Transition Report.

Viamed Ltd

Report Author **David Vicar**

Visit Start Date 08/05/2017

Transition.

This report has been compiled by David Vicar and relates to the assessment activity detailed below:

Visit ref/Type/Date/Duration	Certificate/Standard	Site address
8651653 Transition Audit 08/05/2017 0.5 day(s) No. Employees: 15	FS 28344 ISO 9001:2008	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom

9001 Transition

ISO 9001:2008 has been replaced by ISO 9001:2015.
ISO 9001:2008 certifications will not be valid after three years from the publication of ISO 9001:2015.
All ISO 9001:2008 certificates will remain valid through the period, however the expiry date of ISO 9001:2008 certificates will be limited and will not exceed the transition deadline date and will expire in September 2018. To ensure continued certification you must complete your transition ahead of this date.
Based on the objective evidence provided throughout the assessment process, the current progress made against the revised standard is: 0%

4. Context of the organization

4.1 Understanding the organization and its context

Demonstrated : Partial

Auditor notes : The organisation has determined the sources of external and internal issues relevant to the business, documented in System Model Chart App 1. An issues system is in place to capture and act upon identified issues. A future assessment visit to include review of the monitoring system(s).

4.2 Understanding the needs and expectations of interested parties

Demonstrated : Partial

Auditor notes : The organisation has not clearly identified the interested parties relevant to the QMS or their needs and expectations. The methods of monitoring and review are documented to be the "issue" system, management review and other system reviews. A future assessment visit to include the identification, monitoring and review system with respect to interested parties.

4.3 Determining the scope of the quality management system

Demonstrated : Partial

Auditor notes : The scope of the QMS is documented in Management System Description, 8804 dated 12 Oct 2011. The document identifies ISO 13485, ISO 9001, MDD and CMDCAS but does not clearly identify the year/revision of the management system standards. Elements of the ISO 13485 management system standard are identified as non-applicable (7.5.3.2.2, 7.5.2.2 and 7.5.1.3) in document VM3/COP/02.01. There is no reference to ISO 9001:2015.

4.4 Quality management system and its processes

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. A Quality Manual is maintained. Procedures and roles/responsibilities are documented and identified and ownership of processes is documented in a flowchart. Sequence of and interaction between these processes and records related to operation of these processes can be assessed at future assessments.

5 Leadership

5.1 Leadership and commitment

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. An organisation chart is maintained. Top Management responsibility is identified in the Quality Manual and the Management System Description, 8804 dated 12 Oct 2011. Management Reviews are stated to be held 6-monthly.

5.2 Policy

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. A Quality Policy is maintained and documented to be reviewed yearly, next review Oct 2017. Future assessment to confirm availability and applicability.

5.3 Organization roles, responsibilities and authorities

Demonstrated : Partial

Auditor notes : Structured organizational roles and responsibilities/job descriptions are defined. These will be followed up as part of assessing the processes and their effectiveness.

6 Planning

6.1 Actions to address risks and opportunities

Demonstrated : No

Auditor notes : The information provided states that risks are assessed per process, but is 60-70% complete. Methods of how risks and opportunities are identified has not been provided. A future assessment visit to confirm implementation availability and applicability and to ensure that risk and opportunity management remains current.

6.2 Quality objectives and planning to achieve them

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Measurable quality objectives are identifed in defined headings in management meeting agendas. A future assessment to
include sight of the current objectives and review the planning for how these are to be achieved and monitored.

6.3 Planning of Changes

Demonstrated : Partial

Auditor notes : The process described identifies how compliance with the requirements of 6.3 are intended to be met via the 'issues' system. A future assessment visit to confirm implementation.

7 Support

7.1 Resource

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. System resources are stated to be monitored via the Analysis of Data (13485 clause 8.4) and management review inputs/outputs. There is yearly post market surveillance in place for medical devices and organisational knowledge is monitored via training records. Compliance will be reviewed during subsequent continuing assessment visits.

7.2 Competence

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Records for training and competence are maintained. This will be reviewed during subsequent continuing assessment visits.

7.3 Awareness

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. The MD / CEO is also the management representative and has responsibilities related to promoting the awareness of employees with respect to the policy/objectives and QMS effectiveness. This will be reviewed during subsequent continuing assessment visits.

7.4 Communication

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Communication and feedback requirements are documented with process owners. This will be reviewed during subsequent continuing assessment visits.

7.5 Documented Information

7.5.1 General

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Control of Documents and Records and therefore documented information procedures are established. This will be reviewed during subsequent continuing assessment visits.

8 Operation

8.1 Operational planning and control

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001 which includes the requirements for operational planning. Outsourced suppliers are documented to be certified to 9001 or 13485 apart from one,

plastics cutting, for which incoming inspection activities are stated to be performed. Records and activities related to operational planning will be reviewed during subsequent continuing assessment visits.

8.2 Requirements for products and services

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. A technical file is maintained per medical product. The organisations current system thought to comply. The processes related to sales / customer requirements to be assessed at the next surveillance assessment.

8.3 Design and development of products and services

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Design procedures are maintained and a technical file is maintained per medical product. At the opening meeting it was stated that there are currently no new designs and the process with respect to OBL/Virtual Manufacturer is currently being assessed against EU commission guidance. Compliance to be assessed at the next surveillance assessment.

8.4 Control of externally provided processes, products and services

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Supplier approval, re-approval and purchasing procedures are documented. Compliance to be assessed at the next surveillance assessment.

8.5 Production and service provision

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Requirements for production and service provision, traceability and customer returns / customer property are determined/documented. Compliance to be assessed at the next surveillance assessment.

8.6 Release of products and services

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Requirements related to final inspection and test are documented and records maintained. Compliance to be assessed at the next surveillance assessment.

8.7 Control of nonconforming outputs

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Requirements related to control of NC product are documented and records maintained. Compliance to be assessed at the next surveillance assessment.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Requirements related to Analysis of data are documented and records maintained. Actions are recorded and progressed via the 'issue' system. Compliance to be assessed at the next surveillance assessment.

9.2 Internal Audits

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Requirements related to internal audit are documented and records maintained. Additional mini-audits related to job roles have been identified. Compliance to the requirements for internal audit to be assessed at the next surveillance assessment.

9.3 Management Review

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Requirements related to management review are documented and records retained. Compliance to the requirements for management review to be assessed at the next surveillance assessment.

10 Improvement

10.1 General

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Reference is made to the Intrastats system for monitoring QMS and customer satisfaction. Compliance to be assessed at the next surveillance assessment.

10.2 Nonconformity and corrective action

Demonstrated : Partial

Auditor notes : Viamed are certified to ISO 13485 and CMDCAS requirements in addition to ISO 9001. Reference is made to the 'issues' system for identifying and tracking nonconformities and corrective actions. Procedures related to control of NC product and Corrective actions are maintained. Compliance to be assessed at the next surveillance assessment.

10.3 Continual improvement

Demonstrated : Partial

Auditor notes : The information provided would appear to satisfy the requirements of this element of ISO 9001:2015. Concern related to the ability to identify suitability and effectiveness of procedural changes (as improvements) has been identified and an issue has been raised by Viamed on issue reference 94214. Compliance related to continual improvement will be reviewed during subsequent continuing assessment visits.