Assessment Report.

Viamed Ltd

Report Author **Edward Collins**

Visit Start Date 06/10/2014

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
8042456 Continuing Assessment (Surveillance) 06/10/2014 1 day(s) No. Employees: 17	CE 01389 Healthcare 93/42/EEC Annex II, Sec 3.2 (2007/47) CE MARKING Richard Tully MD 78787 ISO 13485:2003 FM 540797 ISO 13485:2003 CMDCAS FS 28344 + FM 607767 ISO 9001:2008	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of this assessment was to:
To conduct a surveillance assessment to determine the continued effective implementation of the company's management system, in accordance with the company objectives, the management standards, BSI Conditions of Contract and to determine whether a recommendation for continuing certification can be made.

To verify Viamed Ltd continues to effectively implement all requirements of ISO9001:2008.

To verify Viamed Ltd (Company ID 128822) continues to implement all requirements of ISO13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations. GD210 will be used.
To determine if the management system continues to meet the requirements of 93/42/EEC Annex II 3.2

Management Summary.

Overall Conclusion

The objectives of the assessment were met.

The management system continues to be effectively implemented, addresses the proposed scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract . The result of this assessment enable and confirm a recommendation for continued certification

Viamed Ltd continues to effectively implement all requirements of ISO9001:2008.
Viamed Ltd's capacity to systematically meet agreed requirements for products and services supplied within the scope of the certificates is confirmed and they meet the requirements of ISO13485: 2003 and Part 1 of the Canadian Medical Device Regulations.
The management system continues to meet the requirements of 93/42/EEC Annex II 3.2

Obstacles, Omissions and Reliability:
There were no obstacles encountered during the course of the audit. No factors were encountered during the audit that would affect the reliability of this assessment.

Areas Not Audited:
All areas were covered per the assessment plan.

Identification and Dating:

Audit report authors are as per the assessment team listed. The report was finalised and issued on the 12th Oct 2014.

This report is eligible for submission to FDA under FDA ISO 13485 Voluntary Audit Report Submission Program.

Corrective actions with respect to nonconformities raised at the last assessment have been reviewed and found to be effectively implemented.

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.

Opening Meeting and Changes: 4.1, 4.2

The opening meeting was conducted with the presence of the MD.

The assessment plan, objectives and scope of the assessment were confirmed.

The opening meeting and full assessment was performed in English.

Audit Scope:
This visit will cover the location activities for the management system processes at the 15/17 Station Road, (adjacent premises) Cross Hills, Keighley, BD20 7DT address being audited in the UK.

Scope of Certification:
The registration certificates and scope of the registration were confirmed as follows:
FS The design, manufacture, service, repair, maintenance and supply of medical monitoring, ventilation and anaesthetic equipment including that carried out on customer premises.

CE 01389 - The design and manufacture of microstim nerve stimulators, pulse oximeter probes,oxygen hoods, gas respiratory adapters, gas respiratory valves and phototherapy light shields

MD 78787 - The design, outsource manufacture, manufacture and service (including that carried out on customer premises of nerve stimulators and nerve locators, resuscitators, monitoring devices for physiological parameters including accessories) of the following: Apgar timer; Gas Exchange monitors; Oxygen monitors; Oxygen Sensors; Pulse Oximeters; Pulse Oximetry sensors and cables; Temperature monitors; Temperature probes and cables including Temperature probes in catheters ; Cot lids; Gas respiratory adaptors; Gas respiratory valves; Heat shields; Nerve locators; Nerve stimulators; Oxygen hoods and tents ; Phototherapy light shields; Resusitators; Ventilation tube holders; Simulation, Test and Calibration Equipment for monitoring devices.

FM 540797- The design and manufacture of supramaximal nerve stimulators and infant resuscitators.

FM 607767 - The design, development and supply of gas sensors and associated systems.

