Assessment Report

Viamed Ltd
Vandagraph Sensor Technologies Ltd

Assessment dates	30/10/2017 to 31/10/2017
Assessment location	Keighley (000), Keighley (001)
Report author	David Vicar
Assessment standards	Healthcare, ISO 13485:2003, ISO 9001:2008

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Executive summary

The objectives of the assessment were not met. A major nonconformity was identified.

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 assessment.
All areas were covered per the assessment plan.
Audit report authors are as per the assessment team listed. The recommendation included in this assessment is based on assessment of Viamed and Vandagraph Sensor Technologies Ltd, 15/17 Station Road, Cross Hills, Keighley, BD20 7DT, United Kingdom on 30th to 31st October 2017.

The report was finalised and issued on 14th November 2017.

This visit is part of a multi-visit assessment. The last visit (references: 8580193, 8778185, 8789316, 8789318, 8789319) was scheduled for three days 12-14 September 2017, but aborted after the first. See the last report for details. This visit was scheduled for two days to complete the original planned assessment. **This report should therefore be reviewed in conjunction with the last report.**

Please refer to the opening meeting section of this report for client-requested changes to their current Viamed Ltd certificates. FM and CE certificate changes and also certificate cancellations.

Please incorporate the Vandagraph Sensor Technologies certificate into the current contract 200483566 – essentially merging the visits for location -000 and -001.

The management system has not been effectively implemented.
The system does not address the proposed scope of registration and is not in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract.

Further assessment is required prior to a decision regarding a recommendation for certification
A corrective action plan is required to define the action to address the non-conformities identified during this assessment and detailed in this report. The corrective action plan must include the correction (containment), root cause, corrective action, timescales & person responsible for implementation.

All Requirements of ISO 9001:2008 / ISO9001:2015 have not been effectively implemented and this assessment does not enable a recommendation for upgrade to ISO 9001:2015

All Requirements of ISO 13485:2003 and EN ISO 13485:2012 as applicable have not been effectively implemented.
The requirements of ISO 13485:2016 have not been fully and effectively implemented and this assessment does not enable a recommendation for upgrade to ISO13485:2016.

The capacity to systematically meet agreed requirements for products and services supplied within the scope of the certificates is not confirmed and the requirements of ISO 13485:2003 and Part 1 of the Canadian Medical Device Regulations are not being met.

The management system does not meet the requirements of
MDD 93/42/EEC Annex II 3.2

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Assessment objective, scope and criteria

The last visit (references: 8580193, 8778185, 8789316, 8789318, 8789319) was scheduled for three days 12-14 September 2017, but aborted after the first. See the last report for details. This visit was scheduled for two days to complete the original planned assessment. This report should therefore be reviewed in conjunction with the last report.

For Vandagraph Sensor Technologies: To conduct a recertification assessment to determine the effectiveness of 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 standard(s) & BSI Conditions of Contract and to determine whether a recertification recommendation can be made.

For Viamed: To conduct a surveillance assessment to determine the continued effectiveness of implementation of the company's management system, in accordance with the company objectives, policies and procedures, the management standard(s) & BSI Conditions of Contract and to determine whether a recommendation for continuing certification can be made.

Viamed and Vandagraph Sensor Technologies: To verify that all requirements of ISO 9001:2008 and ISO9001:2015 have been and are in the process of being effectively implemented.

Viamed: To verify that all requirements of ISO 13485:2003 and EN ISO 13485:2012 have been effectively implemented.

Viamed: To verify that the requirements of ISO13485:2016 are in the process of being effectively implemented, where this has been agreed with BSI in advance of the visit.

Viamed: To verify that Viamed (Company ID No. 128822) continues to implement all requirements of ISO 13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations. GD210 will be used.

Viamed: To determine if the management system continues to meet the requirements of:
MDD 93/42/EEC Annex II 3.2

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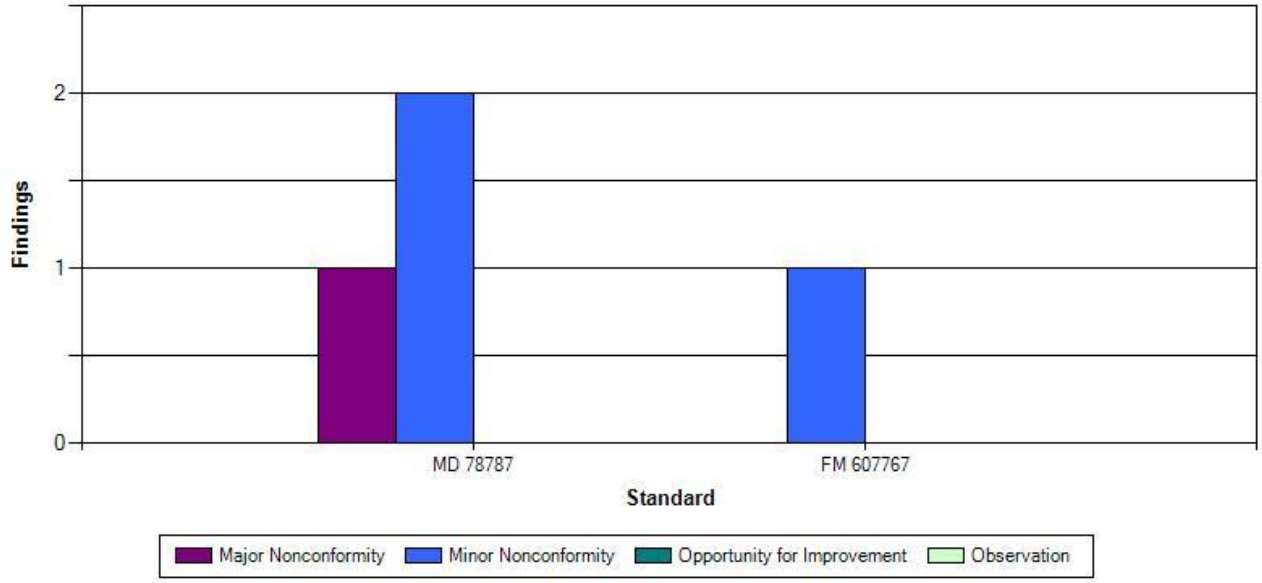
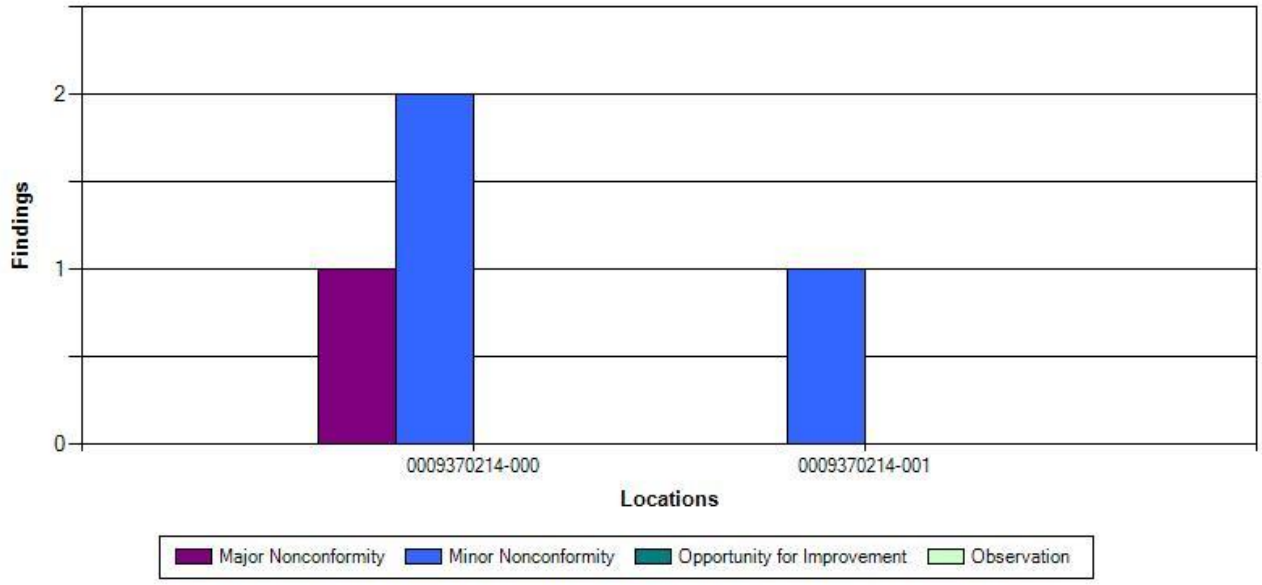
NCR summary

Which standard(s) BSI recorded findings against



Where BSI recorded findings



Definitions:

Nonconformity
Non-fulfilment of a requirement.

Major nonconformity
Nonconformity that affects the capability of the management system to achieve the intended results.
Nonconformities could be classified as major in the following circumstances:
- If there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- A number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor nonconformity
Nonconformity that does not affect the capability of the management system to achieve the intended results.

Opportunity for improvement
It is a statement of fact made by an assessor during an assessment, and substantiated by objective evidence, referring to a weakness or potential deficiency in a management system which if not improved may lead to nonconformity in the future. We may provide generic information about industrial best practices but no specific solution shall be provided as a part of an opportunity for improvement.

