Assessment Report

Viamed Ltd

Assessment dates	07/03/2018 to 07/03/2018 (Please refer to Appendix for details)
Assessment Location(s)	Keighley (000)
Report author	Edward Collins
Assessment Standard(s)	Healthcare, ISO 13485:2003

Table of contents

Executive summary

The objectives of the assessment were met.

Issues related to the ISO 13485:2003 management system have been closed, including the major nonconformity identified at the last continuing assessment visit.

Some minor nonconformities relating to ISO 13485:2016 and ISO 9001:2015 management system issues remain open and will require to be closed before the relevant transition period ends.

Nonconformities raised at technical assessments remain open, including major nonconformities. These require closure by a technical specialist and until resolved places the CE certificate at risk.

Transition has yet to be completed and it is recommended that the ISO 9001 certificate for Vandagraph Sensor Technologies be audited separately before the end of the transition period in Sept 2018.

For Viamed it is recommended that the next assessment, a reassessment visit in Oct 18, be extended to include transition to ISO 13485:2016 before the transition period ends in Feb 2019.

An alternative would be to transition to both management standards in one audit. This would need to be completed before Sept 2018 and the next visit plan of this report would need amending to reflect this.

Changes in the organization since last assessment

There is no significant change of the organization structure and key personnel involved in the audited management system.

No change in relation to the audited organization’s activities, products or services covered by the scope of certification was identified.

There was no change to the reference or normative documents which is related to the scope of certification.

NCR summary graphs

There have been no NCRs raised at this visit.

Your next steps

NCR close out process

See executive summary

No new nonconformities were identified during the assessment. Enhanced detail relating to the overall assessment findings is contained within subsequent sections of the report.

Assessment objective, scope and criteria

Assessment Scope
The management system processes at Viamed Ltd,15/17 Station Road, Cross Hills, BD20 7DT in the UK.

Assessment Objectives
To conduct an onsite follow up assessment to determine whether the effective implementation of agreed corrective actions to address Major nonconformity identified during the previous continuing assessment, report No 8580193, 8789316, 8789318, has occurred, and to determine whether a recommendation for continued certification can be made.

Assessment participants

Name	Position	Opening meeting	Closing meeting	Interviewed (processes)
John Lamb	Chairman	X	X	X
Derek Lamb	MD	X	X	X
Helen Lamb	Director	X	X	X

Assessment conclusion

BSI assessment team

Name	Position
Edward Collins	Team leader

Assessment conclusion and recommendation

The objectives of the assessment were met.

The results of this follow up assessment confirm that the agreed corrective action plan has been effectively implemented sufficiently to address and enable closure of Major nonconformity identified during the previous continuing assessment consequently, a recommendation for continued certification can be made.

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 recommendation included in this assessment is based on assessment of Viamed Ltd,15/17 Station Road, Cross Hills, BD20 7DT in the UK. on the 7th March 2018
The report was finalised and issued on the 9th March 2018.

Use of certification documents, mark / logo or report

The use of the BSI certification documents and mark / logo is effectively controlled.

Findings from previous assessments

Finding Reference	1548900-201710-M1	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2003	**Clause**	7.3
Category	Major		
Area/process:	Risk Management, Customer Requirements, Design and Development: (7.1, 7.3), [7.1, 7.3], {8.3}		
Details:	Design and development and risk management is not effective because evidence of a controlled process could not be demonstrated.		
Objective evidence:	The risk management process VM3COP27.11 includes a scale of 1-4 for severity and occurrence, but does not identify how to determine the boundary/limits between scales. Evidence of consideration of Risk for the Tom Thumb design change in 2005 could not be provided at this assessment. Evidence of updating the Tom Thumb design inputs for a design change in 2005 could not be provided at this assessment. (ref Tom Thumb specification document #2247 dated 6 June 1997) Evidence of Tom Thumb design inputs containing the outputs of risk management could not be provided at this assessment (ref Tom Thumb specification document #2247 dated 6 June 1997 and Tom Thumb risk management file dated 29/9/2017) Evidence of performing a design review on the Tom Thumb design change in 2005 could not be provided at this assessment. Evidence of performing validation of the design change to Tom Thumb in 2005 could not be provided at this assessment. Evidence of appropriate controls related to responsibility authority for design and development between VST and the subcontractor could not be provided at this assessment (ref contract #13859)		
Cause	In respect of risk management – wrong documents presented. 3899 with the 1-4 categories defined. Tom Thumb design change dates from 2004 when now obsolete standards applied. In respect of design input for the change to accept 15 mm bore outlet hose – the wrong document #2247 relating to a technical document was presented In respect of design review and design verification for the change to accept a 15 mm bore hose – the relevant documents were not presented. In respect of the subcontractor controls relating to subcontractor VST – the relevant document could not be recovered from archive		
Correction / containment	In respect of risk management – review documentation for adequacy against 14972:2012. Assess risk documentation for the Tom Thumb In respect of design input for the change to accept 15 mm bore – recover correct documentation. In respect of design review and design verification for the change to		

