Assessment Report

Viamed Ltd

Assessment dates	08/05/2017 to 08/05/2017
Assessment location	Keighley (000)
Report Author	David Vicar
Assessment Standards	ISO 9001:2008

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Executive Summary

The audit objectives have been met.

No obstacles were encountered that affect the reliability of this assessment.

The readiness review forms were completed in a manner that demonstrated the client has an understanding of their management system processes and the changes affecting ISO 9001:2015 and also how this will fit in with ISO 13485:2003, EN ISO 13485:2012 and eventual transition to ISO 13485:2016.

No nonconformities were identified but most areas have been recorded as only partially demonstrated as an onsite review of the evidence is required. Observations have been raised.

The next assessment is a surveillance assessment and also planned for transition to ISO 13485:2016 and ISO 9001:2015. The client may wish to consider availability of senior management to allow for a Top Management discussion to discuss and demonstrate 5.1 leadership and commitment and what the quality management system does for the business and include understanding of the context of the organisation, interested parties and their needs and expectations.

The Health Canada changes within CMDCAS and the new MDSAP requirements were discussed. Viamed are currently reviewing whether Canada will remain a viable market.

Assessment objective, scope and criteria

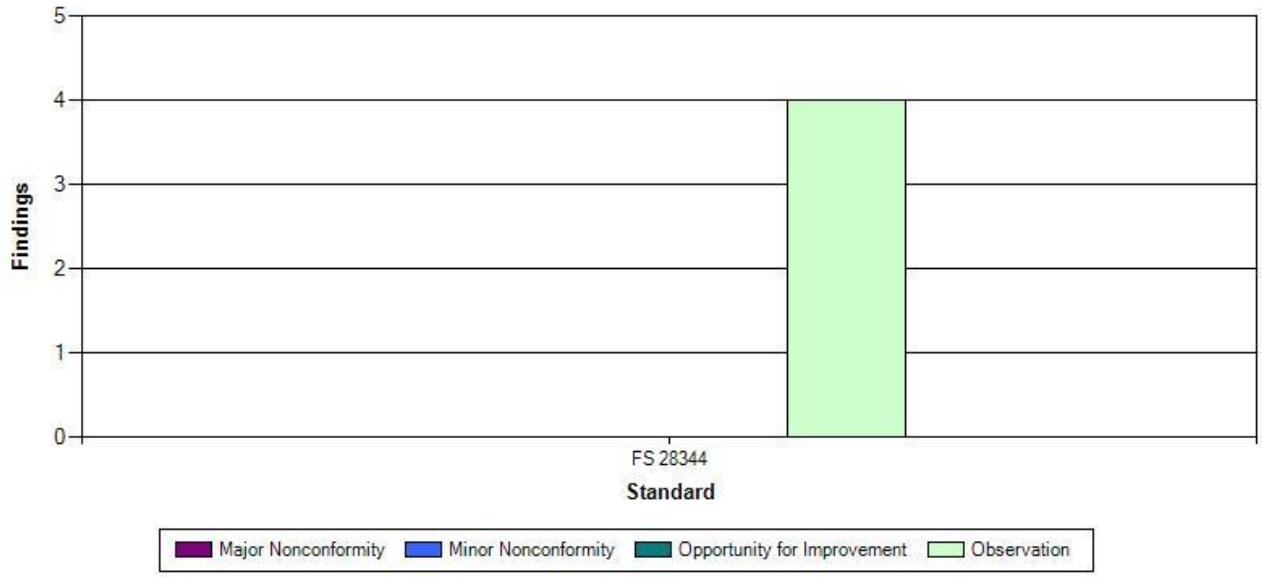
The objective of the assessment was to conduct a readiness review in order to determine the client's degree of compliance to ISO 9001:2015

The management system processes at Viamed Ltd, 15/17 Station Road, Cross Hills, Keighley, BD20 7DT, United Kingdom