Quality Manual version:

Electronic, document number 14445/2014

Exclusions and Non-Applications of Requirements in the QMS:
No exclusions are claimed. Requirements for active implantable and sterility are not applicable due to the nature of the products.

Significant Changes:
There have not been any major or significant changes to the QMS, structure, or device since the last visit.

Adverse Incidents, Field Safety Corrective Actions and Recalls:
There have been no adverse incidents, recalls, or requirement for field safety corrective actions or (vigilance/mandatory problem reports) since the last report.

Corporate Identity of the Manufacturer:
Viamed is a family business designing, manufacturing and distributing a range of medical devices. VST also operates from the same premises as a separate company utilising common resources. For commercial reasons VST has its own ISO 9001 certificate.

Description of the manufacturer:
Viamed distribute a range of medical devices in a world market. Some devices are sold under OBL agreements. The manufacture of some devices is outsourced. Some small scale manufacture takes place of legacy products. Processes include QA, design, manufacture, purchasing, sales, warehousing and distribution.

Critical Subcontractors:
Blue Point Medical GmbH & Co. KG, An der Trave 15, 23923 Selmsdorf, Germany for the manufacture of instrumentation

Instrumentation Industries (Manufacture)

Senior Management of the Assessment Location(s).
Mr D Lamb – MD/CEO

Dates of the Audit:

6th October 2014

Quality Management System – Core QA Processes: 5.6, 8.2.2, 8.5.2, 8.5.3

Management review: A rolling 3 monthly review covers all aspects of the management system within a 12 month period. The last review in July by the MD shows a multi point agenda from the electronic management system covering the requirements of 5.6 including regulatory changes and post market surveillance.

Internal audits: The audit plan is up to date with the schedule with no overdue actions. Two auditors are used to ensure objectivity

Complaints, capa and vigilance: Samples from the complaints and capa log were seen entries since the previous visit. No complaints have been received relating to medical devices. One complaint has recently been received for VST product which is in the early stages of investigation and there have been no vigilance issues. The capa/ncr log showed only minor issues with appropriate investigation to cause.

Core QA processes were seen to be effective and to follow documented procedures

Manufacture of Tom Thumb resuscitator and light shields: 4.1, 4.2, 6.2, 6.3, 6.4, 7.1, 7.5, 7.6, 8.2.3, 8.2.4, 8.3

As no manufacturing was taking place at the time of the visit, samples were taken from stock which included light shields and a Tom Thumb resuscitator. The manufacture and test process for the Tom Thumb was demonstrated in the manufacturing area where component parts were also available. The manufacturing process was documented in VM3COP50.05 and QA form document number 440159 recorded the performance characteristics of the valve and overpressure safety valve. Fombolin grease, specific for use in oxygen rich atmospheres was seen in the area and specified in the manufacturing procedure. All components seen in the manufacturing area had clear status with batch numbers. Manufacturing records showed full component traceability. Control is seen to include marking and instructions for use. Product marking and labelling was seen to meet annex 1 13. Competence records confirmed appropriate skills for those documented as completing the manufacture and testing of tom thumb product. Calibration records confirmed appropriate calibration of the manometer used to verify product performance. The manufacturing environment was appropriate for product sold socially clean. Testing of product uses medical grade gasses.

The light shield taken from stock was seen to have appropriate labelling and marking. Audit trails to the purchase of fabricated items showed communication of appropriate information with the key material supplier detailing the characteristics and dimensions of the product. A technical data sheet 14394 details the key uv blocking characteristics of the product. Document 9064 details the QA packing and checking procedures for light shields and includes labelling and marking instructions. Instructions for use leaflet 0490049 details cleaning and disinfecting of the product.

The manufacture and testing process for Tom Thumb and light shields was seen to be effective.

During the course of the visit logos were found to be used correctly.

Minor Nonconformities Raised at Last Assessment.

