

# Assessment Report

## Vandagraph Sensor Technologies Ltd.

Assessment dates	29/10/2020 to 30/10/2020 (Please refer to Appendix for details)
Assessment Location(s)	Keighley (001)
Report author	Mostafa Seddighi
Assessment Standard(s)	ISO 9001:2015



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## Executive summary

The management system is seen to be achieving its objectives for supplying product and service delivery. These were observed to be used to identify where objectives were not being met and monitor the effectiveness of actions to improve.

The management system continues to work in the context of the business and effectiveness of system seen to be evaluated in management review and actions to maintain and improve the effectiveness were defined.

## Changes in the organization since last assessment

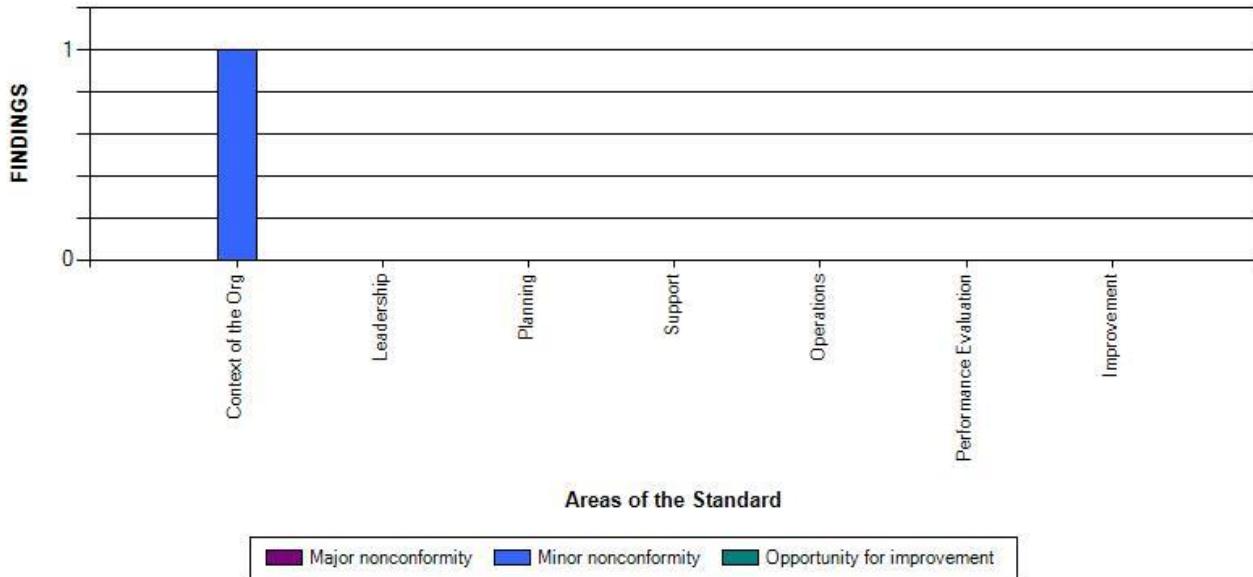
There is no significant change of the organization structure and key personnel involved in the audited management system.

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

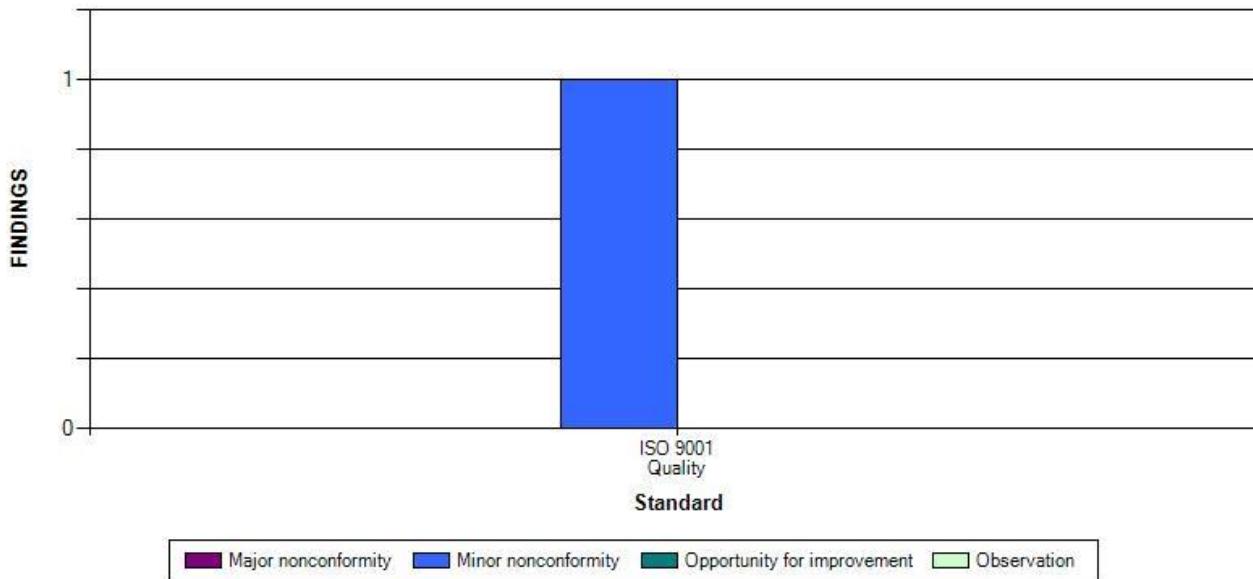
There was no change to the reference or normative documents which is related to the scope of certification.