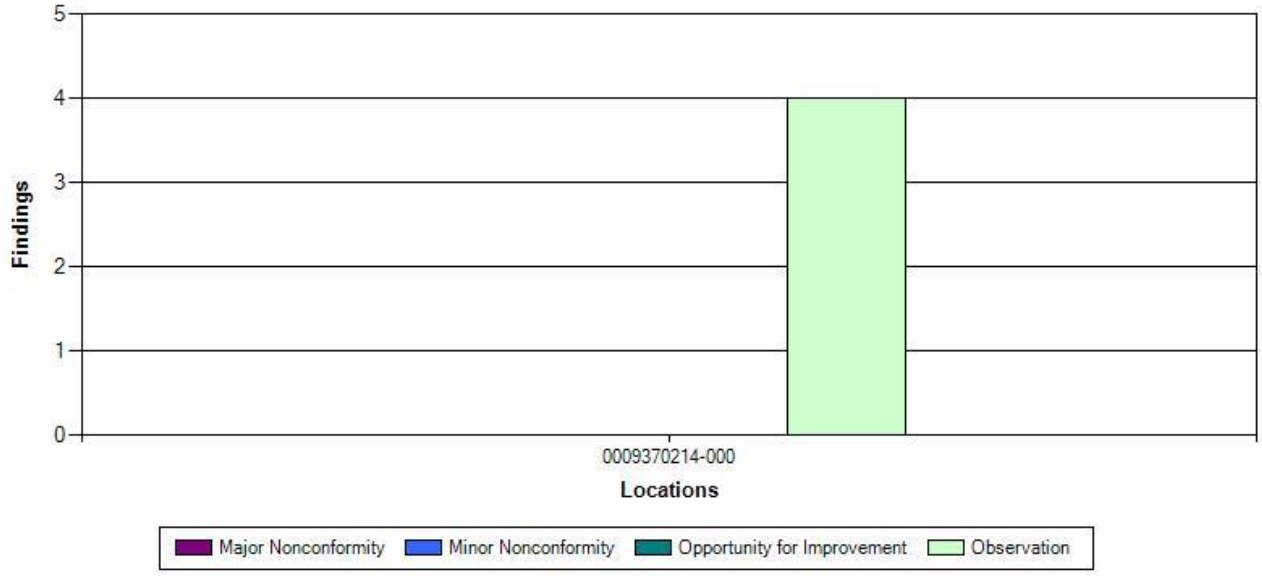
ISO 9001:2015, The readiness review checklist and supporting documents provided by Viamed

NCR Summary

Which standard(s) BSI recorded findings against



Where BSI recorded findings



Definitions:

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.

Assessment Participants

Name	Position	Opening Meeting	Closing Meeting	Interviewed (processes)
Derek Lamb	MD / CEO	X	X	X

Assessment Findings

The assessment was conducted on behalf of BSI by

Name	Position
David Vicar	Team leader

Assessment conclusion and recommendation

The audit objectives have been achieved and the certificate scope remains appropriate. The audit team concludes based on the results of this audit that Viamed Ltd does fulfil the standards and audit criteria identified within the audit report and it is deemed that the management system continues to achieve its intended outcomes.

The organisation has completed the readiness review with respect to ISO 9001:2015. Transition to ISO 9001:2015 can be scheduled and assessed at the next surveillance assessment.

Use of certification documents, mark / logo or report

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

Findings

Opening meeting and closing meeting:
The opening meeting and closing meeting were conducted via telephone with the MD / CEO.

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 with respect to this readiness review were confirmed as follows:

FS 28344 - The design, manufacture, service, repair, maintenance and supply of medical monitoring, ventilation and anaesthetic equipment including that carried out on customer premises.

Quality Manual Version: 2017:19808

Exclusions and Non-Applications of Requirements in the QMS:
ISO 13485 clauses 7.5.3.2.2, 7.5.2.2, 7.5.1.3 relating to the requirements for implantable/active implantable and sterility are stated to be non applicable due to the nature of the products.

Significant Changes:
There have not been any major or significant changes to the QMS, organisational structure, products or process 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). Even these products are 100% given a function check by the client.
InveteC - Wismer Gmbh Ulmweltschutz & Medizintechnik, Alter Holzhafen 18, 23966, Wismar, Germany for the manufacture of Electrochemical Oxygen Sensors.

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

Management Representative:
Mr Derek Lamb – MD/CEO
email: derek.lamb@viamed.co.uk
tel: 01535 634542

Staffing and Audit Durations:
Staffing and effective staffing numbers were reviewed against IAF MD9 annex D and MDP200 (CP0200). The effective number of staff was stated to be 15. Based on the number of effective staff and the planned transitions to include ISO 13485 and ISO 9001:2015 requirements, the audit days are recommended to be 1.5 day surveillance and 3 days recertification.

Transition was discussed. The next surveillance assessment has been arranged to also include transition to ISO 9001:2015 and ISO 13485:2016. An additional assessment day over and above the normal visit cycle is required to support the planned transitions.

Remote Readiness Review of Viamed Quality Management System - ISO 9001:2015: 4, 5, 6, 7, 8, 9, 10:

Detail regarding how the organisation addresses the changes within the 2015 standard are included within the transition report completed and issued together with this report. Not all of the requirements could be assessed for implementation at this remote readiness review and compliance will be sampled at the next assessment visit.

