Assessment Report.

Viamed Ltd

Report Author **John McGowan**

Visit Start Date 08/10/2012

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
7733193 Re-certification Audit (RA Opt 2) 08/10/2012 1 day(s) No. Employees: 17	FS 28344 ISO 9001:2008	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom
7737037 Re-certification Audit (RA Opt 2) 09/10/2012 1 day(s) No. Employees: 17	CONTRACT 200483566 CE 01389 Healthcare 93/42/EEC Annex II, Section 3.2 CE MARKING John Howlett MD 78787 Healthcare ISO 13485: 2003 N/A Stewart Brain FM 540797 ISO 13485: 2003 CMDCAS CMDCAS	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of the assessment was to conduct a recertification and 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 Ben Wall.
- 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
- Sales order process, material planning, purchasing, goods receiving stores control and desptach
- Product - processes including device history records, validation, training, maintenance and calibration,
- Prepare report and complete BSi regulatory checklist

Management Summary.

Overall Conclusion

This was the third 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 Alan Eller.

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 audit sample taken during this visit for the product confirms the ability to meet assessment requirements of BSi as a Notified Body requirements.
Microstim product - Invoice IN123115, order 59041 dated 14/9/22012, dated 14/9/2012, last order for Canada, traceable to QA checks performed 10/9/12, then despatched.
- Tom Thumb product - Service 6345, serial # H000289231
- Tom Thumb product - new build to documented process VM3/COP/50.02 issue 1, details digital photos for build steps, test, calibration and final QA inspection, Product code 599810, serial #040779, bar code 565065 passed Aug/12

Therefore continued certification is recommended to the BSi scheme manager.

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.

Opening Meeting, changes 4.1 ; 4.2 ; 5.1 ; 5.2 ; 5.3 ; 5.4 ; 5.5 ; 5.6 ; 6.1 ; 7.2 ; 8.1 ; 8.2 ; 8.3 ; 8.4 ; 8.5

The opening meeting was conducted in the presence of the Management Representative and Management team detailed in this report.

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 Alan Eller.
- 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
- Sales order process, material planning, purchasing, goods receiving stores control and desptach
- 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.

Quality Manual version:
Quality Manual , held on intranet, dated 2012:11966. 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:
14 Full Time Staff , 3 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:
Please see appendix for details and activities.

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

Date of the Audit
8th and 9th of October 2012

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
John Lamb
Helen 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, March and September 2012, with traceability for overview of 2012 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 COP issue 3. 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 2012 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 Qtr1/12were 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 #2012/001/018/401/002 dated 19/1/2012, reviewed by BSI Scheme Manager at Technical audit
…..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 #2012/001/018/401/002 dated 19/1/2012, review links to customer order PO 2002694743. 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
Records available dated 12/3/2012, analysis would detail any issues raised on performance, eg Supplier non conformances.

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
Product Microstem, licence ref 128822, for Canada is detailed in www.MDALL.com, web site BSi regulatory checklist was completed for pre-audit detail to meet CMDCAS requirements

Product realisation audit 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
Angela Hawthorn
Lisa Lego
Cathy Green
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)
- Nova Oxygen Tent - class 11a
- Nova Oxygen Hood - class 11a
- Resuscitation Unit TC400 - class 11b
- T Adaptor - class IIa
- Tom Thumb Adaptor - class 11a
- 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 Apgar Timer. In discussion with BSi Scheme Manager the client has agreed a roll out of planned checks by BSi for technical file review to ensure compliance with MDD 2007/47/EC. 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 IN123115, order 59041 dated 14/9/22012, dated 14/9/2012, last order for Canada, traceable to QA checks performed 10/9/12, then despatched.
- Tom Thumb product - Service 6345, serial # H000289231
- Tom Thumb product - new build to documented process VM3/COP/50.02 issue 1, details digital photos for build steps, test, calibration and final QA inspection, Product code 599810, serial #040779, bar code 565065 passed Aug/12

Outsource partner (Healthcare Technologies) is used for main assembly of Microstim product, depending on customer demand. Level of outsourced production, forms part of material planning. Supplier performance is monitored validated and revalidated as part of regular management reviews / post market surveillance records are available.