Observation
It is ONLY applicable for those schemes which prohibit the certification body to issue an opportunity for improvement.
It is a statement of fact made by the assessor referring to a weakness or potential deficiency in a management system which, if not improved, may lead to a nonconformity in the future.

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Assessment participants

Name	Position	Opening meeting	Closing meeting	Interviewed (processes)
Derek Lamb	Managing Director	X	X	X
John Lamb	Chairman	X	X	
Cathy Green	Goods Out Supervisor			X
Jonathan Connor	Warehouse Team Leader			X
Steve Nixon	Director			X
Sarah Walton	Office Administrator/Sales			

Status of actions from the previous assessment

Ref	Area/process	Clause
1225837M1	OBL STED review.	Annex II Section 3.2
Scope	CE 97289	
Certificate Standard	Healthcare	
Category	Major	
Details:	Evidence of compliance with various aspects of the technical file requirements could not be reviewed at the time of audit.	
Objective evidence:	Aspects of the technical file which were not available for audit included: Compliance with the Essential Requirements Biocompatibility (V&V) Risk Analysis and Control Summary Product Verification and Validation Clinical evaluation OEM labels for the devices	
Cause	The OEM labels and IFUs are in place an available to review at the clients premises. The technical files for the OEM products are to be made available from Bluepoint upon request. The OEM agreement for Bluepoint is currently under review within which these areas will be defined. The OEM agreement for Envitec is available and the technical files are to be shared when requested. The OEM agreement is currently under review with this company to allow for the technical file to be held locally.	

Correction / containment	The OEM labels and IFUs are in place an available to review at the clients premises. The technical files for the OEM products are to be made available from Bluepoint upon request. The OEM agreement for Bluepoint is currently under review within which these areas will be defined. The OEM agreement for Envitec is available and the technical files are to be shared when requested. The OEM agreement is currently under review with this company to allow for the technical file to be held locally.
Corrective action	The OEM labels and IFUs are in place an available to review at the clients premises. The technical files for the OEM products are to be made available from Bluepoint upon request. The OEM agreement for Bluepoint is currently under review within which these areas will be defined. The OEM agreement for Envitec is available and the technical files are to be shared when requested. The OEM agreement is currently under review with this company to allow for the technical file to be held locally.
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1368854M1	Virtual Manufacture requirements for products	Annex II 3.2
Scope	CE 97289	
Certificate Standard	Healthcare	
Category	Major	
Details:	The Technical Agreement with InveteC is not effective	
Objective evidence:	The client is purchasing the finished product from InveteC, but is not in control of the designs, specifications, etc. and does not hold the documentation mentioned above. The technical agreement requires InveteC to maintain traceability to batch serial number level, but not of any components below.	
Cause	The OEM agreement is currently under review with both Bluepoint and Envitec. The current process is traceable to serial number of the device and any concerns raised are monitored through the supplier returns and corrective action process. Any concerns or investigations performed are reported back to Viamed but only to system level. Without access to the technical files it will not be possible to review to component level. The Labels and IFUs are available to review during the assessment.	
Correction / containment	The OEM agreement is currently under review with both Bluepoint and Envitec. The current process is traceable to serial number of the device and any concerns raised are monitored through the supplier returns and corrective action process. Any concerns or investigations performed are reported back to	

	Viamed but only to system level. Without access to the technical files it will not be possible to review to component level. The Labels and IFUs are available to review during the assessment.
Corrective action	The OEM agreement is currently under review with both Bluepoint and Envitec. The current process is traceable to serial number of the device and any concerns raised are monitored through the supplier returns and corrective action process. Any concerns or investigations performed are reported back to Viamed but only to system level. Without access to the technical files it will not be possible to review to component level. The Labels and IFUs are available to review during the assessment.
Closed?:	No
Justification	This remains open until the agreements are agreed and the technical files are shared. 12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511824-201709-M1	Technical Documentation Assessed	Annex II, Section 3.4
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solutions adopted to fulfill Annex II are incomplete.	
Objective evidence:	No evidence has been provided in the Technical documentation despite request of a system for informing BSI of substantial changes or evaluation of such change.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

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Ref	Area/process	Clause
1511824-201709-M2	Essential Requirements	Annex I
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	Solutions adopted to fulfil Annex I are incomplete.	
Objective evidence:	[ER 4] – Lifetime is not defined in the technical documentation. There is no data in support of lifetime. There is no evidence of lifetime as part of the medical device consideration in the risk management file where lifetime based risks are explicitly stated as "N/A". Individual invoices are not evidence of rationale for device lifetime, and do not represent an analysis of lifetime in evidence of selected duration. There is no evidence of lifetime as defined in ER 4. [ER 5, 8.6] - No testing has been provided for this product. Documentation referenced by the ERC is a statement of model numbers and pictures of cardboard boxes. There is no evidence of support of claimed temperature ranges for shipment. There is no evidence provided of support for ability to meet customer need post shipment such as device testing or visual inspection. There is no evidence of storage testing or considerations in the referenced testing. No evidence to meet ER 5 has been provided. [ER 7.2] - There is no evidence of consideration of contaminants or residues for this device. While not provided sterile, the device in question is used in high risk environments including infants and neonates. No evidence was found in review of the trials and validations for support of lack of contamination. No summary or expect evidence is provided in post market data for contaminants. No risk evaluation associated with contamination was provided. [ER 7.6] - The observation by the manufacture that ingress is not applicable due to the ability to wash the device is not accepted. Ingress protection does not reference the clean ability of the device outside of use. Aspiration of liquid during use while not evaluated as part of risk is applicable to this device. No IPX rating has been defined. Evidence in support of ER 7.6 has not been provided. [ER 8.3, 8.4, 8.5] - Device is listed in all documentation and instructions for use as non-sterile. The technical file however references a single document ID 2253 which states "…the unit is chromed brass, so it can be dismantled and 'autoclaved' if required." This is in contradiction to all other provided evidence and user manuals. The manufacturer has confirmed in the response that the device is intended to be sterilized under certain considerations. The device has incorrectly been listed as non-sterile. No evidence of sterilization validation has been provided. No Microbiology audit has been performed as required for sterile devices. [ER 9.1] - Evidence has not been provided in the form of device testing, design inputs, system validation or structured legacy data that the device is able to be used in conjunction with other devices supplied by the manufacturer or devices used with the device such as the NeoPEEP patient circuit, flowmeter gas hose and hospital equipment. While it is recognized that function of other devices is the responsibility of those manufacturers, use in conjunction with the device under review is the responsibility of the manufacturer per ER 9.1.	

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	[ER 12.8] - Standards Compliance testing and design verification below are not accepted. Testing provided does not contain data which supports the assertion that flow rate accuracy can be maintained. Specifically, there are no claims around accuracy made in the design input specification, and no evidence of accuracy testing provided in the technical documentation.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511824-201709-M3	Risk Management File	Annex I ER 2
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solution adopted to fulfill the essential requirement 2 is incomplete. (Risk)	
Objective evidence:	The risk documentation was generally not found to be acceptable and failed to follow the state of the art processes of EN ISO 14971. Specifically: - No risk management plan was made available as part of the technical documentation. VM3COP27.11 which is referenced fails to cover the topics required by the risk management plan in accordance with ISO 14971. - Risk is not updated using field data: Additional risk documentation has been referenced as applicable such as risk analysis document #2182. This document has not been updated since 1998 - Risks are not calculated both before and after risk controls (per 14971 section 6.4). - An overall acceptability for each hazard is listed pre but not explicitly post-mitigation (per 14971 section 6.4). - There is no evidence that a multidisciplinary team was involved (per 14971 sections 3.3, 4.1(b)). - The risk file explicitly states that the usability is not capable of contributing to misuse and elects to not evaluate the risk, despite the existence of user interfaces and display - Mechanical hazards are systematically not accounted for - Risks related to repeated use and or exposure and materials are deliberately excluded from risk analysis: - Per ISO 14971, section 6, 7, risk control measures have not been proven to be implemented and verified.	

