Assessment Report.

Viamed Limited

Report Author **John McGowan**

Visit Start Date 07/10/2013

Introduction.

This report has been compiled by John McGowan and relates to the assessment activity detailed below:

Visit ref/Type/Date/Duration	Certificate/Standard	Site address
7882179 Continuing Assessment (Surveillance) 07/10/2013 0.5 day(s) No. Employees: 17	FS 28344 ISO 9001:2008	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom
7885651 Continuing Assessment (Surveillance) 08/10/2013 0.5 day(s) No. Employees: 17	CE 01389 Healthcare 93/42/EEC Annex II, Section 3.2 CE MARKING Richard Tully MD 78787 ISO 13485: 2003 ISO 13485: 2003 N/A Richard Tully FM 540797 ISO 13485: 2003 CMDCAS CMDCAS Richard Tully	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of the assessment was to conduct a surveillance of the existing certification to ensure that all elements of the proposed scope of registration and the entire requirements of the management standard are effectively addressed by the organisation's management system.
If this visit is part of a multi-location assessment, the final recommendation will be contingent on the findings from all assessments.
To evaluate the continuing implementation including the effectiveness of the management system, including BSI Conditions of Contract and the companies own policies and procedures (FS28344 - ISO9001:2008 certification)
Continues to implement all requirements of ISO13485:2003 (MD78787 - ISO13485 certification)
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. (FM540797 - CMDCAS certification)
To verify that the management system continues to meet the requirements of 93/42/EEC Annex II 3.2 (CE01389 - CE marking certification)

…….Visit Plan……..
This visit will cover the location activities for the management system processes listed in the schedule below at the main location as documented in this plan and reviewed with the client representative and BSi Scheme Manager Richard Tully.
- QMS – including objectives for quality and improvement The use of BSI and UKAS logos, management review, audits, improvements, preventive action, corrective action, customer feedback, complaints, vigilance and post market surveillance.
Regulatory requirements – Medical device MDR
- Product - processes including device history records, validation, training, maintenance and calibration,
- Prepare report and complete BSi regulatory checklist

Management Summary.

Overall Conclusion

Overall Conclusion
This was the first audit in the BSI three year strategic program.
The objectives of the assessment were met.
The management system has been/continues to be generally effectively implemented.
There was no briefing note or follow up request from BSi Scheme Manager Richard Tully.
Obstacles:
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.
Reliability of audit:
The report is a reliable reflection of the areas observed.
This report is eligible for submission to FDA under FDA ISO 13485 Voluntary Audit Report Submission Program.
The audit sample taken during this visit for the product confirms the ability to meet assessment requirements of BSi as a Notified Body requirements.
Viamed has implemented/continues to implement all requirements of BSI Conditions of Contract and the companies own policies and procedures are effectively addressed by the management system and the following :-
- FS28344 - ISO9001:2008 certification
- ISO13485:2003 (MD78787 - ISO13485 certification
- ISO13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations. GD210 will be used. (FM540797 - CMDCAS certification)
- Meet the requirements of 93/42/EEC Annex II 3.2 (CE01389 - CE marking certification)

The opening meeting was conducted in the presence of the Quality Manager/Managing Director.
The assessment plan, objectives and scope of the assessment were confirmed.
The assessment was performed in English.
Audit scope:
This visit will cover the location activities for the management system processes listed in the schedule below at the main location as documented in this plan and reviewed with the client representative and BSi Scheme Manager Richard Tully.
- QMS – including objectives for quality and improvement The use of BSI and UKAS logos, management review, audits, improvements, preventive action, corrective action, customer feedback, complaints, vigilance and post market surveillance.
Regulatory requirements – Medical device MDR
- Product - processes including device history records, validation, training, maintenance and calibration,
- Prepare report and complete BSi regulatory checklist
- Scope of certification:

The scope for registration certificates were confirmed as follows:
There has been no change to the name on the BSi certificates. The site specific scope details process which forms part of product realisation , ie
……CE01389 - MDD 93/42 ECC 2007/47 - The design and manufacture of microstim nerve stimulators, pulse oximeter probes,oxygen hoods, gas respiratory adapters, gas respiratory valves and phototherapy light shields
……FS28344 - ISO9001:2008 - The design, manufacture, service, repair, maintenance and supply of medical monitoring, ventilation and anaesthetic equipment including that carried out on customer premises.
……..FM540797 - ISO13485:2003 - Health Canada - CMDCAS - The design and manufacture of supramaximal nerve stimulators and infant resuscitators.
……..MD78787 - ISO13485:2003 - 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. Assessment Report.

