Audit Report
Vandagraph Sensor Technologies Ltd.

Audit Reference	3545973
Audit type	Re-certification Audit (RA Opt 2)
Audit Date(s)	11-May-2023 - 12-May-2023
Report author	Andrew Singh
Audit Standard(s)	ISO 9001:2015

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Identification and Dating

Audit report authors are as per the audit team listed. The recommendation included in this audit is based on the audit of the sites documented in the ‘assessed locations’ table towards the rear of this report. This table also defines the audit duration. This report was finalised and issued as identified in the table below.

Executive Summary

The objectives of the audit were met.

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 audit.

All areas were covered per the audit plan.

Witnessing of Testing and Reconciliation

Product testing was not applicable for this audit. Material/ component reconciliation was not applicable for this audit.

Status of findings from previous audits

There were no open nonconformities from previous audits.

Status of findings from this audit

There were nonconformities raised at this audit. These are summarised below. Further details can be found in the sections related to nonconformities raised at this audit later in this report.

No diverging opinions were raised.

Reference	Standard	Clause	Category
2342435-202305-N1	ISO 9001:2015	5.2	Minor
2342435-202305-N2	ISO 9001:2015	9.2	Minor
2342435-202305-N3	ISO 9001:2015	8.4	Minor
2342435-202305-N4	ISO 9001:2015	8.4	Minor

Statutory and regulatory requirements

This is an ISO 9001:2015 only audit

Progress towards strategic objectives

Vandagraph sensors technologies aims to maintain its current status as a supplier of oxygen sensors to manufacturers of scuba diving equipment. During this audit Top

management was interviewed and demonstrated knowledge of the organisations activities and status, evidence of was observed in the management review with actions recorded that demonstrated the strategy towards its objectives.

There were no changes to organisation structure and key personnel observed during this audit.

There were no changes to Activities, products or services covered by the scope of certification observed during this audit.

There have been no changes to references or normative documents observed during this audit.

Audit conclusion

Caveats

Please note that all recommendations are subject to independent review.

If this audit is part of a multi-location audit the final recommendation will be contingent on the findings from all audits.

If the objective of this audit report was to conduct a microbiology audit, the conclusions and recommendations only refer to effective implementation from a microbiology/ sterilisation perspective.

If this audit is conducted in support of CE Marking or the UKCA, the recommendation will be subject to review by a scheme manager and certification will be subject to the relevant technical documentation reviews.

Audit conclusion – ISO 9001 certificate(s):

This conclusion is relevant for the following audit objectives: Re-certification Audit (RA Opt 2).

The management system has generally been effectively implemented. The system addresses the scope of registration and is generally in accordance with the company objectives, applicable requirements of the management standard and BSI Terms of Service. The result of this audit is a recommendation for recertification dependent on submission of a satisfactory corrective action plan.

Summary table

The management system generally meets the requirements of ISO 9001.

Use of certification documents, mark / logo or report:

The client does not make use of any BSI or accreditation logos.

Your Next Steps

Actions required from you

A corrective action plan is required to define the action to address the non-conformities identified during this audit. The corrective action plan must include the correction (containment), root cause, corrective action, timescales and person responsible for implementation.

The plan is to be submitted no later than **09- Jun-2023** by email to **Andrew.Singh@bsigroup.com** and **RSCAPS@bsigroup.com** , referencing the report number: **3545973**.

Next audit considerations

The details of your next audit are documented in the Next Visit section of this Report.

Opening Meeting and Changes

The opening meeting was conducted with the client, attendees are documented in the attendee list.

Audit Objective, Criteria and Scope

Objective:

To conduct a recertification audit to determine the effectiveness of the 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, other applicable regulatory requirements from relevant regulatory authorities and BSI Terms of Service.
To determine whether a recommendation can be made.

Criteria:

ISO 9001:2015

Scope of audit:

The scope of the audit is the documented management system processes, documents and records related to the certificate scope(s) and the location activities at the address(es) defined in the 'assessed locations table' towards the rear of this report.

The objective, criteria and scope were confirmed.

Certificate scope:

Please refer to the appendix for the location certificate scope(s) relevant to this audit, which may be a subset of the main certificate scope shown above.

The certificate scope(s) were confirmed.

FM 607767

The supply of gas sensors and associated systems.