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	- Per ISO 14971, section 8, the risk management plan has not been demonstrated to have been implemented. Controls are not evident as being in place for obtaining relevant production and post-production information.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511824-201709-M4	Pre-Clinical Data	ER 1
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solutions adopted to fulfil essential requirement 1 is incomplete	
Objective evidence:	There is a systemic failure to address usability. While it is recognized that the device has been on the market for a substantial time, compliance to essential requirement 1 is still required. There is a failure to address multiple portions of usability state of the art including: - Failure to provide sufficient rationale for not applying state of the art harmonized standard EN 62366. - There was no evidence of a usability engineering process. - There is no evidence of an application specification. - Foreseeable hazards related to usability were not identified. The risk file explicitly states that the usability is not capable of contributing to misuse and elects to not evaluate the risk. - There was no usability specification was available for review. - There was no design validation was implemented on representative users per a plan, or acceptance. - The manufacturer has not considered EN 60601-1-6 or EN 62366, or supplied sufficient rationale for non/partial compliance - The manufacturer did not perform a retrospective analysis per Annex C of BS EN 62366-1: 2015 (Annex K of IEC 62366: 2015) for the legacy product.	
Cause		
Correction / containment		

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Corrective action	
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511824-201709-M5	Pre-Clinical Data	Annex I ER 3
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solutions adopted to fulfill essential requirement 3 is incomplete.	
Objective evidence:	- Design Inputs are not uniquely or clearly identified. - Design input document has not been updated since 1997, despite design changes being made as late as 2004 in accordance with the risk management file. - The outputs of risk management are stated to be design inputs in the risk management but fail to be expressed in the design input file. - While it is acknowledged that the device has been in the field for many years, there is no evidence of a design control system provided. - No evidence of design verification, current or historical has been provided. ID2471 (Test Reports), ID 2460 (Test reports) state only "The equipment was tested against customer requirements…" Documentation identified by the manufacturer ID 8486, continues to state only general work instruction for shipment tests and makes no mention of design testing, link to risk, design inputs, outputs or acceptance criteria. No data or summary data is made available.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1511824-201709-M6	Pre-Clinical Data	[Annex I ER 2]
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solution adopted to fulfil the Essential Requirement 2 is not complete.	
Objective evidence:	There is no evidence of compliance to claimed standards, including EN 60601-2-10, and EN 60601-1. All clauses of the standard per report ID 11655 (version 1332256919) have been listed explicitly as N/A including clearly applicable standards such as but not limited to section 7.0 and section 9.0. There is no evidence of compliance in part or in full to the harmonized standard EN 60601-1 or a rationale for partial compliance.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1511824-201709-M7	Pre-Clinical Data	ER 7.1
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solutions adopted to fulfill the essential requirement 7.1 are incomplete.	
Objective evidence:	Biocompatibility documentation does not fully meet requirements. Documents ID2474 and, ID7884 (No revisions provided) fail to: - Provide a Biological Evaluation Plan or overall Biological Evaluation Report made by a qualified person - Consider harmonized standards - Consider duration or nature of contact - Provided rationale for use of post market data. - Provide evidence of any consideration of biological impact. - Consider risk related to biological compatibility of the device.	

Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511824-201709-M8	Information Supplied by the Manufacturer	Article 17 & Annex I, ER 13
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The instructions for use and the labels do not meet the requirements of Article 17 The instructions for use and the labels do not meet the requirements of Essential requirement 13 of Annex I.	
Objective evidence:	- Multiple Notified Body ID numbers have bene identified on active labelling: (0123) found on document ID 13654 Revision B. - Precautions related to change in performance are not included - Responses to other sections of the technical file indicate the device is intended for sterilization. Labeling and IFU do not cover sterilization methods. - Special handling instructions as identified in the technical file and IFU are not present on the labeling.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1511849-201709-M1	Essential Requirements	Annex I
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	Solutions adopted to fulfil Annex I are incomplete.	
Objective evidence:	[ER 4] – Only a single point of data has been discussed regarding serial number H0000330. No analysis supports that this data or other available data can support the shelf life of 10 years as stated. Data sheets provided on the "Returns," data sheet are not structure in an analysis in support of lifetime. No testing or report / analysis have been provided in support of lifetime. [ER 5 & 7.2 & 8.6] - Shipment testing was "Simulated," per ID 9027, 3320, and other such documents. However there is no data associated with any packaging testing provided. There is no evidence of protocol, acceptance criteria, or evidence provided of the ability of the package to protect the device in accordance with the MDD ER 5.0 through functional testing or visual inspection. [ER 7.6] - IPX rating is not defined. The Standards Compliance testing below is listed by the client as not applicable without rationale. No evidence for ingress protection has been provided. [9.1] - Evidence provided in the form of document ID 1771 is illegible. The device is used in combination with hospital supplied electrodes. There is no evidence of testing or design inputs and risk considerations for use with incorrect electrodes or other devices. Risk documentation explicitly discounts EMC related issues and compatibility issues. Response by the manufacturer does not provided evidence of function of the device through risk or functional testing. [12.6] - No evidence has been provided of safety in the form of design verification testing or standards compliance testing. There is no evidence of safety from shock. [12.7] - No design verification or standards testing / evaluation have been provided. No evidence of compliance to ER 12.7 has been provided. [12.8] - No design verification or standards testing / evaluation have been provided. No evidence of compliance to ER 12.8 has been provided.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

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Ref	Area/process	Clause
1511849-201709-M10	Information Supplied by the Manufacturer	Annex I, ER 13
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The instructions for use and the labels do not meet the requirements of Essential requirement 13 of Annex I.	
Objective evidence:	- The manufacturer has not provided evidence of compliance in the form of any package label for review despite explicit request. - Special handling and storage instructions were not present in the IFU. - Leads related labels were not provided.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1511849-201709-M2	Risk Management File	Annex 1 ER 2
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solution adopted to fulfill the essential requirements ER 2 is incomplete.	
Objective evidence:	The risk management file fails to take into account multiple portions of the EN ISO 14971. Relevant and demonstrated risks are not accounted for in the risk management file. Examples include: - The risk management plan (ID9471_Microstim_MkIII_Risk_management_plan) does not include the scope of the planned risk management activities, or describe the medical device and the life-cycle phases for which each element of the plan is applicable per ISO 14971 section 3.4a. The plan does not include assignment of responsibilities and authorities per ISO 14971 section 3.4.b. The plan does not include requirements for review of risk management activities per ISO 14971 section 3.4c. The plan does not include criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk per ISO	

	14971 section 3.4d. The plan does not include verification activities per ISO 14971 section 3.4e. The plan does not include activities related to production and post-production information collection and review per ISO 14971 sections 3.4f and 9. - The risk analysis (ID19657_Microstim_MkIII_Risk_analysis) fails to include: identification of the people and organization who carried out the risk analysis per ISO 14971, section 4.1b. Fails to include the scope and date of the risk analysis per ISO 14971, section 4.1c. The risk analysis fails to consider use related failure modes such as Not reading IFU, or accidental errors, while explicitly sting there are "over 700 possible output of the device" (In document ID13106) Ergonomics and usability are explicitly discounted. The risk analysis fails to consider failure modes such as breakage, wear or lifetime. The risk analysis also fails to consider explicitly the use environment such as dropping of the device. - The risk analysis fails to consider risks such as the device influencing the environment electrically, or being influenced by it despite repeated reference in the technical documentation to interference with a pacemaker. - Risk explicitly and incorrectly states there are no connecting parts, despite connection of accessories such as leads and electrodes supplied by the user. - Risks are not calculated both before and after risk controls (per 14971 section 6.4). - The IFU appears to be used to reduce risk in violation of 14971, Annex ZA. Specifically Reference Question 71. C.2.14 in ID 19657. "Possibility of interference with heart rate, if the wires are placed near the pacemaker. Risk is well known and is referred to in the instruction manual." - There is no evidence that the risk documentation includes information from complaints. (Known complaints such as pacemaker interference are not accounted for.) - The risk analysis explicitly and in contradiction to other technical documentation states that the device will not come into contact with the patient or other persons. - Risk management explicitly claims the device does not contain software. However the technical documentation includes software per ID13106 and 3438 Microstim MkIII Software. Risk of software failure are not addressed or considered at all in the risk management.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511849-	Pre-Clinical Data	Annex I ER 1

201709-M3		
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solutions adopted to fulfil the essential requirement 1 are incomplete	
Objective evidence:	The manufacturer has no evidence of a usability process compliant with the requirements. Specifically: - There was no evidence of a usability engineering process: - There is no evidence of an application specification or defined inputs related to intended user profile, or use environment. - Foreseeable hazards related to usability were not identified and were at times deliberately excluded from risk management (See risk management section for details). - Design inputs make no mention of user interfaces, or usability in any fashion. - A questionnaire was provided in documents ID 9152, and ID 3405. Single personnel in 2007 without legible signature signed and completed a single sample. This does not meet the requirements for statistics and coverage of all possible end users. - There is no evidence of a retrospective analysis per Annex C of BS EN 62366-1: 2015 (Annex K of IEC 62366: 2015) for the legacy product.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	**Area/process**	**Clause**
1511849-201709-M4	Pre-Clinical Data	Annex I, ER3
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solution adopted to fulfil the Essential Requirements is not complete.	
Objective evidence:	While there are tests performed against the MicroStim device for output voltages, and resistance in a general sense, there is insufficient evidence of coverage of design inputs by design verification and validation provided in the technical documentation. Specifically: - Explicitly incorrect statements are included in the document ID 3407 Microstim	

	Validation and ID 9153. This pair of document states that "EMC Tests carried out to IEC601." However document ID3280, and ID15602 explicitly state that EMC testing is not to be performed. - Document ID 3407 makes no explicit reference to design inputs relative to accepted protocols and reports in any design instance. - Software was explicitly and deliberately not tested. (ID 13106) - Test reports are not signed and dated. - Test reports do not link in any manner to design inputs under test and lack acceptability criteria, sample size, and protocols. - Document ID 8035 states "Current," design changes being driven by end user in 2009, but there is no evidence of design change control or implementation of such changes.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511849-201709-M5	Pre-Clinical Data	Annex I ER 2
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solution adopted to fulfill the essential requirement 2 is incomplete. (Harmonized standards)	
Objective evidence:	- The manufacturer has stated explicitly that the device is not compliant to EN 60601-1:2006 or any other year. No rationale has been provided for non-compliance to a harmonized standard. While a general statement is made that the device is "Built to this standard," no evidence has been provided of consideration of this or any harmonized standards.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	

Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511849-201709-M6	Pre-Clinical Data	Annex I, ER 2
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solution adopted to fulfil the essential requirements is incomplete.	
Objective evidence:	- The manufacturer considers the harmonized standard EN 60601-1-2:2007 in documents ID3280, and ID15602. However, there was no evidence of full or partial compliance to the standard or a sufficiently documented justification for partial/non-compliance. - Rationale for device being "Unable to be tested," is not unique to the device, and does not constitute a rationale for non-test. The device remains an electromechanical device which is also itself susceptible to EMI. - Evidence supplied indicated the device generates EMI through demonstrated interference with a pacemaker.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

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Ref	Area/process	Clause
1511849-201709-M7	Pre-Clinical Data	ER 7.1
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solutions adopted to fulfill the essential requirement 7.1 are incomplete.	
Objective evidence:	While skin contact with patient and user are stated explicitly in the technical documentation stated in document ID 9471 no tests have been provided in support of biocompatibility, or a rationale for the lack of test or applicability of materials.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1511849-201709-M8	Pre-Clinical Data	12.1a
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The process to ensure that the devices comply with all applicable standards is not effective.	
Objective evidence:	No response has been given by the manufacturer with regard to state of the art compliance to EN 62304. The statement was made "The device is state of the art," is not supported through any software related documentation. The client has confirmed the presence of software through the statement "IC16f8X is the processor used and programmed," and through supply of the raw software file in the technical documentation. Failure to follow state of the art includes but is not limited to: - Failure to classify the safety class of the device. - Failure to follow EN 62304 process or provide rationale for state of the art / partial non-compliance. - Failure to provide design inputs related to software, requirements analysis or traceability	

	- Failure to provide software development process - Failure to demonstrate software maintenance process or resolution analysis - Failure to provide evidence of regression testing for existent software - Failure to consider risk related to existent software. - Failure to provide PEMS testing - Failure to provide SW verification testing
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511849-201709-M9	Clinical Evaluation	Annex X, Section 1.1
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Major	
Details:	The clinical evaluation is inadequate.	
Objective evidence:	- It is unclear the route to Annex X conformity which has been selected. Sufficient evidence for no particular route has been provided. - The client identifies Annex X 1.1.d as their route to conformity as regards the clinical evaluation. However, no clear statement of justification for the exclusion of clinical evaluation based on risk management is provided. Only a reiteration of the Annex X 1.1.d statement is provided. Restatement of the MDD does not constitute a rationale. - A statement that a literature search has been carried out is present. However no literature review has been presented. - There is insufficient evidence that the device performs its clinical indicated use. Referenced document ID 19655 demonstrates there are clear performance issues, and device failures in the field. These are not listed as complaints, and the general statement "Devices perform as intended," is not demonstrably true, or defense of not performing clinical evaluation.	
Cause		
Correction / containment		

Corrective action	
Closed?:	No
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1515871-201705-M1	Intended Use and Classification	Annex IX, Section II
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Major	
Details:	The process to ensure that devices are correctly classified is not effective.	
Objective evidence:	- No mention of device classification was provided in the technical documentation, or in the essential requirements. No Declaration of conformity declaring such compliance was provided. - It is unclear that the device is properly classified (IIa vs IIb) based on intended use statements.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	**Area/process**	**Clause**
1515871-201705-M2	Essential Requirements	Annex I
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Major	
Details:	Solutions adopted to fulfil Annex I are incomplete.	

Objective evidence:	[ER 4] - While the risk management file clear states there is a finite functional lifetime for the device, "Oxygen Sensors measure oxygen, as they do so they use up the electrolyte," no shelf life testing or functional life testing has been provided. No evaluation or derivation of such a lifetime has been provided. [ER 5, 8.6] - No evidence of packaging validation or evidence that the device is shipped within the design limits specified by the OEM gave been provided. No visual inspection or device function testing has been provided post shipment. [ER 7.3] - The ERC states explicitly the device comes into contact with oxygen and other anaesthetic gases. While evidence for accuracy is supplied by EN 80601-2-55 testing explicit evidence for use in combination with other foreseeable gases has not been provided. Risk associated with said contact has not been evaluated. [ER 9.1] - A large list of available devices into which the sensor is installed is provided in the instructions for use. However the technical documentation provided while supplying technical limits to the sensors does not demonstrate in the IFU or in design verification that the device will function when used as indicated.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1515871-201705-M3	Risk Management File	ER2
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solutions adopted to fulfill the essential requirements are incomplete.	
Objective evidence:	The system presented systemically fails to follow ISO 147971 requirements, including but not limited to: The identified risk management document fails to (not limited to): - assignment of responsibilities and authorities per ISO 14971 section 3.4b - review of risk management activities per ISO 14971 section 3.4c - includes verification activities per ISO 14971 section 3.4e - includes activities related to production and post-production information collection and review per ISO 14971 sections 3.4f and 9 While the risk management is recently updated there is no reference to post	

	market surveillance data or evidence of maintenance of the risk management file in light of field data for the devices in question. Risks are not calculated both before and after risk controls (per 14971 section 6.4). Key relevant risks are identified as not applicable, with insufficient or incorrect rationales, including exclusion of monitoring functions as relevant risks.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1515871-201705-M4	Pre-Clinical Data	ER 3
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Major	
Details:	The solution adopted to fulfil the Essential Requirements is not complete	
Objective evidence:	- Despite providing OEM function specifications, evidence of design verification tied to these design inputs was not provided beyond EN 80601-2-55 safety testing. Furthermore design inputs by the manufacturer through which the components were selected IE. requirements which these components must meet, were no provided - Testing against design inputs was not provided beyond standards assessments.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist.	

	30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	Area/process	Clause
1515871-201705-M5	Clinical Evaluation	Annex X 1.1.c
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Major	
Details:	The system for post-market clinical follow-up is inadequate.	
Objective evidence:	While the supplied PMS document ID20910 was reviewed and found to contain data on field failures and resulting evaluation and action, no explicit PMCF or justification for not completing PMCF has been provided.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1515871-201705-M6	Declaration of Conformity	Annex II
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Major	
Details:	The EC declaration of conformity does not fully meet the requirements of Annex II	
Objective evidence:	The manufacturer has failed to provide a Declaration of Conformity per Annex II and the NB-MED Consensus Statement S/01/99 "The EC declaration of conformity is the procedure whereby the manufacturer who fulfills the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product	

	name, product code or other unambiguous reference…"
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1527388-201709-M1	Management Review: 4.2.4, 5.6, 8.2.3, 8.2.4, 8.4	5.6.1
Scope	MD 78787	
Certificate Standard	ISO 13485:2003	
Category	Major	
Details:	Management review is not effective because evidence of an effective process could not be demonstrated at this assessment.	
Objective evidence:	Evidence of monitoring quality objectives and reviewing the monitoring results during management review could not be provided. Management Review Procedure VOP13 (#8668) references the ISO 9001:2008 and ISO 13485:2012 review inputs only. The process was stated to be applicable for both businesses operating at this location. Evidence of reviewing the results of audits, feedback, complaint handling, reporting to regulatory authorities, monitoring and measurement of processes and corrective action could not be provided. Management review record for Vandagraph dated 04/05/2017 was incomplete. There is no documented reason. No new meeting was demonstrated to be scheduled. Records: Viamed - minutes of management review dated 14/02/2017 Vandagraph - minutes of management review 04/05/2017	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective	

	action plan had not been fully accepted at the time of this assessment.

Ref	Area/process	Clause
1527388-201709-M2	Internal Audit: 8.2.2, 4.2.4, 8.2.3, 8.2.4	8.2.2
Scope	MD 78787	
Certificate Standard	ISO 13485:2003	
Category	Major	
Details:	The internal audit process is not effective because planned arrangements and effective implementation were not demonstrated.	
Objective evidence:	While standard annual internal audits numbered 1-12 were seen to be set as repeatable tasks (referred to as issues) in the electronic system and the company procedure (VM3/COP13 #8715 dated 26/11/2011) made provision for internal audits to be conducted, the following were not found to be addressed: 1. 'Audit 10' required for June 2017 had not been completed as set (last conducted June 2016) with no justification recorded. 2. There is no planned interval documented in procedure VM3/COP13 #8715 dated 26/11/2011 and a schedule had not been established and demonstrably adhered to describing the criteria, scope or responsibilities for audits. Criteria does not include clear reference to applicable standards or the MDD/CMDCAS requirements. The process was stated by the MD to be assessing compliance to procedure only, not for compliance to applicable standards or regulatory requirements. 3. Evidence that consideration is made for the status and importance of processes and areas to be audited or the results of previous audits could not be demonstrated. 4. The auditor for the training/competence process dated 2/8/2017 was stated to be also responsible for the HR function. 5. Audit records: for example Audit 02 for VST 17/8/16 provide evidence of identifying issues with the process, but only provided evidence of correction, not corrective action. The corrective action process was not used and justification not provided.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective action plan had not been fully accepted at the time of this assessment.	