Quality Manual version:
Quality Manual , held on intranet, dated 2013:13034. Quality Manual outlines requirements for the QMS compliance. Classic type Quality manual addressing each clause of the standard and requirements.
There are exclusions and Non-application of Requirements in the QMS:
7.5.3.2.2 Exclusion active implantable devices
7 .5.2.2 exclusion for sterile medical devices
77.5.1.3 particular requirement for sterile devices

Significant Changes:
…….Continuing to develop Intrasats Application Software for the Quality Management System.
Number of employees 17 refer to shift detail.
Adverse Incidents, Field Safety Corrective Actions and Recalls:
There have been 1 reportable incidents, as detailed in vigilance analysis below.

Corporate Identity of the Manufacturer:
Establised in 1977, Viamed focuses on the development, production and distribution of innovative medical products worldwide.
The main application for products is critical patient care in hospitals, other marketed areas include:
Emergency Services, General Practitioners, Dental and Veterinary Surgeries...
In addtion Viamed distribute automotive oxygen sensors for use with exhaust emissions testing equipment.
Viamed Ltd
15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT, United Kingdom
Email: info@viamed.co.uk ; Phone: +44 (0)1535 634542 ; Fax: +44 (0)1535 635582
Company registered in England No. 01291765
Viamed Properties Ltd . owns the buildings,
Vandagraph Ltd Same Shareholders.,
Vandagraph Sensor Technologies Limited Same Shareholders,

Description of the manufacturer:

15 Full Time Staff , 2 Part Time

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

Critical subcontractors:
Blue Point Medical. Germany, (Manufacture)
Instrumentation Industries (Manufacture)

Senior Management of the Assessment Location:
Derek Lamb - CEO / Management Representative
John Lamb - Chairman
Helen Lamb - Finance Director

Date of the Audit
7th and 8th of October 2012

Report Identification and Dating
Report compiled by John McGowan of BSi, 26th August 2013. Sign off sheet is uploaded for BSi records, duly signed by the folllowing :-
John McGowan - BSi Lead Auditor
Drew Lamb - Managing Director

The Bsi Regulatory Checklist was completed.

There were no outstanding nonconformities to review from previous assessments.
A minor nonconformity requiring attention was identified. This, along with other findings, is 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 22/10/2013 by e-mail to msuk.caps@bsigroup.com or by fax to +44 (0)1908 228123, referencing the report number.

There were no outstanding nonconformities to review from previous assessments.
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Areas Assessed & Findings.

Quality Management System - Core QA processes : 4.1 ; 4.2 ; 5.1 ; 5.2 ; 5.3 ; 5.4 ; 5.5 ; 5.6 ; 7.1 ; 8.1 ; 8.2 ; 8.3 ; 8.4 ; 8.5

- Personnel involved -
Derek Lamb

- Summary -
Quality Manual (QM) @ held on intranet, details site requirements outlined in the scope. Electronic held, classic type Quality manual addressing each clause of the standard and requirements for the Quality Management System (QMS).
The quality policy linkage to policy statement. Quality Manual links BSi certification as the notified body and reference for scope of product realisation, exclusions for product realisation, clause 7 (refer above).
The scope of registration hasn't changed and is suitable for the client.
There are class 1 devices as outlined in Product Realisation. There are no procedure packs that may fall under Article 12.
Management Review: Site reviews are held by top management with schedule detailed on the intranet task lists. Records available for Quarterly review, October 2013, with traceability for overview of 2013 and business strategy. The action items of quarterly reviews and regular quality forums, demonstrate an inclusive review of data as it is seen to meet key objectives, including appropriate regulatory requirements. Follow up actions from the previous management review and supplier performance, are tracked.
Quality objectives are benchmarked to previous result history, on the following work flow:-
- Orders picked
- Invoices due
- OTD (on time delivery)
- SRS (repairs) allocated per day to actual received
- Purchase order raised
- QA items processed
- Bar codes generated per day
Due to use of closed feedback loops in the intranet QMS (Intrastats), provides preventive action on feedback at stages of the process, eg, utilising bar scan checks by process users from sales to desptach, providing early warning of missing entry in the process.