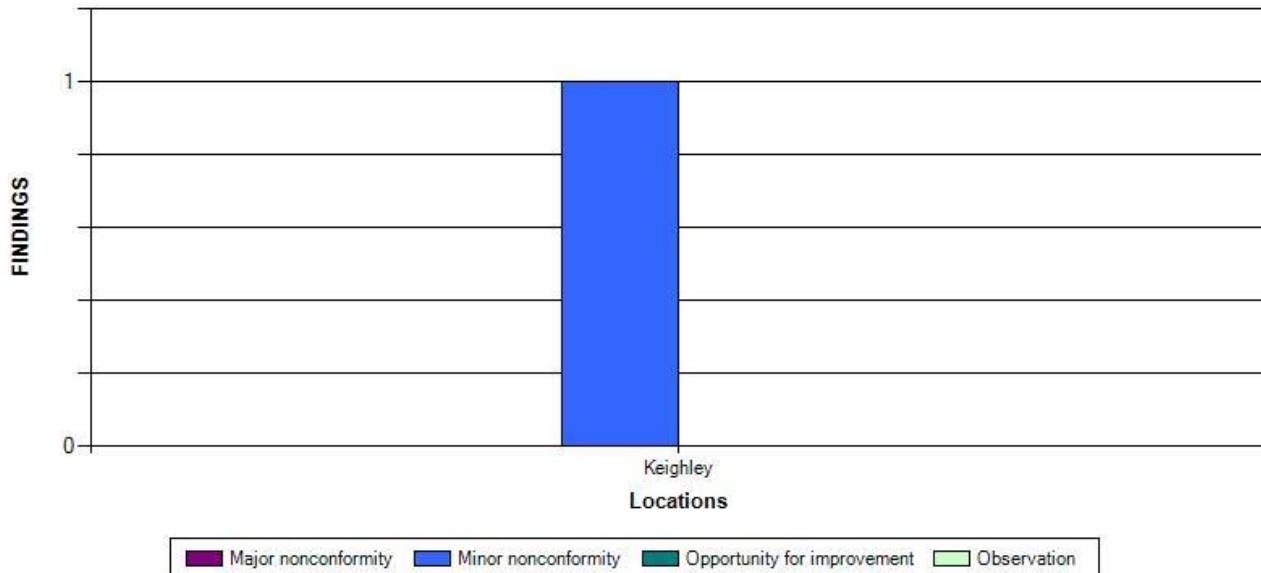
## NCR summary graphs

### Areas of the standard(s) where BSI recorded findings



### Which standard(s) BSI recorded findings against



**Where BSI recorded findings**

## Your next steps

### **NCR close out process**

There were no outstanding nonconformities to review from previous assessments.

A minor nonconformity requiring attention was identified. This, along with other findings, is contained within subsequent sections of the report.

A minor nonconformity relates to a single identified lapse, which in itself would not indicate a breakdown in the management system's ability to effectively control the processes for which it was intended. It is necessary to investigate the underlying cause of any issue to determine corrective action. The proposed action will be reviewed for effective implementation at the next assessment.

Please refer to Assessment Conclusion and Recommendation section for the required submission and the defined timeline.

## Assessment objective, scope and criteria

The objective of the assessment was to ascertain the integrity of the organization's management system over the current assessment cycle to enable recertification and confirm the forward strategic assessment plan.

The scope of the assessment is the documented management system with relation to the requirements of ISO 9001-2015 and the defined assessment plan provided in terms of locations and areas of the system and organization to be assessed.

ISO 9001-2015

Vandagraph Sensor Technologies Ltd management system documentation

## Statutory and regulatory requirements

NA

## Assessment participants

Name	Position	Opening meeting	Closing meeting	Interviewed(processes)
Derek Lamb	MD	X	X	X
Helen Lamb	Account Manager	X	X	X

## Assessment conclusion

BSI assessment team

Name	Position
Mostafa Seddighi	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 the organization 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.