Audit plan and audit language(s):

The audit was performed in English.

There was no requirement for translation.

The audit plan was confirmed.

Required PPE/H&S considerations : None

Notes related to client's questions : No Questions

Senior Management of the audit location:

Derek Lamb Managing Director

Management Representative (including contact details):

Derek Lamb, Managing director
E-mail: derek.lamb@viamed.co.uk
Tel: 01535 634542

Changes in the organisation:

There have not been any major or significant changes to the QMS, organisational structure, products or process, subcontractor/ supplier certification status, or locations from where finished product is shipped since the last audit.

Vigilance

There have been no adverse incidents, recalls, or requirement for field safety corrective actions or vigilance/mandatory problem reports since the last audit.

The client stated that there has been no engagement with any global regulatory bodies in respect of legal compliance or other issues since the last audit.

Device Registration

The client stated that they have NO Class I, IVD self-certified, Article 12 / 22 or custom made devices.

The client stated that they have NO devices which require registration with the MHRA.

Quality Management System

There are no exclusions or non-applications documented.

Staffing and audit duration

Site Reference	Total Employees	Effective Employees	Justification
0009370214-001	3	3	None

There are no shifts in operation.

Review of audit durations

Based on the above details, the durations for the next audits are: Recert 1 man day
The following factors influence these audit durations: No overall % increase / decrease applied

The Audit cycle remains unchanged.

Critical Subcontractors / Suppliers

Summary of Subcontractors

Subcontractor review is not applicable for this audit

Corporate identity of the organisation

Vandagraph Sensor Technologies Ltd is a privately owned family run business based in Keighley that focuses on the supply of oxygen sensors to OEM rebreather manufacturers for diving equipment.

Description of the organisation

Vandagraph Sensor Technologies Ltd is a privately owned family run business based in Keighley that focuses on the supply of oxygen sensors to OEM rebreather manufacturers for diving equipment.

The audit team

Name	Position
Andrew Singh	Team Leader

Attendees

Name	Position	Inter-viewed	Opening Meeting	Closing Meeting
Derek Lamb	Managing Director	X	X	X
Helen Lamb	Director	X	X	X
Michael Lamb	Observer	-	X	X
Cathy Green	Warehouse Supervisor	X	-	-

Processes Audited

Core QMS

ISO 9001:2015, 10.1, 10.2, 10.3, 4, 4.1, 4.2, 4.3, 4.4.1, 5, 5.1, 5.2, 6.1, 6.2, 6.3, 7.1.6, 7.3, 7.4, 7.5, 8.2.1, 8.5.6, 8.7, 9.2, 9.3

Description of the audited process or activity

Andrew Singh

Quality Manual, Quality Policy and Quality Objectives

The Core QMS processes were assessed on site at Vandergraph Sensor Technologies Ltd in the presence of those listed.

Quality Manual:
-DOCID 118336 Quality management route map 09 May 2023

The Quality Manual defined the scope of the quality management system (QMS) and defined any exclusions and/or non-application of clauses with appropriate justification. The Quality Manual outlined the structure of the documentation in the QMS, the contact of the organisational well as needs and expectations of interested parties, The documented procedures for the QMS and a description of the interaction between the processes of the QMS. The manual defined the interested parties.

Quality Policy:
22062 VM3COP.00.00 Company quality policy 16 sept 2017
The Quality Policy was found to be applicable to the purpose of the organization and included a commitment to comply with regulatory requirements. The Quality Policy is reviewed for continuing suitability every year at the management review. The Quality Policy is communicated within the organization through Intrastats the document management system. The quality policy was observed to be described as a secondary document resulting in a minor non conformity.

Quality Objectives:
46732 VST TOP level objectives 29 Oct 2020

The organization had identified several quality objectives at various levels amongst the organization, each of which were measurable to evaluate the organization's progress against the objective.

Top Management Interview
Persons interviewed: Derek Lamb Managing Director

General
The Managing Director explained the current status of the organization and plans for the future. The Managing Director described the key objectives for the next certification cycle and the resources needed to achieve these.

Risks
The Managing Director explained how the organization identifies risks to the business including how they consider and control risk throughout the QMS. Key risks to the QMS were explained and how these were being mitigated.