Internal Audit: Internal audits to ISO13485:2003 are demonstrated to be carried out by suitably qualified and independent auditors, as defined in Procedure VMCOP13 - 26/09/2011. However the audit strategy continues to evolve following System ; Process ; Product audits to the QMS and continue to provide compliance, ie use of closed feedback loops in the intranet QMS (Intrastats).
Audit schedules have been established for 2013 based on risk and previous assessment findings.
The schedule / action tracker is up to date for audits performed, with analysis of overdue actions as detailed above, linking to management review. Audits generally confirm that planned arrangements , with evidence to substantiate findings and any non conformities are being followed up and these reviewed detailed root cause investigation, verified without undue delay. Audit reports for 2013 were reviewed and found to closed out, with evidence of corrective action taken highlighted to all process owners and users, then monitored in quarterly review and via Intrastats application software.

Complaints and Vigilance reporting: The client is responsible to identify vigilance issues and to report in the UK to the MHRA. The documented process COP10 issue 4 ,Complaints Handling, for evaluating complaints against reporting guidance was demonstrated .
Records available for reportable incidents detail the following summary
.....MDD - 1 raised after feedback from MHRA #2013/005/020/401/001 dated 30/5/2013
.....ORA (other regulatory authority) - None
There was a total of 1 reports compiled from customer feedback, since last BSi audit, resulting in 1 reportable events, analysis as above.
There were no product recalls, advisory notices, field failures incidents reported.
COP01 issue 3 ; COP10 issue 4 defines Medical Device Reporting. The process as outlined and as demonstrated and gave confidence

in the ability of the management system to identify and report incidents, protocols for documented procedures require review for process conformance to regulatory requirements (refer above)
Noted traceable to e-mail to MHRA for update notification.
- MHRA #2013/005/020/401/001 dated 30/5/2013. There was no required update for Technical file.

Corrective actions that had been identified are seen to be analysed without undue delay. Review analysis for vigilance, forms part of internal audit program for compliance to MEDDEV 2.12/1 reporting and any subsequent changes.
Advisory Notices/Recall Procedure
COP01 issue 3 ; COP10 issue 4 defines Medical Device Reporting, refer above.
Post Market Surveillance/Feedback: Forms part of regular (at least yearly) reporting as per documented Procedure COP18, Change note 8106. The document defines a systematic process to gain information from data base register, from the post production phase and bring this information to the management review. ie
Quality ; Production ; Supplier ; Stock ; Customer order ; Complaints ; Returns ; Repair files ; Staff reviews ; Sales warning thresholds; Technical files

Corrective Action/Preventive Action: Documented procedure COP 10 issue 4, covers the process for corrective and preventive action process COP 15 issue 3.
It was noted that Intrastats application software, provides use of closed feedback loops in the intranet QMS. Hence preventive action was suitably demonstrated for the Quality Management System, ie
- audit
- trend analysis
- bar scan integrity checks
- risk management / priorities
- trend reporting
- advisory bulletins / regulatory updates / customer
- improvement registrar

As detailed above an overview of the investigation process was demonstrated and samples then confirmed the process as outlined and as documented in procedures.
The sample confirmed a systematic process to identify potential problems, for evaluating proposed action and for verifying and validating the affectivity of the actions taken, eg refer to corrective action analysis above. The analysis also includes internal and external, non conformance and corrective action.
Demonstrated compliance for above QMS processes for the sample taken

Requirements for Canada 4.2
Procedure COP 001 ID 9296, defines requirements. BSi regulatory checklist were completed to detail requirements for the following:

The clients licences detailed on the Medical Devices Active Licence Listing were reviewed and the accuracy of the listing was confirmed. The clients vigilance procedures include requirements for Canada and a review of complaints data shows that complaints are reviewed against the reporting criteria for Canada

Demonstrated compliance for above QMS processes for the sample taken.

Product realisation : 4.1 ; 4.2 ; 5.5 ; 6.2 ; 6.3 ; 6.4 ; 7.1 ; 7.2 ; 7.4 ; 7.5 ; 7.6 ; 8.4

- Personnel involved -
Derek Lamb
Philip Crossley

- Summary -
Various medical device products are manufactured as per scope of BSi licences and classification, ie
- Cot Lids - class 1
- Heat Shield - class 1
- Light Shield - class 1
- Microstim Mk3 - class 11a (CMDR class 2) (technical file audited)
- Nova Oxygen Tent - class 11a
- Nova Oxygen Hood - class 11a
- Resuscitation Unit TC400 - class 11b
- T Adaptor - class IIa
- Tom Thumb Adaptor - class 11a (technical file audited)
- Tube Holder - class 1
- Finger Pulse Oximeter Probe - class IIb