**RECOMMENDED - Corrective Action Plan Required ('Minor' findings only):** The audited organization may be recommended for certification / continued certification, based upon the acceptance of a satisfactory corrective action plan for all 'Minor' findings as shown in this report. Effective implementation of corrective actions will be reviewed during the next surveillance audit.

Please submit a plan to BSI detailing the nonconformity, the root cause, correction and your proposed corrective action, with responsibilities and timescales allocated. The plan is to be submitted no later than 30/10/2020. If the corrective action plan is not received by this date you may be putting your certification status at risk. Send the plan through the BSI Assurance Portal (if this is enabled for your account) or by email to, referencing the report number 3259753.

### Use of certification documents, mark / logo or report

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

## Findings from this assessment

### **Essential Assessment Information: QMS System Review, QMS, Business, Product & Process Changes and Improvements Objectives and Targets Management Responsibility and Changes, 4.3, 6.3:**

Opening Meeting, Manufacturer Information and Changes

The opening meeting was conducted with the presence of Managing Director and Account Manager.

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 follows:

FM607767: The supply of gas sensors and associated systems

Exclusions and Non-Applications of Requirements in the QMS:

- 8.3.2, 8.3.4, 8.3.5, 8.4.1, 8.5.1, 8.5.2, 8.5.4, 8.5.6 (VM3COP02.01 Boundaries ISO 9001:2015 VST DOC ID 23739). See the NC.

Significant Changes:

There have not been any major or significant changes to the QMS, organisational structure, products or process since the last visit.

Description of the manufacturer:

Vandagraph Sensor Technologies (VST) distribute a range of Oxygen sensors in a world market. VST does not manufacture product by itself. Processes include QA, purchasing, sales, warehousing and distribution.

Staffing and Audit Durations:

Staffing and effective staffing numbers were reviewed against IAF MD9 annex D and MDP7300. The effective number of staff was stated to be 3. 20% reduction is permissible due to outsourcing of manufacture. Based on the number of effective staff and the recommended 20% reduction, the audit days are appropriate at 1 day surveillance and 2 days recertification.

Senior Management of the Assessment Location(s).

Derek Lamb MD

### **Context of the organization, QMS boundaries, scope and Processes, policy and Objectives: 4.1, 4.2, 4.3, 4.4, 6.1, 6.2**

The Context of the organization, QMS boundaries, scope and Processes were assessed with MD remotely through Zoom in auditor home office.

Control of these areas is supported by VOP24 Issue 1, 30. 09. 2019: Need Risks and Expectation of External Parties.

This was reviewed and implementation was demonstrated.

Other key documents and records reviewed were:

Scope: DOCID 24442, 1. 12. 2017

VM3COP02.01 Boundaries ISO 9001:2015 VST DOC ID 23739

Intrastats Overview Doc. ID 681 28. 10. 2017

Doc 43198 Need Risks and Expectations of External Parties VST 8. 09, 2020

Route Map to Documents and Procedures 12. 10. 2020 (DOCID 45514)

Policy DOCID 22684 issue date 16. 09. 2017

VOP13 Process monitoring Issue 1, 30. 09. 2019

Objectives: DOCID 46732, issue date 29. 10. 2020

The QMS documentation was seen to contain all the required information including the scope, document structure, process interactions and details and justification for not applicable and excluded clauses. The scope of the QMS included the boundaries and product range.

The Interrelation of personnel was seen to be documented within organization structure

The quality policy was seen to be applicable to purpose of the org and included the required commitment to customer satisfaction, comply with regulations and continuous improvement the effectiveness of the QMS. It is reviewed for continued suitability at management review and is communicated by Intarstats documentation system.

The objectives for the organisation were seen to be set at relevant levels and functions and for each individual process based on identified risks and opportunities and to be measurable and consistent with the quality policy. Performance against these objectives was seen to be monitored through VST Management Meeting and at the management review.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for the quality manual, policy and objectives were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Top Management Discussion, Quality Policy, and objectives: 5.1, 5.2, 6.2, 6.3**

Management responsibility, commitment, strategy and provision of resources was assessed with MD remotely through Zoom in auditor home office.

Overall strategic control is supported by Quality Policy and objectives.

These were reviewed and implementation was demonstrated.

Objectives are determined based on risks and opportunities identified through risk assessment and documented in DOCID 46732, 29. 10. 2020

The organisation's overall quality objectives are

- Maintain and improve QMS, quality and customer satisfaction
- Continuously running the process to achieve intended results

Objectives are defined at the level of process, and is monitored periodically and at management review.

Communication of these objectives and provision of resources to achieve them was demonstrated.