Quality Policy and Objectives
The Managing Director explained how the Quality Policy and Quality Objectives are established. The Quality Policy and Objectives were also discussed during the assessment including how these are communicated to staff amongst the organization.

Planning
The Managing Director explained how planning of the quality management system takes place. This primarily takes place at the management review meetings which is used to evaluate the performance of the QMS. Planning is comprehensive and considers all areas of the business for risk, impacts that could affect the quality management system and resource requirements.

Customer Focus
The Managing Director explained who the organizations typical customers are how they identify and meet their customers' needs.

Management Review and Data Analysis
Documented Procedure(s):

The organization had documented a procedure for conducting management reviews. The procedure defines the frequency by which top management shall review the organization's quality management system as a minimum, once a year, to ensure its continuing suitability, adequacy and effectiveness. Records reviewed of the management review procedure showed that the input for management review covered all the requirements of the standard. Records of management reviews captured points of discussion for all inputs and identified any opportunities for improvement and

resource needs where appropriate.

The organization had documented a procedure to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedure defined the appropriate methods, including statistical techniques and the extent of their use. The procedure defined the sources of data generated as a result from monitoring and measurement as required by the standard.

Internal Audits
Documented Procedure(s): 75461 VOP 13 Internal audit procedure 18 Nov 2021
The organization had documented a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. The organization had documented an audit schedule which specified the planned intervals for conducting internal audits taking into consideration the status and importance of the processes to be audited. The audit criteria, scope, interval and methods where defined and recorded in the audit reports reviewed. It was not observed that issues raised during internal audit were part of the non- conformity review process as per documented procedure resulting in a minor non conformity.

Records of audits were reviewed which showed the results, identification of processes audited and the conclusions of the audits. Actions arising from internal audits were seen to be taken without undue delay to eliminate detected nonconformities and their cause. A recent audit report was reviewed on picking and packing where 1 nonconformities.

Feedback, Complaint Handling
Feedback
Documented Procedure(s): VOP 19 feedback customer complaints vigilance and notifications rev #75995/1637765863 dated 24 Nov 2021

The organization had documented a procedure for the feedback process. The procedure defined the process by which the organization gathers and monitors information relating to whether the organization has met customer requirements and to determine the effectiveness of the quality management system. The procedure includes provisions to gather data from production as well as post-production activities.

Complaint Handling
Documented Procedure(s): VOP 19 feedback customer complaints vigilance and notifications rev #75995/1637765863 dated 24 Nov 2021

The organization had documented a procedure for timely complaint handling in accordance with applicable regulatory requirements. The procedure defined the requirements for receiving and recording information; evaluating information; investigating complaints; determining the need to report the information to the appropriate regulatory authorities; handling of complaint- related product; and determining the need to initiate corrections or corrective actions. Where complaints were not investigated, the justification for this was documented. The complaints log was reviewed and a sample of records of complaints were reviewed which showed complaints were being handled appropriately in a timely manner. The organisation had a procedure for recalling non conforming product.

Improvement - Corrective and Preventive Action
Documented Procedure(s): 90405 VOP10 non conformance, corrective action and preventive actions 25 may 2022

The organization had documented a procedure for reviewing nonconformities (including complaints); determine the cause(s) of nonconformities; evaluating the need for action needed and implementing such action, including, as appropriate, updating documentation; verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; and reviewing the effectiveness of corrective action taken.

The documented procedure also included provisions to determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. The procedure described the requirements for determining potential nonconformities and their causes; evaluating the need for action to prevent occurrence of nonconformities; planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; and reviewing the effectiveness of the preventive action taken, as appropriate.

The NCR log was reviewed and a sample of non-conformance events were assessed. In all cases, non- conformance events were managed appropriately and without undue

delay.

Control of documents and records
Procedure: 75407 Documentation and records, control, creation, storage, retrieval, dated 18 Nov 2021
The organisation had documented the procedure to define the controls needed to review and approve documents for adequacy prior to issue, review, update as necessary and re-approve documents, ensure that the current revision status of and changes to documents are identified, ensure that relevant versions of applicable documents are available at point of use, ensure that documents remain legible and readily identifiable, prevent deterioration or loss of documents, and prevent the unintended use of obsolete documents and apply suitable identification to them. the procedure defined the period for which documents, including obsolete documents, are retained.
The organisation had documented a procedure to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. the procedure defined the retention time for records as required by the standard and applicable regulatory requirements.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Core QMS were found to be generally effective to meet the needs of the organisation but not fully compliant with the requirements of the audit criteria. 2 minor nonconformities were raised.