	accept a 15 mm bore hose – recover relevant documents from the archive. In respect of the subcontractor controls relating to subcontractor VST – recover from archive and review against the changed OBL/manufacturing status of Viamed
Corrective action	In respect of risk management – doc 3899 details the 4 categories used at the time. doc 2402 dated Nov 17 now based on 5 categories of risk and reflects 14971:2012 . Risk assessment for the Tom Thumb design change to accommodate a larger 15mm hose revisited 6th March 2018 to show a rationale. In respect of design input for the change to accept 15 mm bore – Archive documents reflect the design change input requirements. In respect of design review for the change to accept a 15 mm bore hose – Archive documents reflect the applicable standard in 2004, EN 46001 design change clause based on the 2000 version of ISO9001 In respect of design validation for the change to accept a 15 mm bore hose – Archive documents reflect the applicable standard in 2004, EN 46001 design change clause based on the 2000 version of ISO9001 In respect of the subcontractor controls relating to subcontractor VST – Contract recovered from archive. New draft document based on changed OBL/manufacturing status has been prepared.
Closed?:	Yes

Finding Reference	1417669N1	**Certificate Reference**	CE 540537
Certificate Standard	Healthcare	**Clause**	Annex II 5.4
Category	Minor		
Area/process:	Review of Open non-conformities from the last assessment		
Details:	The technical agreement with Bluepoint is not fully effective.		
Objective evidence:	The Bluepoint OEM agreement doe not allow for access to their premises in the event of an unannounced visit from a notified body.		
Cause	Problems with archive documents		
Correction / containment	Not required following cancellation request for certificate		
Corrective action	Contract reissued 19th Nov 2016. Sect 7 requires access by NB to carry out unannounced audits This issue is no longer relevant following cancellation of CE 8871378		
Closed?:	Yes		

Finding Reference	1511849-201709-N2	**Certificate Reference**	CE 01389
Certificate Standard	Healthcare	**Clause**	Annex II, Section 3.2c
Category	Minor		
Area/process:	Design Inputs		
Details:	The evidence of design control was incomplete		
Objective evidence:	While there are design inputs, complete evidence for the ability to comply with the MDD was not demonstrated by the technical documentation. Specifically: - There is no evidence of design inputs related to risk management or traced to risk management. There is no clear means by which to trace design verifications to design inputs. - The design input document fails to cover key elements of the design including but not limited to: user expectations, labeling requirements, safety, training, packaging, interface, environmental, storage and shelf-life, material, regulatory requirements, accuracy claims of outputs and standards.		
Cause	Procedures have not been applied for many years due to lack of design activity		
Correction / containment	Review procedures		
Corrective action	QC 23, 28B and 30 revised based on 2016 with risk management and direct comparison between design input and design output Existing records are seen to be relevant to the design model applicable at the time.		
Closed?:	Yes		

Finding Reference	1527388-201709-N3	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2003	**Clause**	2016:4.1.6
Category	Minor		
Area/process:	Essential Assessment Information, Opening Meeting and Changes: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1		
Details:	Software validation for the application of computer software used in the QMS is not fully effective because a documented procedure and validation records could not be provided.		
Objective evidence:	A documented procedure meeting the requirements of clause 4.1.6 of ISO 13485:2016 could not be provided at this assessment. Records of software validation meeting the requirements of clause 4.1.6 could not be provided at this assessment.		
Cause	Viamed had not completed transition at the time of the visit		
Correction / containment	As part of transition, document the existing validation protocol		
Closed?:	No		
Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective action plan has been accepted but the actions were not able to be reviewed at the time of this assessment. March 18 – Validation demonstrated based on risk. The related procedure will be reviewed at the transition assessment		

