Assessment Report

Viamed Ltd

Report Author

Edward Collins

Visit Start Date

16/09/2008

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
7084282 Continuing assessment 16/09/2008 0.5 day(s) No. Employees: 7	FS 28344 BS EN ISO 9001:2000	Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom
7093219 Continuing assessment 16/09/2008 0.5 day(s) No. Employees: 7	CONTRACT 200483566 CE 01389 ISO 13485: 2003 93/42/EEC, Annex II, Section 3.2 CE MARKING John Howlett FM 75994 XX ISO 13485: 1996 MD 78787 ISO 13485: 2003 N/A Stewart Brain	Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of the assessment is to carry out the fourth continuing assessment visit in the current cycle, to the above standards and certificates. To also confirm the ability of the quality system to meet Notified Body requirements and to sample from core QA, design, goods receiving and purchasing processes.

Management Summary

The areas assessed during the course of the visit were found to be effective and the sample gave confidence that the management system continues to meet the requirements of BSi as a Notified Body.

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

Core QA processes

Management Review: This is carried out as a rolling review using the electronic management system. A systematic review is demonstrated to the requirements of 5.6
Internal Audit: Audits are up to date with the schedule with no overdue actions. Audits are seen to cover 13485 and regulatory aspects, such as risk assessment and post market surveillance.
Feedback/Post Market Surveillance: This is seen to follow a documented and systematic review process.
Complaints and corrective action: Complaints are low and relate to cosmetic issues. Nothing in the complains system relates to the safe operation of devices.
Observation: Whilst the review process can be demonstrated by operational steps in the management system there could be more evidence documented showing a rationale behind the decision making process. e.g. post market surveillance and customer satisfaction

Design

There has been no design activity for a few years. Procedures are seen to be maintained and to cover the requirements of 13485, including risk management.

Goods receiving and purchasing control

Mr Lamb provided an overview of the processes in place for receiving items and for providing material traceability and for the purchasing and supplier review process. Samples were then taken from existing stocks of bought in instruments and components for manufacture. All purchase orders were seen to accurately describe the items being purchased and were all from approved suppliers and the process was seen to be as outlined by Mr Lamb and as documented in procedures.

Assessment Participants

On behalf of the organisation:

Name	Position
Mr Derek 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:	6 months
	Visit duration:	3.5 hours
	Next re-certification:	01/09/2009

Site Address	Certificate Reference/Visit Cycle	
Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom	CONTRACT 200483566	
	Visit interval:	6 months
	Visit duration:	3.5 hours
	Next re-certification:	Not applicable

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.

Certification Assessment Plan

		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Business area/Location	Date (mm/yy):	08/09					
	Duration (days):						
extension to scope		✓					
The strategic plan will be reassessesed at the next visit to take a/c of all schemes and the need for a reassessment visit for Health Canada							

Next Visit Plan

Visit objectives:

To carry out an extension to scope visit to include Health Canada requirements - Proposed scope "The design and manufacture of nerve stimulators, resuscitators, oxygen monitors, pulse oximeter probes, temperature probes, breathing monitors, headboxes and UV light shields"

Visit scope:

ISO 13485 (as it includes Canadian MDR)
Scheme requirements GCP358 for Canada
BSI contract terms
The clients own documented management system

Date	Assessor	Time	Area/Process	Clause
To be confirmed	Edward Collins (tbc)	09.00	Opening Meeting – review of changes since the previous assessment visit.	
		09.15	Extension to scope covering the additional requirements for CANDICAS/Health Canada as it is incoprorated into the clients own ISO13485 quality management system.	
			Completion of A699 checklist, including - Design and manufacture of products intended for sale in Canada	
			Report preparation	
			Closing meeting	

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 (0009370214/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.

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

BSI Product Services
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

Tel: 08450 765600 Fax: 08450 765601