The following people were interviewed

Andrew Singh

Derek Lamb / Managing Director
Helen Lamb / Director

The following documents and records were sampled

Andrew Singh

DOCID 118336 Quality management route map 09 May 2023
24442 VST 9001 scope 01 Dec 2017
29373 VST company responsibilities 23 April 2019
69692 Boundaries and exclusions to system 14 Sept 2021
74925 Need risk and expectations of external parties 15 Nov 2021
22062 VM3COP.00.00 Company quality policy 16 sept 2017

Training task 7833 importance of effective quality management:
Aquib majeed – 274169 10 oct 2022 10 oct 2022
Catherine spence 274170 10 oct 2022 11 oct 2022
Catrin hird 274171 10 oct 2022 – 11 oct 2022
Emily Hanson 274172 24 april 2023
46732 VST TOP level objectives 29 Oct 2020
75461 Viamed operating sub process 18 Nov 2021
Minutes: VST Board meetings and management review 08 Nov 2022
Interview with Derek Lamb
75461 VOP 13 Internal audit procedure 18 Nov 2021
Audit schedule 2023
284669 Internal audit checklist order processing picking packing and dispatch 25 Jan 2023
288861 goods in audit 10 march 2023
90405 VOP10 non conformance, corrective action and preventive actions 25 may 2022
292702 return box 912 raised 18 April 2023
VOP 19 feedback customer complaints vigilance and notifications rev #75995/1637765863 dated 24 Nov 2021
154298 complaint from customer 13 Sept 2019
30 Aug 2019 email from customer accepting response
74788 VM3COP10.02 product recall locate products out in the field 12 Nov 2021
75407 Documentation and records, control, creation, storage, retrieval, dated 18 Nov 2021
Risk assessment for uploading Document ID 75305 18 Nov 2021
49499 server backup system 01 Feb 2022
68945 copy main server files into a prepared backup 04 sept 2021

Sales, supply chain, supplier control and purchasing

ISO 9001:2015, 5.1.2, 5.3, 7.1, 8.2, 8.2.1, 8.2.2, 8.2.3, 8.4

Description of the audited process or activity

Andrew Singh

The Sales, supply chain, supplier control and purchasing processes were assessed on site at Vandergraph Sensor Technologies Ltd in the presence of those listed below.

Sales
Documented Procedure(s): 77675 VOP3 contract review, enquiries, office processes 15 Dec 2021

The organization had documented a procedure for receiving, reviewing and fulfilling customer orders and the client explained the process.
The client manages this process it's ERP system Intrastats
Customer purchase orders were reviewed to understand how the organization reviews purchasing information communicated by the customer.
The client explained the communication channels between the customer and the organization and the support available.
There is no additional training required to operate the product for the intended user

Supplier Management and Purchasing
Procedure: 75847 VOP 05 Supplier review 1637687018

The Supplier Management and Purchasing processes were assessed on site at Vandergraph Sensor Technologies Ltd in the presence of those listed below.
Documented Procedure(s):

The organization had documented a procedure to ensure that purchased product conforms to specified purchasing information. The procedure established the criteria for the evaluation, selection, monitoring and re- evaluation of suppliers. The management of suppliers was seen to be risk- based and proportionate to the risk associated with the products. IT was not observed that all suppliers were reviewed as per documented procedure resulting in a minor non conformity. Supplier agreements were not observed to be maintained for all suppliers observed resulting in a minor non conformity.

The process of ordering materials or services from approved suppliers was explained, including creating purchase orders containing appropriate purchasing information. The process of receiving purchased materials was explained and included the verification of purchased product were appropriate including documentation checks and analytics testing were required.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Sales, supply chain, supplier control and purchasing were found to be generally effective to meet the needs of the organisation but not fully compliant with the requirements of the audit criteria. 2 minor nonconformities were raised.