Documented process for core competency and training COP12, ID8712, provides traceability for personnel yearly training record update, which would include training analysis, eg yearly information for all employees. Traceability demonstrated for product realisation process and support, depending personnel requirement.

Calibration process COP11, ID8713, defines protocols for control of monitoring and measuring devices. Traceability demonstrated to external equipment calibration laboratory, eg
- Manometer CE078 and 149
- CE051 Sonicaid (indication only)
- CE118 Heart monitor (indication only)
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.

Based on sample taken above, process demonstrates compliance.

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

An older version of the logo is in use on letter heads and the client is asked to make use of the current version at the first opportunity

Recertification Audit.

Review of assessment progress and the re-certification plan:

Last rectification review performed November 2009. The scope of the organisation reviewed for changes due to organisation changes and integration .
The organisational scope and exclusions for is still valid and meets the business and licence scope for the organisation, ie
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
Licence Scope for the following is still valid, 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.

Additionally the Quality policy / objectives for organisation is reviewed in the regular management meetings to align with business requirements.

The site has integrated management responsibilities, which is covered in QMS / BSi licences for the following :-
Intranet access to users and remote personnel (
Responsibilities and authorities
Goals and objectives
IT and data back up services

The Quality Management System / Quality Manual / Procedures have integrated processes.
Review of Quality manual has resulted in update to version 9 for updates in intranet and use of data records in the organisation.
Additionally internal audit process now reflects ISO13485 matrix to ensure coverage of QMS over yearly program, prior to management review. Correction, corrective action and preventive action definitions have been reviewed to ensure clarity and understanding by process owners and users.
The three year BSi plan defined in 2009, has been completed.
The new three year plan defined below will under review, for revised processes, customer inputs and deliverables to ensure coverage of organisation, and customer requirements integration.
As normal practice, all areas defined in the next visit plan will require review prior to next BSi audit to ensure coverage of Business Management System.

Review of assessment findings:

n review of BSi reports there are no trends which indicate a lack of investigation for root cause in the subsequent corrective actions for the issues (were non conformities) raised.

Additionally a good commitment was demonstrated by organisation for analysis of the BSi reports for commentary, issues highlighted, ie improvement of measures / objectives to reflect business requirements, monitoring of contracts won, to drive understanding of the ISO13485 by process owners and top management.

Customer satisfaction is managed by the business metrics, eg
…….. Customer feedback
……Customer complaints
……Customer contracts --- Won / Lost
Additionally the corrective action data base collates customer / project / QMS feedback. Demonstrated understanding for root cause investigation, attachments, and tracking of actions and timescales. Results are cascaded to all relevant functions to drive improvement in external and internal customer satisfaction.
Corrective actions are under review for closure by regular reviews and allocation action flags status on the QMS intranet to highlight risk to the business and required feedback / confirmation from customers.

Review of progress in relation to the organisation's objectives:

The Management System provides linkage to Quality Manual and top level business process map, lower level processes, Work Instructions, templates / records are linked to provide ease of access.
Results are monitored as defined above, through management meetings with good evidence of corrective action to drive root cause analysis.
Process owners and users demonstrated a good understanding of KPI's. As a result to drive a better understanding for the effectiveness and efficiency of processes, eg
- review of business metrics, eg Finance ; Sales ; Product Development/Regulatory ; Customer feedback ; Yield analysis

Management system strategy and objectives:

Management business strategy is cascaded to all users. Strategy and objectives are monitored through regular management meetings and results monitored to drive and improve customer focus.