Other key documents and records reviewed were

- Policy issue date 16. 09. 2017, DOCID 22684,
- Doc 43198 Need, Risks and Expectations of External Parties VST 8. 09, 2020,

- Objectives: 46732, 29. 10. 2020
- VST Management Meeting (Live document)

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for management responsibility, commitment, strategy, communication and provision of resources were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Monitoring performance, analysis and Management Review: 9.1.1, 9.1.3, 9.3**

Monitoring performance, analysis and Management Review was assessed with MD remotely through Zoom in auditor home office.

Control of these processes is supported by VOP13 Process Monitoring Issue 1, 30. 09. 2019

This was reviewed and implementation was demonstrated.

Other key documents and records reviewed were

Management Review minutes of meeting: 28. 09. 2020 Issue ID 202841

Task 750, Product Failures New Codes Review DOCID 201003, 16. 10. 2020,

Task 742: Review product feedback - Delivery time (due to COVID-19), Jul. 2020

Task 740: Customer feedback: no negative feedback to require action/ CA

VM3COP02 Organization Complete Overview.

-Each risk/opportunities are addressed based on process ID, and their status and effectiveness is monitored as part of each individual process structure which is filled in.

Status is displayed by Task/Responsibility matrix (monitoring): VM3COP02 Organization Complete Overview.

The management review meetings were seen to be held at documented planned intervals of annually. The records of the management review meetings showed that all the required inputs and outputs of the standard were discussed and actions raised as appropriate.

The required sources of data was seen to be appropriately and compliantly analysed and where the analysis showed the QMS is not suitable adequate or effective actions are raised in the form of Issue/CA.

e.g. Product code 8010012: all repairs data taken and percentage of each individual fault and overall percentage was determined (overall 1.39%) and as target met no CA has been taken.

Conformity of product and process performance is monitored and analysed by trend of defects.

Trend of returned (annual figures for each kind of sensor) is monitored and analysed. no significant deviation has been observed.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for performance analysis and Management Review were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Internal audit: 9.2**

The Internal audit process was assessed with MD remotely through Zoom in auditor home office. Control of this process is supported by Process monitoring VOP13, Issue 1, 30. 09. 2019.

Implementation of the planned internal audit schedule was demonstrated.

Other key supporting documents reviewed were:

- Internal Audit Schedule: QC 17, updated 12. 10. 2020

The following internal audit report samples were taken:

ID 161466 Audit 09, 1. 09. 2020, picking /packing audit report

Issue number 196533: document missing (related sales process/order), open

ID 173585 Audit 07, Handling and storage 4. 09. 2020, no issue raised

ID 184656, Audit 06, Calibration audit 3. 9. 2020, no issue raised

ID 186613, Audit number 10, Documentation control, 7. 09. 2020, no issue raised

ID 1888850 Audit 08, HR & training, 15. 09. 2020

QC 17 Audit Schedule (Audit number and job number, status of audit, issue number..)

Previous finding/issue checked and closed. No issue raised

The internal audit schedule was seen to cover all QMS elements and processes in Audit Schedule (QC17) and by the audit checklist. The internal audit program was seen to cover requirements of ISO 9001-2015, and the QMS and to be scheduled taking into account the status and importance of the processes and area to be audited, as well as the results of previous audits by reviewing the raised issues. The audit records reviewed included the audit criteria, scope, interval, methods, identification of the processes and areas audited and the conclusions.

Where non-conformities were identified during the audits reviewed corrections and corrective actions were seen to be managed by CA/ Issue report including the appropriate and compliant follow up activities.

The organisation has 3 internal auditors/ staff deemed competent by certificate/training to carry out internal audits. Evidence of this competence was assessed.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for internal audit were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## Feedback Processes, Complaint Management: 9.1.2

Customer feedback processes including the management of customer complaints, and returns were assessed with MD remotely through Zoom in auditor home office.

Control of these processes is supported by VOP 19, Issue 1, 30. 09. 2019 (Complaints Vigilance and Notifications VST Ltd.)

These were reviewed and implementation of them was demonstrated.

Other key documents reviewed were:

- Intrastats Complaint handling module
- 7843 Review VST Product Feedback Negative
- Agenda ID 639; VST Feedback- Product Feedback Positive

The organisation has received one customer complaints since last visit.

The following samples were taken:

-complaint 154298, 13. 09. 2019

3 sensors were returned (batch qty 526)

the sensors were replaced as containment.

No CA has been defined as no definite root cause identified

Customer perception is monitored through monitoring sales trend and feedback/issue raised by the customers. A system to register customer issue and take action is in place.

Following samples of feedback were seen.