Ref	Area/process	Clause
1225837N1	OBL STED review.	Annex I ER 13.3e
Scope	CE 97289	
Certificate Standard	Healthcare	
Category	Minor	
Details:	Not all aspects of labelling are covered by labels on the device.	
Objective evidence:	There is no indication of the date the device should be used by and it seems appropriate that there should be as these items may be stored prior to use and do not last forever.	
Cause	The client is in contact with the manufacturer who has informed them that there are no requirements for the Envitec Oxygen Monitor to have a use by date. The product is used in situ with another device which shows if the sensor is working or not. The sensor is calibrated, as per the instructions for use, prior to each use. If the product fails calibration the item will not be used.	
Correction / containment	The client is in contact with the manufacturer who has informed them that there are no requirements for the Envitec Oxygen Monitor to have a use by date. The product is used in situ with another device which shows if the sensor is working or not. The sensor is calibrated, as per the instructions for use, prior to each use. If the product fails calibration the item will not be used.	
Corrective action	The client is in contact with the manufacturer who has informed them that there are no requirements for the Envitec Oxygen Monitor to have a use by date. The product is used in situ with another device which shows if the sensor is working or not. The sensor is calibrated, as per the instructions for use, prior to each use. If the product fails calibration the item will not be used.	
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1417669N1	Review of Open non-conformities from the last assessment	Annex II 5.4
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Minor	
Details:	The technical agreement with Bluepoint is not fully effective.	
Objective evidence:	The Bluepoint OEM agreement doe not allow for access to their premises in the event of an unannounced visit from a notified body.	
Cause		
Correction /		

containment	
Corrective action	
Closed?:	No
Justification	Not part of technical file review. To be reviewed by QMS Auditor. 12/09/2017 - remains open. Due to this visit being aborted it was not possible to review this nonconformity. This will be reviewed at the next planned assessment later this year. 30/10/2017 - Remains open. Bluepoint contract relates to a certificate which has been subject to a cancellation request at this assessment.

Ref	**Area/process**	**Clause**
1511824-201709-N1	Intended Use and Classification	Annex IX, Section II
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Minor	
Details:	The process to ensure that devices are correctly classified is not fully effective	
Objective evidence:	Despite identification of all applicable definitions, the client has chosen rule 10, which is indicated for diagnosis. The device does not diagnose.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - Not part of this assessment. To be reviewed by a technical expert 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	**Area/process**	**Clause**
1511849-201709-N1	Intended Use and Classification	Annex IX, section II
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Minor	
Details:	The process to ensure that devices are correctly classified is not effective.	
Objective evidence:	While the main device was correctly identified and classified as a medical device, Document ID 8023 and 9285 identified in the technical documentation	

	as classification rationales make no mention of the classification of the accessories identified in the technical documentation.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1511849-201709-N2	Design Inputs	Annex II, Section 3.2c
Scope	CE 01389	
Certificate Standard	Healthcare	
Category	Minor	
Details:	The evidence of design control was incomplete	
Objective evidence:	While there are design inputs, complete evidence for the ability to comply with the MDD was not demonstrated by the technical documentation. Specifically: - There is no evidence of design inputs related to risk management or traced to risk management. There is no clear means by which to trace design verifications to design inputs. - The design input document fails to cover key elements of the design including but not limited to: user expectations, labeling requirements, safety, training, packaging, interface, environmental, storage and shelf-life, material, regulatory requirements, accuracy claims of outputs and standards.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - not part of this assessment. Visit was aborted by the client. Refer to Executive Summary 30/10/2017 - remains open. Major nonconformity was raised with respect to design and development and risk management.	

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Ref	Area/process	Clause
1515871-201705-N1	Pre-Clinical Data	Annex I ER 1
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Minor	
Details:	The solutions adopted to fulfill the essential requirements are incomplete	
Objective evidence:	While the ERC ID21171 properly discusses that usability largely does not apply to the device in question as a component only, usability covers the full life of the product including installation. No evidence has been provided for who the end user would be (technicians) or device installation usability beyond basic review of risk of calibration.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert	

Ref	Area/process	Clause
1515871-201705-N2	Information Supplied by the Manufacturer	Annex I, ER 13
Scope	CE 540537	
Certificate Standard	Healthcare	
Category	Minor	
Details:	The information supplied by the manufacturer does not fully meet the essential requirements.	
Objective evidence:	Storage and shipment conditions between labels and IFU are not consistent. Specifically: - Labeling clearly states handling temperature "5-20C" - IFU states "Recommended storage 5-15C" and "Storage -20-50C" neither of which is in line with OEM requirements or labeling. Connection to other devices: It is unclear form the instructions for use / labeling how the end user determines proper connection to other devices. Precautions for change in performance: Incorrectly N/A by the manufacturer. The device is capable of performance issue which may require action or contact of the manufacturer. No instruction is provided. Manufacturer referenced documents 17847 and 17842 safety data sheets have	

	not been provided. Additionally it is unclear if these sheets are provided to the end user. As such no evidence has been provided that performance is provided to the user.
Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	12/9/2017 - not part of this assessment. To be reviewed and closed by a technical specialist. 30/10/2017 - Not part of this assessment. To be reviewed by a technical expert

Ref	**Area/process**	**Clause**
1527388-201709-N1	Essential Assessment Information, Opening Meeting and Changes: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1	2015:7.5.3.2
Scope	FS 28344	
Certificate Standard	ISO 9001:2008	
Category	Minor	
Details:	Control of documented information is not fully effective because evidence of revision control was not clearly provided on the list of needs/expectations of interested parties or the viewable pdf of the Viamed Company Responsibilities document.	
Objective evidence:	Viamed Company Responsibilities document #21556 - electronic revision control was demonstrated but there was no evidence of revision control on the viewable document. The list of Needs/Expectations of Interested Parties had no evidence of revision control. The Quality Policy for Vandagraph Sensor Technologies had a last review date of 24/8/2016 but no future review date set (entry blank) The Quality Policy for Viamed had a missed review date. Set for 24/8/2016.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	

Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective action plan had not been fully accepted at the time of this assessment.

Ref	**Area/process**	**Clause**
1527388-201709-N2	Essential Assessment Information, Opening Meeting and Changes: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1	2015:4.3
Scope	FM 607767	
Certificate Standard	ISO 9001:2008	
Category	Minor	
Details:	The scope of the quality management system is not fully effective because appropriate documented information could not be provided.	
Objective evidence:	Documented information defining the scope of the quality management system and applicable management system standards could not be provided at this assessment. Document #13954 referenced ISO 9001:2008 only. This document did not clearly provide evidence of considering external and internal issues or the requirements of relevant interested parties.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective action plan had not been fully accepted at the time of this assessment.	

Ref	**Area/process**	**Clause**
1527388-201709-N3	Essential Assessment Information, Opening Meeting and Changes: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1	2016:4.1.6
Scope	MD 78787	
Certificate Standard	ISO 13485:2003	
Category	Minor	
Details:	Software validation for the application of computer software used in the QMS is not fully effective because a documented procedure and validation records could not be provided.	
Objective evidence:	A documented procedure meeting the requirements of clause 4.1.6 of ISO 13485:2016 could not be provided at this assessment. Records of software validation meeting the requirements of clause 4.1.6 could not be provided at this assessment.	

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Cause	
Correction / containment	
Corrective action	
Closed?:	No
Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective action plan had not been fully accepted at the time of this assessment.

Ref	**Area/process**	**Clause**
1527388-201709-N4	Essential Assessment Information, Opening Meeting and Changes: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1	2016:4.2.2
Scope	MD 78787	
Certificate Standard	ISO 13485:2003	
Category	Minor	
Details:	The quality manual is not fully effective because the identification of non-applicable clauses are not clearly documented and a contradictory statement was evident.	
Objective evidence:	The list of non-applicable parts of the quality management system standard do not reference clause numbers and identifies active implantable as non-applicable where the standard only references implantable devices. Sterile requirements are identified as non-applicable but an additional statement is included stating that some distributed products are sterile but not opened. The scope does not currently include distribution of sterile devices.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective action plan had not been fully accepted at the time of this assessment.	

Ref	Area/process	Clause
1527388-201709-N5	Top Management Discussion: 5.1, 6.1	2015:6.1.1
Scope	FM 607767	
Certificate Standard	ISO 9001:2008	
Category	Minor	
Details:	Risk and opportunities determination is not fully effective because evidence of identifying risks and actions to address them related to the requirements of 4.1 and 4.2 could not be provided.	
Objective evidence:	Evidence of identifying risks and actions to address them related to the requirements of clause 4.1 and 4.2 of ISO 9001:2015 could not be provided at this assessment.	
Cause		
Correction / containment		
Corrective action		
Closed?:	No	
Justification	This was raised at the aborted assessment on 12 Sept 2017. The corrective action plan had not been fully accepted at the time of this assessment.	

Assessment findings

The assessment was conducted on behalf of BSI by

Name	Position
David Vicar	Team leader

Assessment conclusion and recommendation

Audit objectives are not met.

A major nonconformity was identified during this assessment and two major nonconformities were identified during the aborted assessment in September which impacts both Viamed and Vandergraph Sensor Technologies.

NOT RECOMMENDED – Corrective action closure required (major findings). A recommendation cannot be made until further assessment has been conducted to verify the effective implementation of the corrective actions. A corrective action plan is required for all nonconformities in this report.

Please submit a plan to BSI detailing the nonconformity, the cause, correction and your proposed corrective action, with responsibilities and timescales allocated. The plan is to be submitted no later than 10/11/2017 by e-mail to msuk.caps@bsigroup.com, referencing the report number, or through the BSI Assurance Portal if this is enabled for your account.