During this remote assessment some observations were made with respect to compliance against specific clauses. These are identified below.

Observations

Ref. no	1474476-201705-O1
Area/Process	Remote Readiness Review of Viamed Quality Management System - ISO 9001:2015: 4, 5, 6, 7, 8, 9, 10
Clause	2015:4.2
Scope	FS 28344
Details	Interested parties and their needs and expectations are not clearly documented in the readiness review information provided, or supporting documentation.

Ref. no	1474476-201705-O2
Area/Process	Remote Readiness Review of Viamed Quality Management System - ISO 9001:2015: 4, 5, 6, 7, 8, 9, 10
Clause	2015:4.3
Scope	FS 28344
Details	1. Document VM3/COP/02.01 identifies clauses of the QMS not applicable with respect to ISO 13485. No reference is made to ISO 9001:2015 requirements. 2. The referenced document does not clearly identify which revision (year) of the management system standards for ISO 9001 and ISO 13485 the quality management system intends to meet.

Ref. no	1474476-201705-O3
Area/Process	Remote Readiness Review of Viamed Quality Management System - ISO 9001:2015: 4, 5, 6, 7, 8, 9, 10
Clause	2015:4.4
Scope	FS 28344
Details	Although a Quality Manual is maintained to meet the requirements of ISO 13485 as well as ISO 9001 the sequence and interaction of and between processes was not clearly provided for this remote review.

Ref. no	1474476-201705-O4
Area/Process	Remote Readiness Review of Viamed Quality Management System - ISO 9001:2015: 4, 5, 6, 7, 8, 9, 10
Clause	6.1
Scope	FS 28344
Details	Processes are stated to be under review with respect to identifying risks within the processes. This is stated to be 60-70% complete. Methods for how these risks are identified or how overall risks and opportunities related to clauses 4.1 and 4.2 are identified could not be provided during this remote readiness review.

Our next steps

Clauses without parentheses relate to ISO 13485:2003/2012 and ISO 9001:2008
Clauses in parentheses (…) relate to ISO 13485:2016
Clauses in parentheses […] relate to ISO 9001:2015

Next Visit Plan

Date	Auditor	Time	Area/Process	Clause
12 Sept 2017	David Vicar	09:00	Opening Meeting, QMS System, Document and Record Control, Quality Policy and Objectives, Management Responsibility and Changes	4, 4.2.2, 4.2.3, 5.2, 5.2, 5.3, 5.4, 5.5 (4, 4,1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5) [4, 4.4, 5, 5.1, 5.2, 6, 7.5]
			Management Review and Data Analysis	5.6, 8.4, (5.6, 8.4), [9.3, 9.1.3]
			Internal Audit and Monitoring of Product and Processes	8.2.2 (8.2.4, 8.2.5, 8.2.6) [9.2, 9.1, 8.6]
			Improvement: Preventive and Corrective Action	8.5, (8.5), [10]
			Customer Related Processes, Complaint Handling and Vigilance	7.2, 8.2.1, (7.2, 8.2.1, 8.2.2, 8.2.3), MDD, [8.2, 8.5.5, 9.1.2]
		12:30	Lunch	
		13:00	Customer Related Processes: Sales and dispatch	7.2, 8.2.1, (7.2, 8.2.1, 8.2.2, 8.2.3), [8.2, 8.5.5, 9.1.2]
		14:00	Manufacture and test: Head boxes and phototherapy shields, Tom Thumb resuscitator To include final product release	7.1, 7.5, 7.6, 8.3, 6.3, 6.4 (7.1, 7.5, 7.6, 8.3, 6.3, 6.4) [8.1, 8.5, 7.1.5, 8.7, 7.1.3, 7.1.4]
		15:45	Audit trails, report preparation	
		16:15	Summary – End of day 1	