Ref	Area/Process	Clause
977894N0	Product realisation	4.2.1
Scope	MD 78787	
Details:	Technical File wyas not fully updated	
Requirements:	For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing. NOTE 1 The extent of the quality management system documentation can differ from one organization to another due to a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. NOTE 2 The documentation can be in any form or type of medium.	
Objective Evidence:	French Version of the Instruction for Use for the Tom Thumb product was not available during the review of the Technical File. Additionally an obsolite Standard BS EN 980 was referenced in the essential requirements list as part of the technical file.	
Actions:	Technical files have been amended	
Closed?:	Yes	

Assessment Participants.

On behalf of the organisation:

Name	Position
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 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom	Contract 200483566	
	Visit interval:	12 months
	Visit duration:	1 Days
	Next re-certification:	01/10/2015

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.

VIAMED-0009370214-000|Contract 200483566

		Visit1	Visit2	Visit3	Visit4	Visit5	Visit6
Business area/Location	**Date (mm/yy):**	10/13	10/14	10/15			
	Duration (days):	1.0	1.0	2.0	0.0	0.0	0.0
Core QA processes – Including: The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, corrective action processes, and complaints.		X	X	X			
Design				X			
Discussion with Top Management		X		X			
General objectives for quality and improvement		X	X	X			
Head boxes and phototherapy shields			X				
Manufacture and test:			X	X			
Nerve stimulators				X			
Pulse oximeter probes				X			
Purchasing and supplier controls				X			
Reassessment visit				X			
Sales and order processing				X			
Scheme requirements for vigilance and feedback		X	X	X			
Strategic Review of MD and 9001 certificates		X					
Tom Thumb resuscitator			X				
Document control and quality records				X			
.							
Technical visits are to be carried out by a technical expert to a separate schedule				X			

Next Visit Plan.

Visit objectives:

To conduct a recertification assessment to determine the effective implementation of elements of the QMS applicable within the proposed scope of registration are in accordance with the company objectives, applicable requirements of the management standards & BSI Conditions of Contract and to determine whether a re-certification recommendation can be made.

To verify Viamed Ltd continues to effectively implement all requirements of ISO9001:2008.

To verify Viamed Ltd (Company ID 128822) continues to implement all requirements of ISO13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations. GD210 will be used.
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Audit Scope:
This visit will cover the location activities for the management system processes at the 15/17 Station Road (adjacent premises), Cross Hills, Keighley, BD20 7DT address being audited in the UK.

Date	Assessor	Time	Area/Process	Clause
Oct 2015 Day 1	To be advised	09.00	Opening Meeting – review of changes since the previous assessment visit – changes to quality system, product range or key processes.	
		09.15	Review of strategic review pack and visits carried out since the previous certification decision.	
		10.00	Discussion with top management	5.1
		10.30	QA – including objectives for quality and improvement The use of BSI and UKAS logos, internal audits, management review, corrective action, complaints, customer satisfaction, vigilance, recall and post market surveillance.	5.4.1, 8.2.2, 5.6, 5.4.2, 8.5.2, 8.5.3, 8.5.1, 8.2.1
		12.30	Lunch	
		13.00	Virtual manufacture of nerve stimulators	4.1, 4.2, 6.2, 6.3, 6.4, 7.1, 7.5, 7.6, 8.2.3, 8.2.4, 8.3
		15.00	Document control and quality records	4.2.3, 4.2.4
		16.00	end of day wash up meeting	
		16.30	Leave site	

Day 2		09.00	Sales and order processing	7.2
		10.00	Design	7.3
		11.15	Purchasing and supplier review	7.4
		12.30	Lunch	
		13.00	Technical files – nerve stimulators	4.2
		14.00	Canadian specific requirements	
		15.00	Report preparation	
		16.00	Closing meeting	
		16.30	Leave site	

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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Customer Services
BSI
Kitemark Court,
Davy Avenue, Knowlhill
Milton Keynes
MK5 8PP

Tel: +44 (0)845 080 9000 Fax +44 (0)1908 228123
Email: MK.Customerservices@bsigroup.com