An additional 1 day visit over and above the continuing assessment plan will be necessary to verify that the planned corrective action has been effectively implemented. This visit will take place on 27/11/2017.

Use of certification documents, mark / logo or report

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

Findings

Opening Meeting and changes: (8.5.2), [8.5.2], {10.2}:

The opening meeting was conducted with the presence of the Managing Director (audit representative) and the Chairman.

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 current registration certificates and scope of the registration were stated to be correct as per below, but please also see the requested changes on the following page:

Vandagraph Sensor Technologies:

FM 607767 - The design, development and supply of gas sensors and associated systems.

The scope of this certificate does not include manufacture, but manufacture is not identified to be non-applicable and control of manufacture is involved.
(Ref: NC Raised)

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

CE 01389 - The design and manufacture of microstim nerve stimulators, oxygen hoods, gas respiratory adapters, gas respiratory valves and phototherapy light shields

MD 78787 (ISO 13485:2003/2012)- The design, outsource manufacture, manufacture and service (including that carried out on customer premises of nerve stimulators and nerve locators, resuscitators, monitoring devices for physiological parameters including accessories) of the following: Apgar timer; Gas Exchange monitors; Oxygen monitors; Oxygen Sensors; Temperature monitors; Temperature probes and cables including Temperature probes in catheters; Cot lids; Gas respiratory adaptors; Gas respiratory valves; Heat shields; Nerve locators; Nerve stimulators; Oxygen hoods and tents; Phototherapy light shields; Resuscitators; Ventilation tube holders; Simulation, Test and Calibration Equipment for monitoring devices.

CE 97289 - Design and manufacture of Electrochemical Oxygen Sensors.

CE 540537 - The design and manufacture of Sp02 modules and monitors and sensors, gas flow sensors, breathing gas exchange monitors and sensors, gas sampling lines and temperature probes

FM 540797 (CMDCAS) - The design and manufacture of supramaximal nerve stimulators.

Please refer to the following page for the changes to these Viamed certificates as requested by the client.

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Viamed (requested changes):

CE 01389 Please change to the following: - The design and manufacture of Oxygen Sensors, Supra-Maximal Peripheral Nerve Stimulator & Infant T-Piece Resuscitators.
(The need for a technical file review prior to implementing this change was discussed with the Chairman and Managing Director)

MD 78787 (ISO 13485:2003/2012) Please change to the following -
The design, manufacture and service of: Oxygen Sensors and accessories, Supra-Maximal Peripheral Nerve Stimulator, Simulation Equipment, Infant T-Piece Resuscitators, Apgar Timer & resuscitation cabinets. Includes service of Infant T-Piece Resuscitators & Apgar Timer on customer premises.
Distribution of medical devices from other manufacturers.
Service of medical devices from other manufacturers.
Service on customer premises of other manufacturers' medical devices: Radiant Warmers, Air/Oxygen Blenders & Suction Controllers.

(note that the above requested change has removed some products from the scope)

FS 28344 (ISO 9001:2008) - Please cancel this certificate at client request.

CE 97289 - Please cancel this certificate at client request.

CE 540537 - Please cancel this certificate at client request.

FM 540797 (CMDCAS) - Please cancel this certificate at client request.

Quality Manual Version: Viamed - 2017, #23665, VST Quality Manual #23667

Exclusions and Non-Applications of Requirements in the QMS:
Viamed - Contamination control, Sterile and implantable products.
Vandagraph Sensor Technologies - no non-applicable elements identified.

Significant Changes:
There have not been any major or significant changes to the QMS, organisational structure, products or process since the last visit. Following a recent technical file assessment the client has decided to withdraw several products from the market and to cancel two certificates. See the certificate changes highlighted above.

Adverse Incidents, Field Safety Corrective Actions and Recalls:
There have been no adverse incidents, recalls, or requirement for field safety corrective actions or (vigilance/mandatory problem reports) since the last report.

Corporate Identity of the Manufacturer:
Viamed is a family business designing, manufacturing and distributing a range of medical devices. Vandagraph Sensor Technologies (VST) also operates from the same premises as a separate company utilising common resources. For commercial reasons VST has its own ISO 9001 certificate.

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Description of the manufacturer:
Viamed distribute a range of medical devices in a world market. Some devices are sold under OBL agreements although this is changing following certificate cancellation requests. The manufacture of some devices is outsourced. Some small scale manufacture takes place of legacy products. Processes include QA, design, manufacture, purchasing, sales, warehousing and distribution.

Vandagraph Sensor Technologies Ltd is a sister company to Viamed Ltd operating out of the same premises utilising common staff, facilities and quality system. For operational and business reasons, VST Ltd. requires a separate management certificate.

Critical Subcontractors:
Blue Point Medical GmbH & Co. KG, An der Trave 15, 23923 Selmsdorf, Germany for the manufacture of instrumentation Instrumentation Industries (Manufacture). Even these products are 100% given a function check by the client. The certificate cancellation request may remove Blue Point Medical as a CE critical subcontractor.
Another subcontractor is listed on the CE certificates for the manufacture of Electrochemical Oxygen Sensors. The client has requested that this remain out of the report.

Senior Management of the Assessment Location(s).
Derek Lamb - Managing Director

Name and contact details of the Management Representative:
Derek Lamb - Managing Director
email: derek.lamb@viamed.co.uk
tel: 01535 634542

Staffing and Audit Durations:
Staffing and effective staffing numbers were reviewed against IAF MD9 annex D and MDP200 (CP0200). The effective number of staff was stated to be 15. Based on the number of effective staff and certificates the audit days are appropriate at 1 day surveillance and 2.5 days recertification.

To allow for review and closure of remaining QMS nonconformities and for completion of transition at the next surveillance assessment an additional 1 day duration is recommended.

Note that following transition certificates for ISO 13485:2016 and ISO 9001:2015 will be assessed together which will increase the overall assessment duration.

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Feedback Processes, Complaint Management and Vigilance: (8.2.1, 8.5.2), [8.2.1, 8.2.2, 8.5.2], {8.2, 8.5.5, 9.1.2}:

Feedback Processes, Complaint Management and Vigilance was assessed.
The Managing Director was interviewed in the meeting area and demonstrated implementation of the process.

Feedback, Complaints and vigilance are controlled by VOP19 dated 28 Oct 2017, doc revision ID #23575. Doc revision ID #23647 is used for Vandagraph, where the process is the same but does not include vigilance/reporting due to the non-medical nature of the products.

Post Market surveillance is controlled by VOP13 doc revision ID #23659 and post market surveillance template VM3COP27.11.

Viamed and Vandagraph have a system where feedback is assessed and nonconformances are raised within their system. These nonconformances could be for any issue. Nonconformances are reviewed to determine whether they are formal complaints. In the last 12 months there have been 2 complaints raised for Viamed and 3 for Vandagraph Sensor Technologies. Complaint CCR149 and CCR150 and doc ID #19655 Microstim III Post Market Surveillance 25/4/2017 were sampled for Viamed. The Viamed complaints were seen to be reviewed for vigilance. Justification for not taking corrective action was provided.
Not all negative feedback nonconformities raised on Intrastat are determined to be complaints. A determination related to vigilance was stated to be made for these nonconformities, but not clearly documented in the record.
(Ref: NC Raised)

Complaints CCR147 and CCR148 for Vandagraph Sensor Technolgies were sampled. CCR151 had been opened as a complaint but was waiting on further information at the time of this assessment.

Negative and positive comments are recorded for Viamed and Vandagraph Sensor technologies in order to assess customer satisfaction. A sub-management-review assesses the level of customer satisfaction - records from 30/9/2017 and 18/10/2017 were sampled.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Feedback Processes, Complaint Management and Vigilance were found to be generally effective to meet the needs of the business but not fully compliant with the requirements of the audit criteria.

A minor non-conformity was therefore raised which requires corrective action.

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Improvement - Preventive and Corrective Actions: (8.5.2, 8.5.3), [8.5.2, 8.5.3], {10.2}:

Preventive and Corrective Actions was assessed.
The Managing Director was interviewed in the meeting area and demonstrated implementation of the process.

Preventive and Corrective Action is controlled by VOP10 dated 28 Oct 2017 Doc revision ID #23623.

In the last 12 months there has been 1 corrective action raised internally which affects Viamed and Vandagraph Sensor Technologies. Nonconformity #102038 dated 3 Sept 2017. This relates to the Intrastat system not being able to produce all relevant PDFs held internally. A root cause has been identified and the identified actions are in progress.

Corrective actions relating to third party technical file assessments by BSI were not assessed as part of this visit. These are in progress and under review by the scheme manager.

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

Supply Chain, purchasing and Supplier Risk Management: {8.4.1, 8.4.2, 8.4.3}:

Supply Chain and purchasing was assessed for the Vandagraph Sensor Technologies business.
The Managing Director was interviewed in the meeting area and demonstrated implementation of the process.

Supplier Evaluation and purchasing is controlled by VOP05 dated 25 Oct 2017 Doc revision ID #23353.

The Vandagraph Sensor Technologies has 1 major supplier which has been requested to remain confidential. The supplier was last re-evaluated on 27 Jan 2017 and was graded 'A' - the best grade allowed (records provided). A contract exists between this supplier and Vandagraph Sensor Technologies and was seen to be dated and current.

P/O records VSTPO00711 and VSTPO00659 were sampled and seen to be effective.

