Assessment Report

Viamed Ltd

Report Author

Edward Collins

Visit Start Date

08/11/2010

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
7260526 Continuing Assessment (Surveillance) 08/11/2010 0.5 day(s) No. Employees: 14	FS 28344 ISO 9001:2008	Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom
7265281 Continuing Assessment (Surveillance) 08/11/2010 0.5 day(s) No. Employees: 14	CONTRACT 200483566 CE 01389 93/42/EEC Annex II, Section 3.2 CE MARKING MD 78787 + FM 540797 ISO 13485: 2003 CMDCAS	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, including BSI Conditions of Contract and the companies own policies and procedures, to verify that the client continues to implement all requirements of ISO13485 as it incorporates Part 1 of the Canadian Medical Device Regulations (GD210 will be used), ISO 9001 and to verify that the management system continues to meet the assessment requirements of 93/42/EEC Annex II 3.2

Management Summary

The areas assessed during the course of the visit were found to be effective 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 clients capacity to systematically meet agreed requirements for products and services supplied within the scope of the certificates is confirmed and continues to meet the requirements of ISO13485: 2003 as it incorporates Part 1 of the Canadian Medical Device Regulations and the assessment requirements of BSi as a Notified Body in respect of 93/42/EEC Annex II 3.2

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 a wide range of legacy products, however manufacture is a small part of the companies overall processes. Most sales are for product either as a virtual manufacturer or under own brand labelling certificates.
The client has one licence for product sold into Canada and the clients licence remains unchanged and represents current sales activity in Canada. The scopes of current certificates remain appropriate and relevant.
The clients technical visit is now overdue.
Management certificates have different expiry dates. As part of a strategy to provide one reassessment visit for all management certificates in Nov 2012 a strategic review will be carried out at the next visit for the clients ISO 9001 certificate.

Core QA processes

Internal audit: Audits are scheduled to a rolling 12 month plan and includes regulatory requirements. Actions are up to date with no overdue actions.
Management review: A rolling management review is demonstrated to 5.6
Post market surveillance: Procedures document a process utilising 14 sources of information aimed at providing early warning of any post production problems. Review of this data is demonstrated as part of the management review process.
Complaints and vigilance: No complaints have been logged since the previous visit and no incidents have been reported.

Head boxes and phototherapy light shields

These mechanical products have no moving parts and are manufactured from existing stocks of sheet material by outsourced suppliers. Existing stocks of product manufactured in the last year were traced back to manufacturing, purchasing and technical documents. Technical files are seen to follow current meddev guidance. Purchasing documents and manufacturing drawings detail the materials and construction, including manufacturing tolerances. No instructions are considered necessary. Product marking is seen to follow Annex 1 13 with serial numbers traceable to the year of manufacture.

Tom Thumb resuscitator

Items from recent stock were examined for product marking, instructions for use and manufacturing information. Records showed traceability of key components, clear manufacturing and test criteria and testing using equipment calibrated to traceable national standards. The build standard includes specified oxygen friendly lubricant. Technical documentation is seen to follow recognised meddev guidance. Product marking and instructions for use are seen to meet Annex 1 13 and instructions for use carry issue status.

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:	01/11/2011

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:	01/11/2012

Re-certification by Strategic Review will be conducted on completion of the cycle, or sooner as required. The review will focus on the strengths and weaknesses of your Management System.

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	11/12		
	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		✓	✓	✓	✓		
Completion of CE checklist PCA 92		✓			✓		
Completion of Canadian checklist A699					✓		
Sales and order processing					✓		
Design					✓		
Manufacture and testing			✓	✓	✓		
Purchasing and supplier controls					✓		
Reassessment visit					✓		
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Annex II technical visits to be carried out by a technical expert every two years and is now overdue.							

Next Visit Plan

Visit objectives:

To carry out a continuing assessment in line with the next visit and strategic plans and to carry out a reassessment by strategic review in respect of ISO 9001.

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
Oct 2011	To be confirmed	09.00	Opening Meeting – review of changes since the previous assessment visit – changes to quality system, product range or key processes.	
		09.15	Strategic review to ISO 9001(part A) review of strategic review pack and visits carried out since the previous ISO 9001 certification decision.	
		10.00	Discussion with top management	
		10.30	QA – including objectives for quality and improvement The use of BSI and UKAS logos, internal audits, management review, corrective action, preventive action, complaints, vigilance and post market surveillance.	
		12.00	Lunch	
		13.00	Manufacture and testing of medical devices, including the role as a virtual manufacturer with audit trails to purchasing, competence, calibration, quality and technical records as appropriate.	
		14.30	Strategic review (ISO 9001) part B All aspect of the management system as it is seen to deliver stated objectives	
		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.

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Appendices

This visit includes 1hr offsite planning and reporting activity