The following people were interviewed

Andrew Singh

Derek Lamb / Managing Director
Helen Lamb / Director

The following documents and records were sampled

Andrew Singh

77675 VOP3 contract review, enquiries, office processes 15 Dec 2021
Customer orders 8010050 CST141676 Due date 14 April 2023
PO 12300542 31 Jan 2023
Order confirmation: CST141676 01 March 2023
PO: PST3020
Delivery note (goods in): 8132955569 qty 61 03 2023
Shipping confirmation 11 may 2023
CST143042 due date 10 may 2023
RST141676-2 12 May 2023
75847 VOP 05 supplier review 28 Nov 2022
Supplier review - Viamed limited – 28 Nov 2022
Supplier review HW 11 Oct 2022
PO: 143026 19 April 2023
PO 116679 admin charges April 2023
VOP 07 rev 75973 Stock handling and control 24 Nov 2021

Supporting processes

ISO 9001:2015, 5.1, 5.3, 7.1, 7.1.3, 7.1.5.2, 7.2, 7.3, 8.5.1, 8.7

Description of the audited process or activity

Andrew Singh

Supporting processes
The supporting processes were assessed in the Vandergraph Sensor Technologies Ltd meeting room in the presence of those listed.

Validation, change management, software validation
Procedure: 91486 VOP 27 software validation 10 June 2022
the organisation had documented a procedure for validation of processes which included defined criteria for review and approval of the processes, equipment qualification and qualification of personnel, use of specific methods, procedures and acceptance criteria, as appropriate, statistical techniques with rationale for sample sizes, requirements for records, revalidation, including criteria for revalidation, and

approval of changes to the process.
The organisation has validated QMS software since the previous assessment. software validation records for the Intrastats where reviewed which showed the QMS software had been successfully validated.

control of nonconforming product
procedure:75943 VOP 20 goods in purchasing, returns, repairs, inspection/rejection 24 Nov 21
the organisation had documented a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. the procedure stated product may be reworked or released under concession following approval by the appropriate authority.
the organisation documented a recall procedure if nonconforming product was detected after delivery. there have been no recalls and as such, there were no records to review.

Calibration process
The organisation stated to have no requirements for calibration.

HR, competence and training, responsibility's and authorities.
Procedure: 93320 VOP2 personnel and responsibility staff and staffing issues, training, roles and tasks 01 July 2022
The organisation had documented the processes for establishing competence, providing needed training, and ensuring awareness of personnel. The organisation had determined the necessary competence for personnel performing work affecting product quality, provided training or take other actions to achieve or maintain the necessary competence, ensure that its personnel are aware of the relevance and importance of the activities and how they contribute to the achievement of the quality objectives, and maintained records of education, training, skills and experience in the form of individual training records.
A sample of employee training records were reviewed and in all cases, employees were seen to be appropriately trained, and the training method was seen to be proportionate to the complexity of the process.

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

The following people were interviewed

Andrew Singh

Derek Lamb / Managing Director
Helen Lamb / Director

The following documents and records were sampled

Andrew Singh

91486 VOP 27 software validation 10 June 2022
270649 Task Scan incorrect product 01 sept 2022
279353 attempt to qa stock if not trained 05 Dec 2022
275152Out of date document check 21 Oct 2022
75403 risk assessment for uploading documents 18 Nov 2021
75405 – risk assessment for the upload of document VOP01 18 Nov 2021
75943 VOP 20 goods in purchasing, returns, repairs, inspection/rejection 24 Nov 21
RMA 915
SRS68446 25 April 2023
SRS68099 08 March 2022
RST133464-1 10 may 2022
93320 VOP2 personnel and responsibility staff and staffing issues, training, roles and tasks 01 july 2022
VOP 12 31024/1569847051 dated 30 sept 2019
Cathy training: picking and packing
VST order processing 01/01/2017
VST packing and shipping 01/01/2017
Robert Conor training: goods in process
VST order processing 10 July 2012
VST sensors 03/02/2014
Kate griffiths training: sales
Sales order processing
Sending of invoices 16 may 2022 Sophie Lines
Helen Lamb – Internal audit training
23 Oct 2020 9001:2015 auditor training update with Derek lamb
9001:2015 audit training based on VST 04 oct 2017 with John Lamb