13 Sept 2017	David Vicar	09:00	Control of Monitoring and Measuring Devices, control of nonconforming product	7.6, 8.3 (7.6, 8.3) [7.1.5, 8.7]
		10:30	Control of Suppliers, Purchasing and incoming inspection. Including OBL/Virtual Manufacturer requirements. Consideration of new requirements within ISO 13485:2016 and ISO 9001:2015	7.4 (7.4) [8.4]
		12:00	Infrastructure and work environment – consideration of new requirements within ISO 13485:2016 and ISO 9001:2015	6.3, 6.4 (6.3, 6.4) [7.1.3, 7.1.4]
		12:30	Lunch	
		13:00	Design, Development and Risk Assessment Processes - consideration of new requirements within ISO 13485:2016 and ISO 9001:2015	7.1, 7.3 (7.1, 7.3) [8.1, 8.3]
		14:30	Human Resources: Competency, Awareness and Training	6.2.2 (6.1, 6.2) [7.1.1, 7.1.2, 7.2, 7.3]
		15:45	Audit trails, report preparation	
		16:15	Summary – End of day 2	
14 Sept 2017	David Vicar	09:00	Checklist: Transition to ISO 9001:2015 and ISO 13485:2016	(4, 5, 6, 7, 8, 9, 10)
			MDD Checklist	8.5.1, 7.2.1, MDD
		11:00	Report preparation, audit trails	
		12:00	Closing meeting, leave site 12:30, report to follow.	

Next visit objectives, scope and criteria

Visit Objective:

To conduct a surveillance assessment and transition assessment to determine the continued effectiveness of implementation of the company's management system, in accordance with the company objectives, policies and procedures, the management standard(s) & 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 all requirements of ISO 9001:2015 have been effectively implemented where this has been agreed with BSI in advance of the visit.

To verify Viamed Ltd continues to effectively implement all requirements of ISO13485:2003 and EN ISO 13485:2012.
To verify all requirements of ISO 13485:2016 have been fully and effectively implemented where this has been agreed with BSI in advance of the visit.

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

Visit Scope:

The management system processes and location activities at Viamed Ltd, 15/17 Station Road, (adjacent premises) Cross
Hills, Keighley, BD20 7DT address being audited in the UK.

Visit Criteria:

Viamed Ltd's management system documentation, ISO 9001:2008, ISO 9001:2015, ISO 13485:2003, ISO 13485:2012, ISO 13485:2016, ISO 13485 under CMDCAS and the MDD 93/42/EEC Annex II 3.2 and the BSI conditions of contract

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.

Your next steps

NCR close out process

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.

How to contact customer service

'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/FS 28344).

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

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

Tel: +44 (0)345 080 9000

Email: MK.Customerservices@bsigroup.com

Appendix: Your certification structure & on-going assessment programme

Scope of Certification

FS 28344 (ISO 9001:2008)
The design, manufacture, service, repair, maintenance and supply of medical monitoring, ventilation and anaesthetic equipment including that carried out on customer premises.

Assessed location(s)

The audit has been performed at Central Office.

Keighley / FS 28344 (ISO 9001:2008)

Location reference	0009370214-000
Address	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom
Visit type	Transition Audit
Assessment reference	8651653
Assessment dates	08/05/2017
Audit Plan (Revision Date)	19/04/2017
Deviation from Audit Plan	No
No. of Full Time Equivalent Employees	15
Total No. of Effective Employees at the site	15
Scope of activities at the site	Main Certificate Scope applies.
Assessment duration	0.5 day(s)

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.

Certification assessment programme

Certificate Number - FS 28344
Location reference - 0009370214-000

		Audit1	Audit2	Audit3
Business area/Location	**Date (mm/yy):**	09/16	09/17	09/18
	Duration (days):	1.5	1.5	3
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				X
Manufacture and test:		X	X	X
Head boxes and phototherapy shields			X	X
Nerve stimulators		X		X
Tom Thumb resuscitator			X	X
Pulse oximeter probes				X
Purchasing, supplier controls, incoming inspection		X		X
Sales and order processing and dispatch.			X	X
OBL/Virtual Manufacturer requirements		X	X	X
HR/Training/Competence			X	X
Work Environment and Infrastructure			X	X
Recertification				X
Top Management Discussion			X	X
Transition to ISO 9001:2015 and ISO 13485:2016 (1 additional day over and above the assessment cycle)			X	

Expected outcomes for accredited certification.

What accredited certification to ISO 9001 means

ISO 9001:2015 specifies requirements for a quality management system when an organization: needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements; and aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

What accredited certification to ISO 9001 does not mean

1) It is important to recognize that ISO 9001 defines the requirements for an organization's quality management system, not for its products and services. Accredited certification to ISO 9001 should provide confidence in the organization's ability to "consistently provide product that meets customer and applicable statutory and regulatory requirements". It does not necessarily ensure that the organization will always achieve 100% product conformity, though this should of course be a permanent goal.
2) ISO 9001 accredited certification does not imply that the organization is providing a superior Product or service, or that the product or service itself is certified as meeting the requirements of an ISO (or any other) standard or specification.

Notes

This report and related documents are 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. If you wish to distribute copies of this report external to your organisation, then all pages must be included.

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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.