JFD Ltd sales record (CID10868)

Customer positive feedback: 2. 04. 2020 (Beyond Technical)

Sample id 151898, 15557, 151896 (Positive feedback)

Product Feedback Negative is triggered to MD once a month, the ID 201568, 22. 10. 2020, seen as sample. no issue was raised.

Based on feedback information analysis no CA/PA has been issued, and no opportunity found.

The compliant handling records reviewed included appropriately and compliantly recorded information, investigation, and corrective action determination and completion as required. If a complaint was not investigated justification had been recorded. Relevant customer communication was seen to have been completed.

returned product was seen to be compliantly identified, distinguished and handled.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for feedback processes including customer complaints, and returns were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Improvement - Risk and Prevention, Nonconformity, and Corrective Actions including Process Change Management. 8.7, 10**

Improvement processes including the management of corrective and preventive actions and process change were assessed with MD remotely through Zoom in auditor home office.

Control of these processes is supported by Process VOP10 Issue 1, 28. 10. 2020 (Non-conformance, Corrective and Preventive Actions).

These were reviewed and implementation was demonstrated.

Other key documents reviewed were:

The organisation has initiated 2 corrective actions since last visit of which 2 corrective actions are still open.

The following samples were taken:

NC: QC 21 NC Report

167501, 03. 03. 2020

sales order entry issue: wrong delivery date set (Human error)

The order has been corrected.

CA is determined to prevent re-occur  
CA is still on going and monitors

Issue 202853, 28. 10. 2020  
Customer return (incorrect body size)  
Investigation is in-process.

The records reviewed showed that non-conformities and potential non-conformities have been appropriately and compliantly identified, reviewed and investigated to determine root cause. The need for action was seen to have been determined, implemented and include a verification of the effectiveness of the action.

Where process changes have been required the records showed that an evaluation of the impact on QMS, interested parties and product has taken place. A process is in place to ensure changes that require reporting or notification to the notified body.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for improvement including preventive and corrective actions and process change management were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Sales/Order Processing and Customer Related Processes: 8.2, 8.5.2, 8.5.3, 8.5.5**

Sales processes and customer related processes was assessed with MD and Account Manager in client office.

Control of these processes is supported by VOP03, Issue 1, 30. 09. 2019.

This was reviewed and implementation was demonstrated.

The following sales orders and product despatch records were sampled:

- Order 126736, 22. 10. 2020, Product code 8030498
- Order 124898-1, 13. 07. 2020., product code 8010004, #800, Order confirmation: CST 124898, 13. 07. 2020, Delivery note 8. 10. 2020, (sample of SN JJ126762-or JJ127700-JJ127011, traceable to PO: PST 1408)
- Order 123555-2, 30. 01. 2020, Product 8010004 (Oxygen Sensor R17JJ-CCR), Order confirmation: CST123555, 27. 04. 2020, delivery note DST123555-2, 26. 06. 2020 # 500 (SN: JJJ1258458-JJ125899, JJ125900-JJ125999, JJ126000-JJ126034)
- Order 123996, 25. 03. 2020, #400, Product code 8010006, (Oxygen Sensor rEvo CR22D), Order confirmation CST123996, 22. 05. 2020, Delivery note DST123996-1, 15. 10. 2020 SN 010135888-010135899, 010135900-010135999, 010136000-010136067
- Order 125923, 10. 09. 2020, Product 8010008, Order Confirmation CST125923, Product 8010008, Oxygen Sensor-NaNM01, #200, Delivery note DST125923-1, 21. 10. 2020, SN M01109604-M01109616

Stock is checked by the system and if available enough Picking list is generated by the system based on order. Review status is displayed by ticked box and confirmation is sent to the customer.

VST supplies oxygen sensors based on specified requirements by the customer and each product dedicated specifically to a customer by assigned product code.

Contract review results (Checking product code, available stock, delivery time,..) are recorded in Intrastats – Customer Sales Order module. Once checking completed order is transferred to ready to process list and for further processing (issue picking list, picking and despatching).

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for sales, customer related produces and product despatch were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Purchasing – Goods In, control of externally provided products, and supplier evaluation: 7.4, 8.5.2, 8.5.4**

Supply chain management, purchasing, goods inward, warehousing and traceability were assessed with Managing Director and Account Manager in client office.

Control of these processes is supported by VOP 05, Issue 1, 30. 09. 2019, Supplier Control, Supplier Review, Purchase Orders, Supplier returns, and rejection.

These were reviewed and implementation was demonstrated.

Other key documents and records reviewed were:

- Intrastats- Purchasing module
- VOP06 measurement, Control, Calibration, QA Stock (including Incoming inspection) issue 1, 30. 09. 2019
- DTI Quality Assurance Register
- AVL: Intrastats Suppliers used from 30/08/2017

The following sample (only supplier) were taken:

- Env. GmbH, last review 26. 10. 2020 (ISO 13485-2016 certified)

Suppliers are re-validated or re-assessed at least once per year.