Operations including control of subcontract manufacture

ISO 9001:2015, 4.4.1, 7.1, 7.1.3, 7.1.5.2, 8.1, 8.4, 8.5, 8.5.4, 8.6, 9.1

Description of the audited process or activity

Andrew Singh

Operations processes were audited on site at vandergraph sensors ltd in the presence of those listed
The Control of Production and Service Provision, QC and Batch Release processes were assessed in the Vandergraph Sensor Technologies Ltd meeting room in the presence of those listed.
The client provided a tour of the production areas and provided a brief explanation of the key processes in each area.
Briefly, the manufacturing areas comprised of a warehouse with a goods in area storage shelves with a divider for storage of materials for Vandergraph sensors technologies and a goods out area.
During the tour, it was seen that product realization processes were planned and conducted in controlled conditions. Inspection points throughout product realization and acceptance criteria were defined for the monitoring and measurement of product.
The infrastructure and work environment were seen to be suitable for the operations being conducted.
Following the production tour, records were reviewed which appeared to capture appropriate manufacturing information, were complete and accurate, and captured a record of the quantity released for distribution.

Infrastructure Requirements and Maintenance
The Infrastructure Requirements and Maintenance processes were assessed on site at vandergraph sensors ltd in the presence of those listed.
The organization had documented the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix- up and ensure orderly handling of product.
The organization had also documented the maintenance activities, including the interval of performing such activities, where such activities, or lack thereof, could affect product quality.

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

The following people were interviewed

Andrew Singh

Derek Lamb / Managing Director
Helen Lamb / Director
Cathy Green / Warehouse Supervisor

The following documents and records were sampled

Andrew Singh

Customer orders 8010050 CST141676 Due date 14 April 2023
PO 12300542 31 Jan 2023
Order confirmation: CST141676 01 March 2023
PO: PST3020
Delivery note (goods in): 8132955569 qty 61 03 2023
Shipping confirmation 11 may 2023
CST143042 due date 10 may 2023
RST141676-2 12 May 2023
31036 VOP18 maintenance building fabric and infrastructure 30 sept 2019

Minor (4) nonconformities arising from this audit

Finding Reference	2342435-202305-N1	Certificate Reference	FM 607767
Certificate Standard	ISO 9001:2015	Clause	5.2
Location Reference	0009370214-001		
System NC	No		
Authorised to close	QMS Auditor		
Remote closeout	Yes		
Category	Minor		
Area/process	Core QMS		
Details	The process for the quality policy is not fully effective as it was defined as a secondary level document		
Clause requirements	**5.2** Policy		
Objective Evidence	22062 VM3COP.00.00 Company quality policy 16 sept 2017		

Finding Reference	2342435-202305-N2	Certificate Reference	FM 607767
Certificate Standard	ISO 9001:2015	Clause	9.2
Location Reference	0009370214-001		
System NC	No		
Authorised to close	QMS Auditor		
Remote closeout	Yes		
Category	Minor		
Area/process	Core QMS		
Details	The process for internal audit is not fully effective as it was not clear that all issues raised during internal audit were part of the non- conformity review process as per documented procedure		
Clause requirements	**9.2** Internal audit		
Objective Evidence	Picking packing audit 2023		

Finding Reference	2342435-202305-N3	Certificate Reference	FM 607767
Certificate Standard	ISO 9001:2015	Clause	8.4
Location Reference	0009370214-001		
System NC	No		
Authorised to close	QMS Auditor		
Remote closeout	Yes		
Category	Minor		
Area/process	Sales, supply chain, supplier control and purchasing		
Details	the process for supplier review is not fully effective as It was not observed that the review for Viamed as a supplier was being conducted as per the procedure.		
Clause requirements	**8.4** Control of externally provided processes, products and services		
Objective Evidence	VOP 05 rev #75847/1637687018 Viamed limited – 28 Nov 2022		

Finding Reference	2342435-202305-N4	Certificate Reference	FM 607767
Certificate Standard	ISO 9001:2015	Clause	8.4
Location Reference	0009370214-001		
System NC	No		
Authorised to close	QMS Auditor		
Remote closeout	Yes		
Category	Minor		
Area/process	Sales, supply chain, supplier control and purchasing		
Details	The process for the control of suppliers is not fully effective as it was not observed that an agreement was in place to determine the controls applied to Viamend as a supplier.		
Clause requirements	**8.4** Control of externally provided processes, products and services		
Objective Evidence	Viamed to VST PO: 143026 19 April 2023		

