Assessment Report

Viamed Ltd

Report Author

Edward Collins

Visit Start Date

21/10/2008

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
7247777 Initial assessment 21/10/2008 1 day(s) No. Employees: 14	FM 540797 CMDCAS CMDCAS Paul Brooks	Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of the assessment was to conduct an extension to scope certification assessment to ISO 13485 as it includes requirements of Part 1 of the Canadian Medical Device Regulation and GD 210, for products intended for sale into Canada.

Proposed scope of registration FM 540797 ()

Location	Scope
Viamed Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom	The design and manufacture of supramaximal nerve stimulators and infant resuscitators

Management Summary

We are pleased to recommend that the scope of activities detailed in this report meet registration requirements. The recommendation will be independently verified within BSI. Upon verification your certificate of registration will be issued.

The areas assessed during the course of the visit were generally found to be effective and the audit sample gave confidence that the clients documented ISO 13485 quality management system meets the requirements of products intended for sale into Canada.

There were no outstanding nonconformities to review from previous assessments.

4 minor nonconformities requiring attention were identified. These, along with other findings, are contained within subsequent sections of the report.

A minor nonconformity relates to a single identified lapse, which in itself would not indicate a breakdown in the management system's ability to effectively control the processes for which it was intended. It is necessary to investigate the underlying cause of any issue to determine corrective action. The proposed action will be reviewed for effective implementation at the next assessment.

Please submit a plan to BSI detailing the nonconformity, the cause and your proposed corrective action, with responsibilities and timescales allocated. The plan is to be submitted no later than 04/11/2008 by e-mail to msuk.caps@bsigroup.com or by fax to +44 (0)1908 228123, referencing the report number.

Areas Assessed & Findings

Audit rationale

The client has existing and established products for which licences are sought to sell into Canada. These products have CE licences and are covered by a European 9001 and 13485 certificates. Irrespective of classification, design has not been excluded from these management certificates. This visit therefore concentrates on the additional requirements for Canada and the proposed scope "The design and manufacture of supramaximal nerve stimulators and infant resuscitators" These devices are socially clean and do not require sterilisation. The manufacture of nerve stimulators is outsourced.

Core QA requirements

With the exceptions noted in the minor nonconformities the clients documented arrangements for vigilance and recall are seen to incorporate requirements for Canada.
Technical documentation for products in the proposed scope were seen and these were seen to have been reviewed for Canadian requirements, including classification rationale and risk management activity.
Requirements to inform Canada and BSi of significant changes are incorporated into the management system for both product and management system changes.
The requirement for annual obligation to inform by the 1st Nov each year is also incorporated into the management system.

Outsource control

Mr Lamb provided an overview of the outsourcing arrangements in place for the manufacture of nerve stimulators. One batch has been manufactured some time ago which was delivered with certificates of conformity detailing the 100% final electrical function testing carried out. This testing is repeated on a sample quantity to a closely defined inspection and test procedure using a calibrated oscilloscope. Outsourcing control includes supplier audit and formal contract specifying arrangements for inspection, test and certification of manufactured product.
Observation: Existing arrangements were based on a re launched product in a new enclosure with close day to day contact with the manufacturer. This was some time ago and these arrangements need reviewing when the stock has been depleted to ensure that they remain appropriate

Minor Nonconformities Arising from this Assessment

Ref	Area/Process	Clause
A225496/1	Medical Device Licence Amendment	7.3.7
Details:	Whilst procedures require changes to be notified they are not specific and do not mirror the specific requirements of 34 of the MDR	

Ref	Area/Process	Clause
A225496/2	Problem reporting and advising the Minister	8.5.1
Details:	Whilst supplier agreements exist between the manufacturer and the distributor in Canada detailing the responsibility for recall in Canada these are not specific in respect of the requirements of mandatory problem reporting to the Minister in the event of a recall (59 to 61 of the MDR)	

Ref	Area/Process	Clause
A225496/3	Quality records	4.2.4
Details:	Whilst the client in the UK retains records indefinitely and longer than the predicted life of the product, arrangements in Canada are not specified (55 of the MDR)	

Ref	Area/Process	Clause
A225496/4	Labelling and marking	7.5.3.1
Details:	As the instructions for use are only available in English it is not clear how this would be made available in French without any undue delay should it be requested (21 to 23 of the MDR)	

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

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	11/11			
	Duration (days):	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				✓			

Next Visit Plan

Visit objectives:

To carry out the first continuing assessment visit in the revised strategic plan

Visit scope:

ISO 9001, ISO 13485 (as it incorporates Part 1 of the Canadian Medical Device Regulation and GD 210, for products sold into Canada), 93/42 EEC 3.2 annex II, Scheme requirements MPD 240 and GCP358 for Europe and Canada, BSI contract terms
The clients own documented management system

Date	Assessor	Time	Area/Process	Clause
Nov 2009	To be confirmed	09.00	Opening Meeting – review of changes since the previous assessment visit – changes to quality system, product range or key processes. Review of product licences held for Canada	
		09.15	Part A of strategic review: Assessment progress against the strategic assessment plan, assessment findings over the certification cycle, progress in relation to management system objectives, completion of the 3-year plan, trends in nonconformities.	
		10.00	QA – including objectives for quality and improvement The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, corrective action, complaints, vigilance and post market surveillance. Close out of any outstanding nonconformities/issues raised at previous visits.	
		12.30	Lunch	
		13.30	Completion of PCA 92 CE marking checklist	
		14.30	Strategic review part B: Management commitment (stakeholder focus, management system policy, objectives, organisation, communication), the effectiveness of the inter-action of all elements of the system, the effectiveness of the management system in the light of internal or external changes and continued compliance.	
		15.30	Report preparation	
		16.30	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.

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

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