



Assessment Report.

**Report
Author**

Edward Collins

Visit Start Date

26/02/2014

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Introduction.

This report has been compiled by Edward Collins and relates to the assessment activity detailed below:

Visit ref/Type/Date/Duration	Certificate/Standard	Site address
8077440 Stage 1 Audit 26/02/2014 0.5 day(s) No. Employees: 4	FM 607767 ISO 9001:2008	VST Ltd 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of the assessment was to determine the organisation's readiness for the stage 2 audit and to ensure its effective planning.

Management Summary.

Overall Conclusion

The objectives of the assessment have been achieved

I am pleased to confirm your readiness to go for Stage Two assessment

Progress has been established towards certification. There are no known nonconformities at this time.

The stage 2 audit duration is planned to be one day.

The scope of the audit is - The design, development and supply of gas sensors and associated systems.

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

Mandatory Requirements.

Justified Exclusions:

No exclusions are claimed

Areas Assessed & Findings.

Overview :

VST is a subsidiary company operating out of the same premises as Viamed who manufacture medical ventilation and anaesthetic equipment and who are an existing customer of BSi holding a range of certificates that includes management certificates for ISO 9001 and ISO 13485.

VST share premise, quality management systems and staff with Viamed. For operational reasons a separate certificate is required for VST who supply gas sensors and associated electronics to oem manufacturers who incorporate these into equipment used in the diving industry. The proposed scope for VST is a small proportion of overall business activity taking place on site. Of the four staff involved, the full time equivalent is one. Regulatory requirements for the product are determined by the oem manufacturers. The EMC directive will apply to these products.

Core QA System :

This is established as part of Viamed. A separate quality policy is documented for VST. All other systems are shared.

Core QA processes :

Management review and internal audits are established and use the same electronic management system as Viamed.

Core objectives: These have yet to be fully established, however the electronic management system used to monitor and measure key measurable is established

Assessment Participants.

On behalf of the organisation:

Name	Position
Mr Lamb	MD

The assessment was conducted on behalf of BSI by:

Name	Position
Edward Collins	Team Leader

Next Visit Plan.

Visit objectives:

The objective of the assessment is to conduct a certification assessment to ensure the elements of the proposed scope of registration and the requirements of the management standard are effectively addressed by the organisation's management system and to confirm the forward strategic plan.

The scope of the assessment is the documented management system with relation to the requirements of ISO 9001 and the defined assessment plan provided in terms of locations and areas of the system and organisation to be assessed.

Date	Assessor	Time	Area/Process	Clause
20 th May 2014	Edward Collins (to be advised)	09.00	Opening Meeting - review of changes since the previous assessment visit - changes to quality system, product range or key processes.	4.1, 4.2
		09.15	QA - including objectives for quality and improvement. Internal audits, management review, corrective action, preventive action and customer satisfaction. Document and Quality records control.	5.4.1, 8.2.2, 5.6, 5.4.2, 8.5.2, 8.5.3, 8.5.1, 8.2.1, 4.2.3, 4.2.4
		11.00	Design and development	7.3
		12.00	Sales order processing	7.2
		12.30	Lunch	
		13.00	Purchasing and supplier control	7.4
		14.00	Order fulfilment	7.1, 7.5
		15.00	Report preparation	
		16.00	Closing meeting	
		16.30	Leave site	

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the organisation within 30 days of an agreed visit date. It is a condition of Registration that a deputy management representative be nominated. It is expected that the deputy would stand in should the management representative find themselves unavailable to attend an agreed visit within 30 days of its conduct.

Notes.

The assessment was based on sampling and therefore nonconformities may exist which have not been identified.

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