Finding Reference	1527388-201709-N4	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2003	**Clause**	2016:4.2.2
Category	Minor		
Area/process:	Essential Assessment Information, Opening Meeting and Changes: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1		
Details:	The quality manual is not fully effective because the identification of non-applicable clauses are not clearly documented and a contradictory statement was evident.		
Objective evidence:	The list of non-applicable parts of the quality management system standard do not reference clause numbers and identifies active implantable as non-applicable where the standard only references implantable devices. Sterile requirements are identified as non-applicable but an additional statement is included stating that some distributed products are sterile but not opened. The scope does not currently include distribution of sterile devices.		
Cause	Viamed had not completed transition at the time of the visit		
Correction / containment	Review QA system against 2016 clauses		
Corrective action	Quality manual has been updated to reflect 2016 and the none applicability of aspects of sterility and implantable which are justified due to the nature of the products and service in scope		
Closed?:	Yes		

Finding Reference	1548900-201710-N1	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2003	**Clause**	2016:8.3.3
Category	Minor		
Area/process:	Feedback Processes, Complaint Management and Vigilance: (8.2.1, 8.5.2), [8.2.1, 8.2.2, 8.5.2], {8.2, 8.5.5, 9.1.2}		
Details:	Actions in response to nonconforming product detected after delivery is not fully effective because evidence of review for vigilance is not clearly documented for nonconformities received which are not identified to be complaints.		
Objective evidence:	Not all negative feedback nonconformities raised on Intrastat are determined to be complaints. A determination related to vigilance was stated to be made for these nonconformities, but not clearly documented in the record. ref microstim returns.pdf document #19655		
Cause	Viamed had not completed transition at the time of the visit		
Correction / containment	Amend system to show a vigilance review for all product issues, complaints and returns.		
Corrective action	The QMS has been amended with a review button for all issues, including returns		
Closed?:	Yes		

Finding Reference	1548900-201710-N3	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2003	**Clause**	2016:8.4
Category	Minor		
Area/process:	Servicing: (7.5.1.2.3, 7.5.4), [7.5.4], {8.5}		
Details:	Analysis of data is not fully effective because procedure VOP13 does not clearly include determination of appropriate methods, including statistical techniques and the extent of their use		
Objective evidence:	VOP13 ref #23659		
Cause	Viamed had not completed transition at the time of the visit		
Correction / containment	Review documentation against 2016		
Corrective action	VOP 15 ref 23735 details analysis of data, including statistical techniques		
Closed?:	Yes		

Finding Reference	1565762-201712-N1	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2003	**Clause**	5.6
Category	Minor		
Area/process:	Review of nonconformities		
Details:	Management review is not fully effective because not all inputs and outputs required by ISO 13485:2016 or ISO 9001:2015 were demonstrated to be considered and covered in the samples provided for Viamed and Vandagraph Sensor Technologies.		
Objective evidence:	Procedure VOP13 revision #23731, dated 3/11/2017 Management review record for Viamed dated 11 October 2017 Management review record for Vandagraph Sensor Technologies dated 18 October 2017		
Cause	Viamed had not completed transition at the time of the visit		
Correction / containment	Review input and output of management review against 2016		
Closed?:	No		
Justification	March 18 – input and output now reflect 2016 Application will be reviewed at the transition assessment		

Findings from this assessment

Opening Meeting, Manufacturer Information and Changes:

The opening meeting was conducted with the presence of Top Management as shown in the "assessment participants" section of this report
The assessment plan, objectives and scope of the assessment were confirmed.
The opening meeting and full assessment was performed in English.

Scope of Certification:
The registration certificates and scope of the registration were confirmed as documented in the "scope of assessment" appendix of this report

Changes to CE 01389 and MD78787 have been requested as below see report 885587/ 8855876

MD 78787 (ISO 13485:2003/2012) Please change to the following - The design, manufacture and service of: Oxygen Sensors and accessories, Supra-Maximal Peripheral Nerve Stimulator, Simulation Equipment, Infant T-Piece Resuscitators, Apgar Timer & resuscitation cabinets. Includes service of Infant T-Piece Resuscitators & Apgar Timer on customer premises. Distribution of medical devices from other manufacturers. Service of medical devices from other manufacturers. Service on customer premises of other manufacturers' medical devices: Radiant Warmers, Air/Oxygen Blenders & Suction Controllers.

CE 01389 Please change to the following: - The design and manufacture of Oxygen Sensors, Supra-Maximal Peripheral Nerve Stimulator & Infant T-Piece Resuscitators.