Next visit plan

Date	Auditor	Time	Area/process	Clause
01-May-2024	On-site		Opening meeting and follow-up from previous assessment	
			Opening meeting and follow-up from previous assessment	
01-May-2024	On-site		Core QMS	
			Scope/product changes, manual, policy, confirm essential audit information	ISO 9001:2015, 4.4.1, 5.1, 5.2, 6.2, 7.3
			Scope, context of the organisation, interested parties, organisational knowledge	ISO 9001:2015, 4.1, 4.2, 4.3, 7.1.6
			Management review, objectives, targets, analysis of data	ISO 9001:2015, 10.1, 10.3, 9.3
			Internal audit process	ISO 9001:2015, 9.2
			Corrective & preventive action processes	ISO 9001:2015, 10.2, 4.4.1, 6.1, 6.3, 8.5.6, 9.3
			Complaints/feedback processes	ISO 9001:2015, 8.2.1, 8.7
			Incidents/ recalls/ notifications/ reports/ vigilance/ post market surveillance	ISO 9001:2015, 7.4, 8.2.1, 8.7
			Control of documents and records	ISO 9001:2015, 7.5
01-May-2024	On-site		Sales, supply chain, supplier control and purchasing	
			Supply chain: purchasing, outsourcing, supplier controls, traceability	ISO 9001:2015, 7.1, 8.4
01-May-2024	On-site		Lunch	

01-May-2024	On-site		Manufacturing/operations including control of subcontract manufacture	
			Production planning	ISO 9001:2015, 4.4.1, 8.1, 8.5, 9.1
			operations [Oxygen sensors]	ISO 9001:2015, 4.4.1, 8.1, 8.5, 9.1
			Goods-in, warehouse controls, picking, distribution, dispatch	ISO 9001:2015, 7.1, 8.4
01-May-2024	On-site		Supporting processes	
			Validation, change management, software validation	ISO 9001:2015, 8.5.1
			HR, competence and training, responsibilities and authorities	ISO 9001:2015, 5.1, 5.3, 7.1, 7.2, 7.3
01-May-2024	On-site		Audit trails and report preparation	
01-May-2024	On-site		Closing meeting, report to follow	

Next visit objectives, scope and criteria

Audit Objectives

- To conduct a surveillance audit to determine the continued effectiveness of implementation of the company's management system, in accordance with the company objectives, policies and procedures, the management standards and applicable regulatory requirements from relevant regulatory authorities and BSI Terms of Service. To ensure that all requirements are covered during the certification period and to determine whether a recommendation for continuing certification can be made.

Audit Criteria

- The client's documented quality management system and associated documents and records
- BSI Conditions of Contract

- ISO 9001:2015

Audit scope

The management system processes, procedures and records at:

- Vandagraph Sensor Technologies Ltd.
  15 Station Road
  Cross Hills
  Keighley
  BD20 7DT
  United Kingdom

Appendix: Your certification structure & ongoing audit programme

Scope of certification

FM 607767

The supply of gas sensors and associated systems.

Certificate scheme: ISO 9001:2015
Scheme manager:

Audited location(s)

FM 607767 (ISO 9001:2015)

Location reference	0009370214-001
Address	Vandagraph Sensor Technologies Ltd. 15 Station Road Cross Hills Keighley BD20 7DT United Kingdom
Visit type	Re-certification Audit (RA Opt 2)
Assessment reference	3545973
Assessment dates	11-May-2023 - 12-May-2023
Audit plan (revision date)	09-May-2023
Deviation from audit plan	No
Total number of Employees	3
Effective number of Employees	3
Scope of activities at the site	Main certificate scope applies
Audit duration	2 day(s)

Certification assessment programme

		CAV1	CAV2	Recert
Business Area / Location	**Date (mm/yy)**	**05/24**	**05/25**	**05/26**