Incoming goods process is monitored and yearly records were demonstrated to be maintained. The records for 2017 identified some returns BOX564, BOX563, BOX562 and BOX 569 which were sampled and seen to be documented as reviewed.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Supply Chain, purchasing and Supplier Risk Management were found to be effective to meet the needs of the business and compliant with the requirements of the audit criteria.

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Risk Management, Customer Requirements, Design and Development: (7.1, 7.3), [7.1, 7.3], {8.3}:

Design and Development and Risk Management was assessed.
The Managing Director and Sales/Marketing Director were interviewed in the meeting area and demonstrated implementation of the process.

Design, Research and Development is controlled by VOP17 Doc revision ID #23639.

Risk Management is controlled by VM3COP27.11

There have been no new designs for approximately 15 years. Current designs are maintained and occasional revisions made. There have been no new designs for Vandagraph Sensor Technologies since the certificate was issued.

The risk management process VM3COP27.11 includes a scale of 1-4 for severity and occurrence, but does not identify how to determine the boundary/limits between scales.

Evidence of consideration of Risk for the Tom Thumb design change in 2005 could not be provided at this assessment.

Evidence of updating the Tom Thumb design inputs for a design change in 2005 could not be provided at this assessment. (ref Tom Thumb specification document #2247 dated 6 June 1997)

Evidence of Tom Thumb design inputs containing the outputs of risk management could not be provided at this assessment (ref Tom Thumb specification document #2247 dated 6 June 1997 and Tom Thumb risk management file dated 29/9/2017)

Evidence of performing a design review on the Tom Thumb design change in 2005 could not be provided at this assessment.

Evidence of performing validation of the design change to Tom Thumb in 2005 could not be provided at this assessment.

Evidence of appropriate controls related to responsibility authority for design and development between VST and the subcontractor could not be provided at this assessment (ref contract #13859)

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Design and Development and Risk Management were found to be not effective to meet the needs of the business and not compliant with the requirements of the audit criteria.

A major non-conformity was therefore raised which requires corrective action.

Operations: [Manufacture of Tom Thumb, control of manufacturer for VST], monitoring and measurement equipment and final batch records : (7.1, 7.5.1, 7.5.3, 7.5.4, 7.6, 8.3), [7.5.1, 7.5.8, 7.5.9, 7.5.10, 7.6, 8.3], {8.1, 8.5, 7.1.5, 8.7, 7.1.3, 7.1.4} 7.4.1, 7.5, 7.6, 8.3, 8.4, 4.2.4 :

Manufacturing, control of monitoring and measurement equipment, final inspection and test were assessed.
The Managing Director was interviewed in the meeting area and the warehouse team leader was interviewed in the manufacturing area and demonstrated implementation of the process.

Manufacturing is through subcontractor agreements and on-site assembly.
The main subcontractor has been requested to remain confidential. Subcontractor agreements exist with this subcontractor, document revision ID #13859 and #16256 for Vandagraph Sensor Technologies and Viamed with this subcontractor.

There was no current production in progress at the time of this assessment. Evidence of recent manufacture was available through batch records and parts showing as manufactured but awaiting final test. Some products had been through final test.

Batch records for final product release. Records PS2450 (Foetal Heart Simulator) including certificates of calibration, PS2438 (Tom Thumb) were sampled. Each device is allocated a barcode and traceability from the device barcode to intrastat was demonstrated. The batch records for the products through final test from PS2438 (serial numbers 0401432 to 0401435) were seen to contain evidence of test results and the name of the person authorising release. The test status was demonstrated to be appropriately recorded to differentiate those tested from those yet to be tested.

VOP06 for Measurement control, calibration and QA stock, Doc revision ID #23310 is used for the control of monitoring and measuring equipment.
Monitoring and Measuring Equipment was seen to be in use:
FM6 Foetal Monitor (ref CE051)
TTi 3 GHz counter (ref CE185)
Pressure tester (ref CE078 and CE149)
This equipment was demonstrated to be in calibration and traceable to national standards. Pressure testers CE078 and CE149 were checked internally using CE178 which was demonstrated to be in calibration and traceable to national standards.

No processes requiring validation have been identified. Other than the intrastat system, it was stated that no software is used with respect to production and service provision. A minor nonconformity related to validation of the intrastat system was raised at the last assessment.

Control of nonconforming product was demonstrated. A shelf in the manufacturing area was identified to be the Quarantine area and stock was clearly identified with a hold label, clearly packaged and referencing an internal issue number #102122 and #102123. The reason for their quarrantine/hold status was recorded.

The incoming inspection process was demonstrated. Evidence of incoming inspection for POR11491 and POR11474 was demonstrated.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Manufacturing, control of monitoring and measurement equipment, final inspection and test were found to be effective to meet the needs of the business and compliant with the requirements of the audit criteria.

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Human Resources, Competence, Awareness and Training: (6.1, 6.2), [6.1, 6.2], {7.1.6, 7.2, 7.3}:

Training and Competence was assessed.
The Managing Director was interviewed in the meeting area and demonstrated implementation of the process.

Training and competence is controlled by VOP12 Doc revision ID #23527.

The training records for P.Crossley, M. Green, J. Connor, S. Walton and C. Green were sampled. Competence was seen to be assessed for the areas of activities these people were observed performing during this assessment. The intrastat system was demonstrated to show that if a user is not recorded as trained in a process then intrastat will not allow them to complete the process and they are directed to request training.

Procedures were demonstrated to be risk assessed. Effectiveness checks are determined to be via performance reviews, with the frequency of review set proportionate to risk levels.

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

Sales, Customer Related Processes and Product Despatch: (7.5.1, 7.5.3, 7.5.5), [7.5.1, 7.5.8, 7.5.9, 7.5.10, 7.5.11], {8.5.2, 8.5.3, 8.5.4, 8.5.5}:

Sales and dispatch was assessed.
The Office Administrator was interviewed in the office area and demonstrated implementation of the process.

Sales is controlled by VOP03 - Enquiries/Orders.

Sales order process for ORD89070 was observed during this assessment and the process was demonstrated and seen to be effective. Records for ORD89049, ORD88948, ORD89045 for Viamed and VSORD00857, VSORD00856 were sampled for Vandagraph Sensor technologies and demonstrated to be effective.

The process for handling incomplete orders was described. During the sales order process a parts page is available which identifies useful information such as warranty info, spares and alternative products.

Orders are colour coded on the system to identify back orders, orders in picking, accounts on hold, overridden orders (special cases), orders which can be picked and orders on hold.

The dispatch process was demonstrated for order ORD88857 (yellow - can be picked). The warehouse was seen to be clean and tidywith parts stored on the shelves and clearly identified. Parts on the shelf for Stock room 15 block 9 were sampled and seen to be correctly identified on the intrastat system.

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

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Servicing: (7.5.1.2.3, 7.5.4), [7.5.4], {8.5}:

Servicing was assessed.
The Managing Director was interviewed in the meeting area and the warehouse team leader was interviewed in the repair area and they demonstrated implementation of the process.

Servicing is controlled by VOP09 dated 28 October 2017. Doc revision ID #23619

There are no service activities related to Vandagraph Sensor Technologies.

The procedure covers internal servicing/repairs and on-site servicing for Viamed products.

A list is maintained of hospital sites and the items on each site. The list identifies scheduled visits on a service contract and also one-off visits.

The last visit record for Royal Blackburn hospital was sampled. Summary report dated 5/10/2017. The record indicated the devices serviced and their pass/fail status. The individual record for serial number 440121 was sampled (Tom Thumb) and the test record was seen to contain the test results and testing records demonstrated the results to be within the defined acceptance criteria.

Repair records SRS66238 and SRN29007 were seen to be matched on intrastat and approved for repair by the customer. Repairs pending were seen to be located in bins with their SRS numbers clearly identified. These returns were seen to be clearly isolated from other production/manufacturing stock.

Input from servicing records was demonstrated to be considered during post market surveillance as part of analysis of data. Analysis of Data procedure VOP13 Doc revision #23659 does not clearly include determination of appropriate methods, including statistical techniques and the extent of their use. (Ref: NC Raised)

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Installation and Servicing were found to be generally effective to meet the needs of the business but not fully compliant with the requirements of the audit criteria.

A minor non-conformity was therefore raised which requires corrective action.

Infrastructure and Work Environment: (6.3, 6.4), [6.3, 6.4, 7.5.2, 7.5.5], {7.1.3, 7.1.4}:

Infrastructure and Work Environment was assessed.
The managing director was interviewed in the meeting area and demonstrated implementation of the process.

Infrastructure and Work Environment is controlled by VOP11 - Equipment control office and warehouse, Doc revision ID #23322 and VOP18 - maintenance building, fabric and infrastructure. Doc revision ID #23326.

Records for general office and workshop were sampled - process 5906, 5907 and 5908.

Rolling tasks for maintenance activities are documented, including monitoring tasks to ensure that the maintenance activities are appropriately completed.

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Fire safety certificate was sampled from July 2017. Doc #21621 - Airedale Fire Protection Services.

The workshop and office environments were seen to be clean, tidy and well lit, appropriate for the work activities observed during this assessment.

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

Major (1) nonconformities arising from this assessment.