In review of Design and Technical files, there has been no new product design for Technical file submission since year 2000, for Product Tom Thumb.
The BSi regulatory checklist was completed as forms part of this report.
Documented processes, (currently under review to reflect Intrastats) details Marketing, Sales, Contract review held on the Goldmine and Intrastats application software for customer order / quotes process to the following stages:-
……Orders received by fax, phone call, customer advisor.
…..Orders and customer requirements / demand / schedule forms part of material planning for release of requested application software, held on intranet.
……Orders processed using Intrastats software application, then customer notified for supply of equipment, traceability of quotes and orders, eg customer requirements from order / quotes / repair / service, eg :-
- Microstim product - Invoice IN127610, order 63084 dated 12/06/2013, shipped 05/07/2013, last order for Canada, traceable to QA checks
- Tom Thumb product - Invoice IN128875, order 64279, shipped 27/09/2013, S/N: 040932, ID 674932, traceable to QA checks

Calibration process COP11, ID8713, defines protocols for control of monitoring and measuring devices. Traceability demonstrated to external equipment calibration laboratory, eg
- Manometer CE078 and 674700
Records detail recalibration and analysis of results for applicable pass / fail criteria. Noted that ESD benches and associated equipment form evaluation as part of regular maintenance checks.
During the course of the visit logos were found to be used correctly.

Based on sample taken above one non conformity was raised. This requires a corrective action, refer to report content.

Minor Nonconformities Arising from this Assessment.

Ref	Area/Process	Clause
977894N0	Product realisation	4.2.1
Scope	MD 78787 at VIAMED-0009370214-000	
Details:	Technical File wyas not fully updated	
Requirements:	General The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, e) records required by this International Standard (see 4.2.4), and f) any other documentation specified by national or regional regulations. Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained. 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.	

Assessment Participants.

On behalf of the organisation:

Name	Position
Mr Derek Lamb	Managing Director
Refer to report deatil for other personnel audited	

The assessment was conducted on behalf of BSI by:

Name	Position
John McGowan	Team Leader
Sebastian Brzozowski	Trainee

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:	0.5 Days
	Next re-certification:	01/11/2015

Site Address	Certificate Reference/Visit Cycle	
Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom	FS 28344	
	Visit interval:	12 months
	Visit duration:	0.5 Days
	Next re-certification:	01/11/2015

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|FS 28344 & 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
.				X			
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					
Technical visits are to be carried out by a technical expert (Qtr 1/12) to a separate schedule				X			
Tom Thumb resuscitator			X				

Next Visit Plan.

Visit objectives:

Visit objectives:
To carry out the second continuing assessment in the current cycle in line with the next visit and strategic plan.
Audit of the continuing suitability and continued effective implementation of the Quality Management System in meeting the requirements detailed in visit scope, plus associated support documentation and additional customer requirements, company objectives, policies and procedures.
Visit scope:
To evaluate the continuing implementation including the effectiveness of the management system, including BSI Conditions of Contract and the companies own policies and procedures (FM26022 - ISO9001:2008 certification)
Continues to implement all requirements of ISO13485:2003 (MD78787- ISO13485 certification)
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. (FM540797 - CMDCAS certification)
To verify that the management system continues to meet the requirements of
93/42/EEC Annex II 3.2 (CE01389 - CE marking certification)

Date	Assessor	Time	Area/Process	Clause
06/10/2014	Edward Collins	9am	Opening Meeting – review of changes since the previous assessment visit – changes to quality system, product range or key processes	4.1 ; 4.2 ; 5.1 ; 5.2 ; 5.3 ; 5.4 ; 5.5 ; 5.6 ; 7.1 ; 8.1 ; 8.2 ; 8.3 ; 8.4 ; 8.5
		9:10	.QMS – including objectives for quality and improvement The use of BSI and UKAS logos, management review, audits, improvements, preventive action, corrective action, customer feedback, complaints, vigilance and post market surveillance. Regulatory requirements – Medical device 2007/47/E	4.1 ; 4.2 ; 5.1 ; 5.2 ; 5.3 ; 5.4 ; 5.5 ; 5.6 ; 7.1 ; 8.1 ; 8.2 ; 8.3 ; 8.4 ; 8.5
		12:30	Lunch	
		1pm	Product processes including device history records, validation, training, maintenance and calibration	4.1 ; 4.2 ; 5.5 ;6.3 ; 6.4 ; 7.1 ; 7.5 ; 7.6 ; 8.4
		3pm	Prepare report for closing meeting at 4pm, leave site 4:15pm	

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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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.

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Should you wish to speak with BSI in relation to your registration, please contact our Customer Engagement and Planning:

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Appendices.

CRITICAL SUPPLIERS LIST

Blue Point Medical. Germany, (Manufacture)

Instrumentation Industries (Manufacture)