Quality Manual Version:

Exclusions and Non-Applications of Requirements in the QMS:

Electronic QMS working in real time

Significant Changes:
There have not been any major or significant changes to the organisational structure, products or process since the last visit. No changes outside of the subject of this visit have been made since the previous 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 single entity not part of a larger organisation. Vandagraph Sensor Technologies (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 although this is changing following certificate cancellation requests. 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:
A subcontractor is listed on the CE certificates for the manufacture of Electrochemical Oxygen Sensors. The client has requested that this remain out of the report.

Senior Management of the Assessment Location:

Derek Lamb - Managing Director and Management Representative
email: derek.lamb@viamed.co.uk
tel: 01535 634542

Closure of 1548900-201710-M1:

Most of the issues in this nonconformity relate to a minor design change that took place some 13 years ago. The design change did not affect the form and function of the device as it delivers gas to the patient. The material and bore dimensions through which gas is delivered to the patient did not change. The change was in the outer dimension of the socially clean output connector to accommodate a larger bore connection tube. The design review evidence currently available does not meet current standards and meddev guidance but was not seen to be inconsistent with standards current in 2004 when the modification was made.

Design:

The underlying issue is that there has been no new and original design activity for many years resulting in no available audit sample which demonstrates operation of a management system to ISO 13485:2016 and the MDD.

The relevance of this will be discussed with the Scheme Manager and a Scheme Managers briefing sought for the next assessment.

Next visit objectives, scope and criteria

Assessment Scope
The management system processes at Viamed Ltd,15/17 Station Road, Cross Hills, BD20 7DT in the UK.

Assessment Objectives
To conduct a recertification assessment to determine the effectiveness of implementation of the QMS applicable within the proposed scope of registration, in accordance with the company objectives, policies and procedures, applicable requirements of the management standards, BSI Conditions of Contract and to determine whether a certification recommendation can be made.
To verify that all requirements of ISO 13485:2003 and EN ISO 13485:2012 continue to be effectively implemented.
To verify that the requirements of ISO13485:2016 have been effectively implemented
To determine if the management system continues to meet the requirements of MDD 93/42/EEC Annex II 3.2

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the organization 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.

Next visit plan

Date	Auditor	Time	Area/process	Clause
Day 1	TBC	09.00	Opening meeting, review of changes since the previous visit to product range and key processes	
		09.30	Discussion with Top Management	5.1
		10.00	Core QA processes - Including: management review, internal audits, preventive action, analysis of data corrective action processes, feedback and recall	4.1, 4.2, 4.2.4, 4.2.5, 8.1, 8.2.1, 8.2.2. 8.2.3, 8.2.4, 8.4, 8.5
		11.30	Complaints and vigilance reporting	8.2.2, 8.2.3
		12.30	Lunch	
		13.00	Manufacture, service and testing of Infant T-Piece Resuscitators, Apgar Timer & resuscitation cabinets with audit trails to calibration, quality, validation and technical records/technical files as required	4.2, 6.3, 6.4, 7.5, 7.6, 8.2.5, 8.2.6, 8.3
		15.30	Report preparation	
		16.00	End of day wash up meeting	
		16.30	Leave site	
Day 2		09.00	Customer communication processes Sales order process	7.2
		10.00	Goods receiving	7.5, 8.2.6, 8.3
		11.00	Purchasing and supplier control	7.4
		12.30	Lunch	
		13.00	Design	7.3
		14.30	Technical files	4.2.3
		15.30	Report preparation	
		16.00	End of day wash up meeting	
		16.30	Leave site	

Day 3		09.00	Manufacture and testing of Infant T-Piece Resuscitators with audit trails to calibration, quality, validation and technical records/technical files as required	4.2, 6.3, 6.4, 7.5, 7.6, 8.2.5, 8.2.6, 8.3
		10.30	Outsourcing control	4.1.5
		11.30	Application of risk management	4.1.2 7.1
		12.30	Lunch	
		13.00	Manufacture and testing of Oxygen Sensors and accessories with audit trails to calibration, quality, validation and technical records/technical files as required	4.2, 6.3, 6.4, 7.5, 7.6, 8.2.5, 8.2.6, 8.3
		14.30	Oxygen sensor technical files	4.2.3
		15.30	Report preparation	
		16.00	End of day wash up meeting	
		16.30	Leave site	
Day 4		09.00	Document control and Quality records	4.2.4, 4.2.5
		09.30	Control of nonconforming product	8.3
		10.00	HR and competence	6.2
		10.30	Role of the organisation Change control QA software validation	4.1.1, 4.1.4, 4.1.6
		11.30	Report preparation	
		12.00	Closing meeting	
		12.30	Leave site	
			Full report to follow	

