerve stimulator	
		10.30	Sales and order processing	
		11.00	Canada specific requirements Document control and quality records	
		12.00	Lunch	
		13.00	Competence requirements	
		13.30	Technical files	
		14.30	Contingency for any audit trails or items not covered in the review period.	
		15.30	Report preparation	
		16.00	Closing meeting	
			Full report to follow	

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the organisation within 30 days of an agreed visit date. It is a condition of Registration that a deputy management representative be nominated. It is expected that the deputy would stand in should the management representative find themselves unavailable to attend an agreed visit within 30 days of its conduct.

Notes

The assessment was based on sampling and therefore nonconformities may exist which have not been identified.

If you wish to distribute copies of this report external to your organisation, then all pages must be included.

BSI, its staff and agents shall keep confidential all information relating to your organisation and shall not disclose any such information to any third party, except that in the public domain or required by law or relevant accreditation bodies. BSI staff, agents and accreditation bodies have signed individual confidentiality undertakings and will only receive confidential information on a 'need to know' basis.

'Just for Customers' is the website that we are pleased to offer our clients, designed to support you in maximising the benefits of your BSI registration - please go to www.bsi-emea.com/JustForCustomers to register. When registering for the first time you will need your client reference number and your certificate number (43207441/CE 01389).

The Carbon Dioxide emissions due to the planning, delivery and administration of this assessment will be fully off-set through the BSI CarbonNeutral® project. For more information on CarbonNeutral® please visit www.bsigroup.co.uk/en/Assessment-and-Certification-services/Management-systems/News-and-Events/Carbon-Neutral.

This report and related documents (“Report”) is prepared for and only for BSI’s client and for no other purpose. As such, BSI does not accept or assume any responsibility (legal or otherwise) or accept any liability for or in connection with any other purpose for which the Report may be used, or to any other person to whom the Report is shown or in to whose hands it may come, and no other persons shall be entitled to rely on the Report.

Should you wish to speak with BSI in relation to your registration, please contact our Operations Support Team:

Customer Services
BSI
PO Box 9000
Milton Keynes
MK14 6WT

Tel: +44 (0)845 080 9000 Fax: +44 (0)1908 228123