

Assessment Report



Organisation Viamed Ltd
Report Author Edward Collins
Visit Start Date 21/08/2007

BSI
Management
Systems

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
4866504 Continuing assessment 21/08/2007 0.5 day(s)	FS 28344 BS EN ISO 9001:2000	Viamed Ltd 15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT United Kingdom
7020529 Continuing assessment 21/08/2007 0.5 day(s)	CONTRACT 200483566 CE 01389 ISO 13485: 2003 93/42/EEC, Annex II, Section 3.2 CE MARKING John Howlett FM 75994 ISO 13485: 1996 MD 78787 ISO 13485: 2003 N/A Stewart Brain	Viamed Ltd 15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT United Kingdom

The objective of the assessment is to carry out the second continuing assessment visit in the strategic plan sampling from core QA process and the manufacture and testing of devices to the above certificates and standards.

Management Summary

The areas assessed during the course of the visit were generally found to be effective.

There were no outstanding issues/nonconformities to review from previous assessments.

No new issues or 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 objectives for quality and improvement

These are stated to be to deliver safe and reliable product, promptly in full. The current quality policy is currently under revision and it is anticipated that a new quality policy and objectives will be documented before the next visit.

Core QA processes

Management review: This is not a fixed event but an ongoing review of system elements driven by the software management system. The system is fully traceable and has operational steps to show that the review has taken place. The system is geared towards generating corrective actions from the review. There could be value in ensuring/documenting a rationale behind the decision making process which ensures that objectives have been met.

Post Market Surveillance/Feedback: Data was presented from the management system which demonstrated an ongoing review of information available in the post production phase. To assist in differentiating between 9001 (customer satisfaction) and the regulatory requirements of 13485 there could be value in reviewing the software tabs to give separate review information.

Complaints: One complaint has been received since the last visit which on investigation was found not to be valid.

Microstim DB3

A sample of the above product was taken from stock and was satisfactorily trailed back to the technical documentation, manufacturing and test and the legal contract with the sub contract manufacture. The technical documentation has all the recommended headings, including a general description, declaration of conformity, classification rationale, risk analysis, essential requirements checklist, labelling and marking, instructions for use, bill of materials and the 100% final testing procedure.

The legal document was drawn up when the intention was to carry out a 100% final inspection at Cross Hills. The sub contractor now carries out this testing and only a sample from the batch is tested. There could be a clearer link between the legal document and the technical documentation which defines the testing to be carried out.

Assessment Participants

The assessment was conducted on behalf of BSI by:

Name	Role
Edward Collins	Team leader

... and on behalf of the organisation:

Name	Position
Mr Derek Lamb	IT
Mr John Lamb	Dir

Continuing Assessment

BSI believes in a partnership approach that provides added value service. It is on this basis that we propose a programme of continuing assessment as detailed below.

Site Address	Certificate Reference/Visit Cycle
Viamed Ltd 15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT United Kingdom	FS 28344
	Visit interval: 6 months
	Visit duration: 3.5 hours
	Next re-certification: Not applicable

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

Next Visit Plan

Visit objectives:

To carry out the third continuing assessment visit in the assessment cycle in line with the next visit and strategic plans.

Visit scope:

ISO 9001

ISO 13485

MDD 93/42/EEC annex II

BSI contract terms and scheme protocol

The clients own documented management system

Date	Assessor	Time	Area/Process	Clause
17/03/2008	Edward Collins	09.00	Opening Meeting – review of changes since the previous assessment visit.	
		09.15	QA – including the effectiveness of the quality management system with regard to achieving the organization's objectives. Progress on planned activities aimed at continual improvement of system performance. The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, corrective action processes and complaints.	
		10.00	Design	
		12.00	Lunch	
		13.00	goods receiving and purchasing	
		15.00	Report preparation	
		16.00	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 issues 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.

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The CO2 emissions due to the planning, delivery and administration of this assessment have been fully offset through the BSI CarbonNeutral® project. For more information on CarbonNeutral® please visit www.bsi-uk.com/carbonneutral.

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

Team:

BSI Management Systems UK
PO Box 9000
Milton Keynes
MK14 6WT

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

Appendices

Plan of Assessment up to and including the next Review

Planned Month Duration	03/07 1 Day	09/07 1 Day	03/08 1 Day	09/08 1 Day	03/09 1 Day	09/09 1 Day
Business Activity						
Electronic Product Design, Purchase, Manufacture and Distribution - Nerve Stimulators, oxygen monitors, pulse oximetry devices, temperature probes, APGAR timer and breathing monitors		P		P		
Cots and Cabinet Product Design, supply, manufacture and Distribution - Headboxes, oxygen tents and phototherapy light shields	P					
Gas Delivery Devices Design, Purchase, Manufacture and Distribution - Resuscitators, respiratory valves and respiratory adaptors.			P		P	
Service and Repair				P		
Sales and Administration				P		
Goods receiving and purchasing			P			
Management Review of Performance against Objectives and Policy	P	P	P	P	P	P
Complaints and Notifications	P	P	P	P	P	P
Action Management – Corrective/Preventive Action	P	P	P	P	P	P
Internal Audits	P	P	P	P	P	P
Strategic Review						P

Plan subject to change as circumstance demand.

Terminology changes:

The client is advised that the terminology relating to issues and nonconformities will, on the 1st Jan 2008, revert to the previous terminology of nonconformity and major nonconformity.