Appendix: Your certification structure & on-going assessment programme

Scope of certification

CE 01389 (Healthcare)

The design and manufacture of microstim nerve stimulators, oxygen hoods, gas respiratory adapters, gas respiratory valves and phototherapy light shields

Certificate Scheme: 93/42/EEC Annex II, Sec 3.2 (2007/47)

Scheme manager: Konstantinos Flampouris

MD 78787 (ISO 13485:2003)

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; 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; Resuscitators; Ventilation tube holders; Simulation, Test and Calibration Equipment for monitoring devices.

Certificate Scheme: ISO 13485: 2003

Scheme manager: Konstantinos Flampouris

CE 97289 (Healthcare)

Design and manufacture of Electrochemical Oxygen Sensors.

Certificate Scheme: 93/42 OBL Annex II, Sect 3.2 (2007/47)

Scheme manager: Konstantinos Flampouris

CE 540537 (Healthcare)

The design and manufacture of Sp02 modules and monitors and sensors, gas flow sensors, breathing gas exchange monitors and sensors, gas sampling lines and temperature probes

Certificate Scheme: 93/42 OBL Annex II, Sect 3.2 (2007/47)

Scheme manager: Konstantinos Flampouris

FM 540797 (ISO 13485:2003)

The design and manufacture of supramaximal nerve stimulators.

Certificate Scheme: CMDCAS

Scheme manager:

Assessed location(s)

The audit has been performed at Central Office.

/ CE 01389 (Healthcare) / MD 78787 (ISO 13485:2003) / FM 540797 (ISO 13485:2003) / CE 97289 (Healthcare) / CE 540537 (Healthcare)

Location reference	0009370214-000
Address	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom
Visit type	NCR Close Out Visit
Assessment reference	8881700
Assessment dates	07/03/2018
Deviation from audit plan	No
Total number of Employees	17
Effective number of Employees	15
Scope of activities at the site	Main certificate scope applies.
Assessment duration	0.5 day(s)

Certification assessment programme

Certificate number - Contract 200483566
Location reference - 0009370214-000

		Audit1	Audit2	Audit3
Business area/location	**Date (mm/yy):**	09/16	09/17	07/18
	Duration (days):	1	1	3.5
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
General objectives for quality and improvement		X	X	X
Scheme requirements for vigilance and feedback		X	X	X
Design and risk				X
Manufacture and test, monitoring and measuring, control of NC product and process validation:		X	X	X
Purchasing and supplier controls		X		X
Sales and order processing			X	X
Reassessment visit				X
Discussion with Top Management				X
Transition to ISO 13485:2016 and ISO 9001:2015 - 1 additional day over the visit cycle required.				X

Definitions of findings:

Nonconformity:

Non-fulfilment of a requirement.

Major nonconformity:

Nonconformity that affects the capability of the management system to achieve the intended results. Nonconformities could be classified as major in the following circumstances:

- If there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- A number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor nonconformity:
Nonconformity that does not affect the capability of the management system to achieve the intended results.

Opportunity for improvement:
It is a statement of fact made by an assessor during an assessment, and substantiated by objective evidence, referring to a weakness or potential deficiency in a management system which if not improved may lead to nonconformity in the future. We may provide generic information about industrial best practices but no specific solution shall be provided as a part of an opportunity for improvement.

Observation:
It is ONLY applicable for those schemes which prohibit the certification body to issue an opportunity for improvement.
It is a statement of fact made by the assessor referring to a weakness or potential deficiency in a management system which, if not improved, may lead to a nonconformity in the future.

How to contact BSI

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

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Notes

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This audit was conducted on-site through document reviews, interviews and observation of activities. The audit method used was based on sampling the organization's activities and it was aimed to evaluate the fulfilment of the audited requirements of the relevant management system standard or other normative document and confirm the conformity and effectiveness of the management system and its continued relevance and applicability for the scope of certification.

As this audit was based on a sample of the organization's activities, the findings reported do not imply to include all issues within the system.

Regulatory compliance

BSI conditions of contract for this visit require that BSI be informed of all relevant regulatory non-compliance or incidents that require notification to any regulatory authority. Acceptance of this report by the client signifies that all such issues have been disclosed as part of the assessment process and agreement that any such non-compliance or incidents occurring after this visit will be notified to the BSI client manager as soon as practical after the event.