Supplier performance is reviewed by MD based on criteria defined in VOP05.

Following Purchase orders sampled and reviewed:

PO: PST1408, 6. 07. 2020, Part number 8010004, Description E1001721, OOD103-2V Oxygen Sensor, #400,

Incoming inspection: booked to the system by HL, 4. 08. 2020, Goods in ID 5362

Supplier QA report was provided including SN, Label number, date, spec and off set.

PO: VSTPO01052, 30. 01. 2020, product 8010004, description E1001721, OOD103-2V

Booked in to Intrastats: 5. 06. 2020 #83, 23. 06. 2020 #200, 25. 09. 2020 # 217.

PO: VSTPO01045, 22. 01. 2020, Product code 8010006, description E1002733, OOD103

#600, Booked in to the system: 29. 09. 2020 #200, 02. 10. 2020 #200, 12. 10. 2020 # 100, 20. 10. 2020 #100

PO: PST1412, 06. 07. 2020, Product 8010008, Description E1002734, OOD103 #100

Booked in to the system: 20. 10. 2020 #100.

VST receives manufactured products (packed and labelled) from supplier.

Accepted goods in are booked in to Intrastats and either directly despatches to the customer or transfers to the warehouse, and if testing is a requirement, transferred to the goods awaiting QA and / or labelling.

Products were seen to be supplied to a documented specification according to a written agreement or purchase order information.

Goods in processes and processing was seen to include:

- a paperwork check of quantity and expected delivery matching the actual content.
- a visual inspection of the goods/packing for damage
- a check of certificates of conformity/QA report as required

The above was seen to ensure that the extent of control over externally provided products is commensurate with risk and that purchased product conforms to specified purchasing information. returned products are controlled by NC control process VOP10 and are identified by assigning SRN, and if required to be returned to the supplier Service Repair sheet and RMA is issued. These products are held in quarantine area. e.g.:

Service Repair Sheet 67621, SRN 33204, 22. 10. 2020, (Product 8010007, SN S01112560)  
RMA748 to return to supplier.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for goods in, warehousing and traceability were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## Infrastructure Calibration and Maintenance: 7.1.3, 7.1.4, 7.1.5

Control of infrastructure, calibration and maintenance was assessed with Managing Director in Client office.

Control of these processes is supported by VOP18 issue 1, 30. 10. 2019 Maintenance of Building, Fabric and Infrastructure and an issued calibration/maintenance schedule in Intrastats software.

These were reviewed and implementation was demonstrated.

Other key documents and records reviewed were:

- Intrastats Calibration module.
- VOP06 Measurement, Control, Calibration, QA Stock (including Incoming inspection issue) issue 1, 30. 09. 2019.

Measuring devices (only Voltmeter) is used to measure returned product for verification test to investigate the defect.

The following samples of calibrated monitoring and measuring instruments were taken and evidence was provided that demonstrated traceability to national/ international measurement standards.

- Volt meter CE0179, Barcode 682836, 16. 12. 2109, (Ref device used CE076 SN 6939K6, Cert 1580162, last calibration 14. 09. 2020)
- Volt meter CE0180 barcode 682937, date of calibration 27. 01. 2020 by CE076

As no production operations are performed so no equipment is used. The main infrastructure is warehouse, admin building and computer network and software. IT infrastructure are maintained by IT responsible, the other infrastructure is managed/maintained under Task 127 (Actions log). The last

check was performed on Feb. 2019.

No special work environment conditions is required for product preservation.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for infrastructure and control of monitoring and measuring devices were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Human Resources, Competence, Awareness and Training: 7.2, 7.3, 7.4, 7.1.2, 7.1.6**

Human resources, competency, awareness and training was assessed with MD remotely through Zoom in auditor home office.

Control of these processes is supported by VOP12 Training Issue 1, 30. 09. 2019.

This was reviewed and implementation was demonstrated.

Other key documents and records reviewed were:

- VOP02 Issue 1, (Personnel, responsibility and training)
- VST Company Responsibilities

Competency requirements are defined in process documentation/procedure.

The following samples were taken:

- Robert Conner training records (46) training on goods in process 05. 2012,
- ISO 9001-2015 Internal audit training records: 4. 10. 2017 (John Lamb)
- ISO 9001-2015 transition training 19. 01. 2016 (D. Lamb)
- Director of VST: Purchase Order Process 2. 05. 2020  
Lead Free Oxygen Sensor 23. 10. 2019
- Sales Order handling: Sarah Walton Intrastats Sales Order Processing 1. 03. 2020 (sign off 16. 09. 2020)

Monitoring/observing the job is used to evaluate the effectiveness of training.