	Duration (days)	1	1	2
Opening meeting and follow-up from previous assessment		X	X	X
Opening meeting and follow- up from previous assessment		X	X	X
Core QMS		X	X	X
Scope/ product changes, manual, policy, confirm essential audit information		X	X	X
Scope, context of the organisation, interested parties, organisational knowledge		X	X	X
Management review, objectives, targets, analysis of data		X	X	X
Top management discussion, to include: customer focus/ policy/ responsibilities/ strategy/ objectives/ targets/ communication/ resources		-	-	X
Internal audit process		X	X	X
Corrective & preventive action processes		X	X	X
Complaints/feedback processes		X	X	X
Incidents/ recalls/ notifications/ reports/ vigilance/ post market surveillance		X	X	X
Control of documents and records		X	-	X
Sales, supply chain, supplier control and purchasing		X	X	X
Customer related process/ sales/ order		-	X	X
Supply chain: purchasing, outsourcing, supplier controls, traceability		X	-	X
Manufacturing/operations including control of subcontract manufacture		X	X	X
Production planning		X	-	X
operations [Oxygen sensors]		X	X	X
Product verification		-	X	X
Work environment / infrastructure & maintenance processes		-	X	X
Goods- in, warehouse controls, picking, distribution, dispatch		X	X	X
Supporting processes		X	X	X

Validation, change management, software validation	X	-	X
Control of nonconforming product	-	X	X
HR, competence and training, responsibilities and authorities	X	X	X

Justified exclusions / non applicable clauses

FM 607767

There are no exclusions or non-applications documented for this certificate.

Audit Specific - Recertification

The recertification packs have been reviewed for certificates: FM 607767

Since the last recertification, a total of 4 days audit (including this audit) have been completed.

This was in line with scheme requirements and the three year plan. The audit durations (surveillance and recertification) were in accordance with the appropriate duration guidance.

Over the cycle there have been 1 nonconformities raised in surveillance and technical audits.

A further 4 nonconformities have been raised at this audit.

No adverse trends have been identified.

Non conformities have arisen from various clauses of ISO 9001:2015 and demonstrate no trend.

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

Audits have ensured coverage of major process activities listed in the certification assessment plan. All processes included in the scope of certification have been audited as planned.

Product ranges or services/activities included in the certificate scope have been audited as planned.

There are no technical file assessments required for certificate(s) under review at this site.

There have been no complaints made about this client to BSI over this period.

Management system strategy and objectives

The top management discussion was held. Refer to the Processes Audited section for further details.

Top management demonstrated knowledge, understanding and implementation of their responsibilities.
Consideration of the management strategy has been used in developing the ongoing certification assessment plan.

Review of progress in relation to the organisation's objectives

The organisation has been generally successful in meeting their service delivery objectives over the last cycle.

There have been no reported adverse events, recalls or field safety corrective actions over this cycle.

Review of the audit progress and recertification plan

This recertification audit has been planned for 2 days. This was based on the effective number of employees and international guidance as incorporated into BSI procedures.

Continue with the current total audit days for the next audit cycle.

The next audit cycle, based on the current number of effective employees and international guidance will be:
Surveillance durations: Surveillance audits: 1 day
Recertification (days): Recertification audits: 2 days
Overall factors for increase/reduction: No overall % increase / decrease applied

BSI client management impartiality and surveillance strategy

Auditor qualifications have been reviewed and found to be appropriate.

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

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.

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 to register. When registering for the first time you will need your client reference number and your certificate number (43207441/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/contact-us/

https://www.bsigroup.com/en-GB/global-contact-details/

Appeals
An Appeal is defined as a request for reconsideration of any decision made by BSI related to the certification process, for example an appeal against a nonconformity raised by an auditor during an audit.

If you wish to contest a decision made *or* a nonconformity raised during this audit that you have been unable to resolve through your Client Manager/ Auditor, you may appeal in writing within 21 calendar days of the closing meeting of the audit to the Head of Compliance & Risk using MedDevComplianceandRisk@bsigroup.com.
Please provide the audit report reference number, date of the audit, or the nonconformity reference number and the technical details supporting your disagreement.

Complaints
A Complaint is defined as an expression of dissatisfaction, other than an appeal, by any person or organisation, to BSI, relating to the activities or behaviour of someone working on behalf of BSI or the products or services of BSI.

If you wish to raise a complaint related to the activities or behaviour of your auditor, or other aspects of the products and services provided by BSI, that you have been unable to resolve through your Client Manager/Auditor then you may submit a complaint in writing at any time to the Head of Compliance & Risk using MedDevComplianceandRisk@bsigroup.com . Please provide the audit report reference number or date of the audit and the details of your complaint.

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 audit 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.