There has been considerable change in the organisation and this will continue during the next strategic review period, eg new business won, monitoring of resource to meet customer delivery demand. Therefore continuing commitment was demonstrated by the Top Management to drive improvement in the effectiveness, efficiency and maintaining QMS. This will be monitored in future BSi audits.

Additionally the following initiatives are currently being reviewed for implementation to drive improvement :-

- Update/investment of intranet computer system (Intrastats) to provide online analysis for the organisation, users and internal audit processes
- Continual review for ease of access by remote personnel to ensure understanding of QMS and vigilance requirements, eg access to intranet bar coding

BSI Client Management:

The reports in this review period demonstrate compliance to Medical devices, licence scope, UKAS CMDCAS and BSi requirements / rules, therefore a recommendation for continuing assessment and certificate update has been made in this report.
There has been no issues during this review period for corrective action submissions, invoices, audit timings / cancellations.

All assessments conducted over the last 3 years have been conducted by Edward Collins ; John McGowan, as detailed in attached reports, which has ensured impartiality of the audit process, and as per MD9 assessment days.
Auditors were suitably qualified and hold the correct BSI T-codes for the activities assessed.

On behalf of BSi I would like to thank all personnel for the commitment and improvement demonstrated during this Strategic review period

Shift Details.

An evaluation of the shift patterns and processes undertaken on them has been completed and it has been concluded that sufficient evidence of conformance from all shifts can be seen during the normal assessment times.

Total of 17 - 14 Full Time Staff , 3 Part Time
Shift patterns are Day Shift (8am to 6pm - core hours)

Assessment Participants.

On behalf of the organisation:

Name	Position
Derek Lamb	CEO / Quality Manager
Refer to report deatils for other personel audit	Report details

The assessment was conducted on behalf of BSI by:

Name	Position
John McGowan	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	FS 28344	
	Visit interval:	12 months
	Visit duration:	3.5 hours
	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	CONTRACT 200483566	
	Visit interval:	12 months
	Visit duration:	3.5 hours
	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.

Business area/Location		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
	Date (mm/yy):	10/13	10/14	10/15			
	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		☐	☐	☐			
Manufacture and test:			☐	☐			
Tom Thumb resuscitator			☐				
Head boxes and phototherapy shields			☐				
Pulse oximeter probes				☐			
Nerve stimulators				☐			
Sales and order processing				☐			
Design				☐			
Purchasing and supplier controls				☐			
Reassessment visit				☐			
.				☐			
Technical visits are to be carried out by a technical expert (Qtr 1/12) to a separate schedule				☐			

Next Visit Plan.

Visit objectives:

To carry out the fourth 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
07/10/2013	John McGowan	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
	John McGowan	9:15	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/EC	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
	John McGowan	12pm	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
	John McGowan	12:30	Lunch	
	John McGowan	1pm	Follow up on issues from morning - Prepare report for closing meeting at 4pm	

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.

BSI, its staff and agents shall keep confidential all information relating to your organisation and shall not disclose any such information to any third party, except that in the public domain or required by law or relevant accreditation bodies. BSI staff, agents and accreditation bodies have signed individual confidentiality undertakings and will only receive confidential information on a 'need to know' basis.

'Just for Customers' is the website that we are pleased to offer our clients following successful registration, designed to support you in maximising the benefits of your BSI registration - please go to www.bsigroup.com/j4c to register. When registering for the first time you will need your client reference number and your certificate number (43207441/CE 01389).

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.

This report and related documents is prepared for and only for BSI's client and for no other purpose. As such, BSI does not accept or assume any responsibility (legal or otherwise) or accept any liability for or in connection with any other purpose for which the Report may be used, or to any other person to whom the Report is shown or in to whose hands it may come, and no other persons shall be entitled to rely on the Report.

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

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HP2 4SQ

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Email: MK.Customerservices@bsigroup.com

Appendices.

CRITICAL SUPPLIERS LIST

Blue Point Medical. Germany, (Manufacture)

Instrumentation Industries (Manufacture)