Sign off training records by MD is defined as evidence of competence.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring of competency, awareness and training were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## **Control of Documents and Records: 7.5**

Control of documents and records was assessed with MD in client office.

Control of these processes is supported by Documented Information Control Procedure VOP01 issue 1, 30. 09. 2019 and Intrastats Software.

This was reviewed and implementation was demonstrated.

The documents and records reviewed during the assessment were seen to have been reviewed and approved for adequacy prior to issue by relevant functions, available at points of use (through access to Intrastats), legible and readily identifiable. The current revision status of and changes to documents were seen to be identified. IT back up processes are in place to prevent loss of documents and records.

Obsolete documents were seen to be appropriately identified and controlled by Admin page of Intrastats software and to be retained indefinite.

Records were seen to be retained electronically indefinitely

Documents of external origin were seen to be appropriately and compliantly identified and their distribution controlled by Intrastats.

Valid rev of documents are available in Intrastats and users can access to valid revision of documents by defined access pass.

Expired documents are flagged as out of date to the end user. This is checked regularly by Document controller.

Printed documents are valid for defined period of time.

User can Request amendment of documents through Intrastats

Document Controller has access to Admin page of Intrastats and manage the documentation (publish new revision or remove out dated version). Document creation/amendment, review and approval, assign for training, assigning exp. date, .. are handled through Admin page.

History of document and previous revisions are kept in Admin document.

Expired documents are identifiable by flag and colour code in admin page (this page is not accessible to the end user)

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for control of documents and records were found to be effective to meet the needs of the organisation and compliant with the requirements of the assessment criteria.

## Minor (1) nonconformities arising from this assessment.

<b>Finding Reference</b>	1970578-202010-N1	<b>Certificate Reference</b>	FM 607767
<b>Certificate Standard</b>	ISO 9001:2015	<b>Clause</b>	4.3
<b>Category</b>	Minor		
<b>Area/process:</b>	Context of the organization, QMS boundaries, scope and Processes, policy and Objectives: 4.1, 4.2, 4.3, 4.4, 6.1, 6.2		
<b>Statement of non-conformance:</b>	Scope of the QMS was not fully effective.		
<b>Clause requirements</b>	<p>Determining the scope of the quality management system</p> <p>The organization shall determine the boundaries and applicability of the quality management system to establish its scope.</p> <p>When determining this scope, the organization shall consider:</p> <ul style="list-style-type: none"> <li>a) the external and internal issues referred to in 4.1;</li> <li>b) the requirements of relevant interested parties referred to in 4.2;</li> <li>c) the products and services of the organization.</li> </ul> <p>The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.</p> <p>The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.</p> <p>Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.</p>		
<b>Objective Evidence</b>	<p>Exclusion and non-application was not effectively determined and justified.</p> <p>VM3COP02.01 Boundaries ISO 9001:2015 VST DOC ID 23739</p> <p>8.5.2, 8.5.4, and 8.5.6 are identified as NA by DOC ID 23739, while the organization is responsible to meet these requirements regarding the defined scope. 8.4.1 was identified as NA but responsibility of selection of supplier is not clear.</p>		
<b>Cause</b>			
<b>Correction/containment</b>			
<b>Corrective action</b>			

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## Next visit objectives, scope and criteria

The objective of the assessment is to conduct a surveillance assessment and look for positive evidence to verify that elements of the scope of certification and the requirements of the management standard are effectively addressed by the organization's management system; that the system is demonstrating the ability to support the achievement of statutory, regulatory and contractual requirements and the organization's specified objectives as applicable with regard to the scope of the management standard; to confirm the ongoing achievement and applicability of the forward strategic plan.

The scope of the assessment is the documented management system with relation to the requirements of ISO 9001-2015 and the defined assessment plan provided in terms of locations and areas of the system and organization to be assessed.

ISO 9001-2015  
VST Ltd management system documentation

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
	Assessor 1		Scope and Policy	4.3, 5.2
			Organisational context	4.1, 4.2
			Management System Support	4.4, 7.1.1, 7.1.3, 7.1.4, 7.1.5, 7.5
			Objectives / Performance Monitoring & Measurement	6.2, 9.1.1, 9.1.3
			Management Review	9.3
			Supply Chain	7.4
			Internal Audits	9.2
			Actions / Non-Conformity / Incidents / Complaints	8.7, 10.2
			Risk Management / Prevention	6.1, 10.3
			Legal and Other Requirements	4.2, 8.2.2, 8.5.5

## Appendix: Your certification structure & ongoing assessment programme

### Scope of certification

#### FM 607767 (ISO 9001:2015)

The supply of gas sensors and associated systems. Previous certificate expired 18/6/2017 Recertification ended 30/11/2017 The expiration date of this certificate is extended for 6 months in accordance with BSI Procedure GP 158 Business Continuity – Managing Extraordinary Events (Reference to IAF ID3)

### Assessed location(s)

The audit has been performed at Central Office, Permanent Locations.

