

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
7011634 Continuing assessment 18/04/2008 0.5 day(s)	FS 28344 BS EN ISO 9001:2000	Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom
7020530 Continuing assessment 18/04/2008 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 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 third, one day continuing assessment visit in the current assessment cycle to the above standards and certificates sampling from core QA processes, design and gas delivery products

Management Summary

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

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 not a fixed event but an ongoing review of system elements driven by the software management system. Management Review is demonstrated to have taken place consistent with the requirements of 5.6

Post Market Surveillance/Feedback: Data was presented from the management system which demonstrated an ongoing review of information available in the post production phase.

Complaints: No complaints relate the clients own CE marked product and all have been investigated to any underlying root cause.

Internal Audit: These are up to date with the plan with no outstanding actions

Design

There has been no new and original design for some time and no design change activity since 2005. Design Procedures remain in place

Technical files - Tom Thumb product

Completed product was taken from stock and trailed back to the relevant technical information.

The technical files were seen to contain relevant headings and included clinical data, classification rationale, declaration of conformity and listings of normalised standards.

Goods receiving and purchasing

Mr Lamb provided an overview of the purchasing and materials management processes. Samples were then taken from items in stock and traced to purchasing documents and supplier review information. The computer software process provides a fully traceable process to incoming material. All suppliers in the sample were seen to be approved as outlined and as documented in procedures. Whilst all purchase orders described the items being purchased, some of the purchase orders had general descriptions. E.g. PO5446 for a plastic light shield did not specify the plastic material to be used which had specific filtering properties and PO 5914 for pressure gauges referred to Tom Thumb rather than a unique code or unambiguous description.

Assessment Participants

On behalf of the organisation:

Name	Position
Mr Derek Lamb	IT

The assessment was conducted on behalf of BSI by:

Name	Role
Edward Collins	Team leader

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 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

Next Visit Plan

Visit objectives:

To carry out the fourth 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 (MPD 240)

The clients own documented management system

Date	Assessor	Time	Area/Process	Clause
16/09/2008	Edward Collins	09.00	Opening Meeting – review of changes since the previous assessment visit.	
		09.15	QA – including objectives for quality and improvement. The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, vigilance, post market surveillance, corrective action processes and complaints.	
		11.00	Sales and order processing	
		12.00	Lunch	
		13.00	* Electrical product design and manufacture	
		15.00	Report preparation	
		16.00	Closing meeting	
			* The client has a diverse product range which may not be in manufacture at the time of the visit, in which case records will be examined from recent production	

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.

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'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 CO2 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.bsi-uk.com/carbonneutral.

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

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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
<i>Business Activity</i>						
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