#### Keighley / FM 607767 (ISO 9001:2015)

Location reference	0009370214-001
<b>Address</b>	Vandagraph Sensor Technologies Ltd. 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom
<b>Visit type</b>	Re-certification Audit (SR Opt 1)
<b>Assessment reference</b>	3259753
<b>Assessment dates</b>	29/10/2020
<b>Deviation from audit plan</b>	No
<b>Total number of Employees</b>	3
<b>Effective number of Employees</b>	3
<b>Scope of activities at the site</b>	Main certificate scope applies.
<b>Assessment duration</b>	2 day(s)

## Certification assessment programme

**Certificate number - FM 607767**  
**Location reference - 0009370214-001**

		<b>Audit1</b>	<b>Audit2</b>	<b>Audit3</b>	<b>Audit4</b>	<b>Audit5</b>	<b>Audit6</b>
<b>Business area/location</b>	<b>Date (mm/yy):</b>	07/18	09/19	07/20	09/2021	9/2022	09/2023
	<b>Duration (days):</b>	1	1	2	1	1	2
Scope and Policy		X	X	X	X	X	X
Organisational context		X	X	X	X	X	X
Leadership and Commitment		X		X			X
Management System Support		X	X	X	X	X	X
Planning and Resources		X		X		X	X
Human Resource Management		X	X	X			X
Control of Documents and Records		X		X		X	X
Objectives / Performance Monitoring & Measurement		X	X	X	X	X	X
Management Review		X	X	X	X	X	X
Supply Chain		X		X	X		X
Internal Audits		X	X	X	X	X	X
Actions / Non-Conformity / Incidents / Complaints		X	X	X	X	X	X
Risk Management / Prevention		X		X	X	X	X
Legal and Other Requirements				X	X	X	X
Improvement		X	X	X			X

## Mandatory requirements – recertification

The Recertification Review Pack has been reviewed prior to the assessment by the Client Manager.

All requirements of the standard have been implemented.

The entirety of scope / processes has been assessed during the current review period.

The certificate structure and location activities have been reviewed.

Based on the recertification process, the management system continues to demonstrate the ability to support the achievement of statutory, regulatory and contractual requirements.

### **Complaints received by BSI**

There have been no complaints received by BSI during the certification period.

There were no complaints to BSI over this period.

### **Strategic review pack summary**

- The recertification packs have been reviewed for certificates FM 607767
- Since the last recertification a total of 4.5 days assessment (including this audit) have been completed.
- This was in line with scheme requirements and the recertification plan (three year plan).

The assessment durations (surveillance and recertification audits) were in accordance with the IAF MD9 duration guidance with decrease in duration due to outsourcing manufacturing.

Over the cycle there have been 1 non-conformities have been raised in surveillance visits, and a further 1 minor nonconformities have been raised at this audit.

- Assessment has ensured coverage of major process activities listed in the Certification Assessment Plan.
- All of the processes included in the scope of certification have been assessed as planned
- Product ranges included in the certificate scope have been assessed

### **Progress in relation to management system objectives.**

VST has been generally successful in meeting their service delivery objectives over the last three years.

### **Leadership, commitment and strategy**

The top management discussion was held with the CEO. Refer to the findings section for further information.

Consideration of the management strategy has been used in developing the ongoing Certification Assessment Plan.

### **Effectiveness of the Management System**

Management Review, internal audit, corrective action and preventive action processes are considered to be generally effectively implemented.

### **Impartiality review**

Assessor qualifications have been reviewed and found to be appropriate.

Assessor impartiality has been reviewed and it is confirmed there is no conflict of interest.

Continue with the current total assessment days/cycle.

### **Justified exclusions / non-applicable clauses**

Justified exclusions / non-applicable clauses have been confirmed for certificate: FM 607767

details:

8.3, 8.5.1

## 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.

## 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

'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](http://www.bsigroup.com/j4c) to register. When registering for the first time you will need your client reference number and your certificate number (47502495/FM 607767).

Should you wish to speak with BSI in relation to your certification, please contact your local BSI office – contact details available from the BSI website:

[https://www.bsigroup.com/en-GB/UK-office-locations/](http://www.bsigroup.com/en-GB/UK-office-locations/)

## 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 organization, then all pages must be included.*

*BSI, its staff and agents shall keep confidential all information relating to your organization 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.*

*This audit was conducted 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.*