Ref. no	1548900-201710-M1
Area/process	Risk Management, Customer Requirements, Design and Development: (7.1, 7.3), [7.1, 7.3], {8.3}
Clause	7.3
Scope	MD 78787
Certificate Standard	ISO 13485:2003
Category	Major
Statement of non-conformance:	Design and development and risk management is not effective because evidence of a controlled process could not be demonstrated.
Clause requirements	Design and development
Objective evidence	The risk management process VM3COP27.11 includes a scale of 1-4 for severity and occurrence, but does not identify how to determine the boundary/limits between scales. Evidence of consideration of Risk for the Tom Thumb design change in 2005 could not be provided at this assessment. Evidence of updating the Tom Thumb design inputs for a design change in 2005 could not be provided at this assessment. (ref Tom Thumb specification document #2247 dated 6 June 1997) Evidence of Tom Thumb design inputs containing the outputs of risk management could not be provided at this assessment (ref Tom Thumb specification document #2247 dated 6 June 1997 and Tom Thumb risk management file dated 29/9/2017) Evidence of performing a design review on the Tom Thumb design change in 2005 could not be provided at this assessment. Evidence of performing validation of the design change to Tom Thumb in 2005 could not be provided at this assessment. Evidence of appropriate controls related to responsibility authority for design and development between VST and the subcontractor could not be provided at this assessment (ref contract #13859)

Cause	
Correction / containment	
Corrective action	

Minor (3) nonconformities arising from this assessment.

Ref. no	1548900-201710-N1
Area/process	Feedback Processes, Complaint Management and Vigilance: (8.2.1, 8.5.2), [8.2.1, 8.2.2, 8.5.2], {8.2, 8.5.5, 9.1.2}
Clause	2016:8.3.3
Scope	MD 78787
Certificate Standard	ISO 13485:2003
Category	Minor
Statement of non-conformance:	Actions in response to nonconforming product detected after delivery is not fully effective because evidence of review for vigilance is not clearly documented for nonconformities received which are not identified to be complaints.
Clause requirements	Actions in response to nonconforming product detected after delivery When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5). The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5).
Objective evidence	Not all negative feedback nonconformities raised on Intrastat are determined to be complaints. A determination related to vigilance was stated to be made for these nonconformities, but not clearly documented in the record. ref microstim returns.pdf document #19655
Cause	
Correction / containment	
Corrective action	

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Ref. no	1548900-201710-N2
Area/process	Operations: [Manufacture of Tom Thumb, control of manufacturer for VST], monitoring and measurement equipment and final batch records : (7.1, 7.5.1, 7.5.3, 7.5.4, 7.6, 8.3), [7.5.1, 7.5.8, 7.5.9, 7.5.10, 7.6, 8.3], {8.1, 8.5, 7.1.5, 8.7, 7.1.3, 7.1.4} 7.4.1, 7.5, 7.6, 8.3, 8.4, 4.2.4
Clause	2015:4.3
Scope	FM 607767
Certificate Standard	ISO 9001:2008
Category	Minor
Statement of non-conformance:	The scope of the VST quality manual is not fully effective because manufacturing is not in the certificate scope but manufacturing is not identified as a non applicable element of the VST quality management system
Clause requirements	Determining the scope of the quality management system The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system. 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. 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.
Objective evidence	Certificate FM 607767 VST Quality Manual document reference #23667
Cause	
Correction / containment	
Corrective action	

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Ref. no	1548900-201710-N3
Area/process	Servicing: (7.5.1.2.3, 7.5.4), [7.5.4], {8.5}
Clause	2016:8.4
Scope	MD 78787
Certificate Standard	ISO 13485:2003
Category	Minor
Statement of non-conformance:	Analysis of data is not fully effective because procedure VOP13 does not clearly include determination of appropriate methods, including statistical techniques and the extent of their use
Clause requirements	Analysis of data The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).
Objective evidence	VOP13 ref #23659
Cause	
Correction / containment	
Corrective action	

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Our next steps

Next visit plan

Date	Auditor	Time	Area/process	Clause
27/11/2017	Assessor 1	09:00	Opening Meeting	
		09:30	Review actions taken to address the three major nonconformities raised at the last assessment.	8.5.2, 7.1, 7.3, 5.6 and 8.2.2 / 8.2.4
		12:30	Lunch	
		13:00	Continued: Review actions taken to address the three major nonconformities raised at the last assessment.	8.5.2, 7.1, 7.3, 5.6 and 8.2.2 / 8.2.4
		14:00	Report Preparation	
		16:00	Closing Meeting	

Next visit objectives, scope and criteria

Assessment Scope
The management system processes at Viamed and Vandagraph Sensor Technologies Ltd, 15/17 Station Road, Cross Hills, Keighley, BD20 7DT, United Kingdom

Visit objectives:
To conduct an onsite follow up assessment to determine whether the effective implementation of agreed corrective action(s) to address Major nonconformity(ies) identified during the previous continuing and re-certification assessment, report No 8855872 and 8855876 has occurred, and to determine whether a recommendation for continued certification can be made.

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.

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Your next steps

NCR close out process

Corrective actions with respect to minor nonconformities raised previously have not been implemented.
Both major nonconformities and minor nonconformities requiring attention were identified. These, along with other findings, are contained within subsequent sections of the report.
A minor nonconformity relates to a single identified lapse in the management system. A major nonconformity indicates a breakdown in the management system's ability to effectively control the processes for which it was intended. The identification of a major nonconformity places the validity of certification at risk. It is necessary to investigate the underlying cause of any nonconformity 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.

How to contact customer service

'Just for Customers' is the website that we are pleased to offer our clients following successful registration, designed to support you in maximising the benefits of your BSI registration - please go to www.bsigroup.com/j4c to register. When registering for the first time you will need your client reference number and your certificate number (43207441/FS 28344).

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

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

Tel: +44 (0)345 080 9000

Email: MK.Customerservices@bsigroup.com

Appendix: Your certification structure & on-going assessment programme

Scope of certification

FS 28344 (ISO 9001:2008)

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

Certificate Scheme:

Scheme manager:

CE 01389 (Healthcare)

The design and manufacture of Oxygen Sensors, Supra-Maximal Peripheral Nerve Stimulator & Infant T-Piece Resuscitators.

Certificate Scheme: 93/42/EEC Annex II, Sec 3.2 (2007/47)

Scheme manager: Konstantinos Flampouris

MD 78787 (ISO 13485:2003)

The design, manufacture and service of: Oxygen Sensors and accessories, Supra-Maximal Peripheral Nerve Stimulator, Simulation Equipment, Infant T-Piece Resuscitators, Apgar Timer & resuscitation cabinets. Includes service of Infant T-Piece Resuscitators & Apgar Timer on customer premises.
Distribution of medical devices from other manufacturers.
Service of medical devices from other manufacturers.
Service on customer premises of other manufacturers' medical devices: Radiant Warmers, Air/Oxygen Blenders & Suction Controllers.

Certificate Scheme: ISO 13485: 2003

Scheme manager: Konstantinos Flampouris

CE 97289 (Healthcare)

Design and manufacture of Electrochemical Oxygen Sensors.

Certificate Scheme: 93/42 OBL Annex II, Sect 3.2 (2007/47)

Scheme manager: Konstantinos Flampouris

CE 540537 (Healthcare)

The design and manufacture of Sp02 modules and monitors and sensors, gas flow sensors, breathing gas exchange monitors and sensors, gas sampling lines and temperature probes

Certificate Scheme: 93/42 OBL Annex II, Sect 3.2 (2007/47)

Scheme manager: Konstantinos Flampouris

FM 540797 (ISO 13485:2003)

The design and manufacture of supramaximal nerve stimulators.

Certificate Scheme: CMDCAS

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Scheme manager:

FM 607767 (ISO 9001:2008)
The design, development and supply of gas sensors and associated systems.
Certificate Scheme:
Scheme manager:

Assessed location(s)

The audit has been performed at Central Office.

/ CE 01389 (Healthcare) / MD 78787 (ISO 13485:2003) / FM 540797 (ISO 13485:2003) / FS 28344 (ISO 9001:2008) / CE 97289 (Healthcare) / CE 540537 (Healthcare)

Location reference	0009370214-000
Address	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom
Visit type	Continuing assessment (surveillance)
Assessment reference	8855872
Assessment dates	30/10/2017
Audit plan (revision date)	18/09/2017
Deviation from audit plan	No
No. of full time equivalent employees	15
Total no. of effective employees at the site	15
Scope of activities at the site	Main certificate scope applies.
Assessment duration	1.5 day(s)

Keighley / FM 607767 (ISO 9001:2008)

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	8855876

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Assessment dates	31/10/2017
Audit plan (revision date)	18/09/2017
Deviation from audit plan	No
No. of full time equivalent employees	15
Total no. of effective employees at the site	15
Scope of activities at the site	Main certificate scope applies.
Assessment duration	0.5 day(s)

Changes in the organization since last assessment

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

The following changes in relation to the certified organization activities, products or services covered by the scope of certification were identified:

Viamed have requested certificate cancellations and also changes to their remaining certificates after reviewing their market and service provision. They are moving away from OBL/Virtual Manufacture and the products which remain are to be under another legal manufacturer's name. Refer to the section in this report (Opening Meeting and Changes.

Vandagraph has no changes identified related to products or services.

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

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Certification assessment programme

Certificate number - Contract 200483566
Location reference - 0009370214-000

		Audit1	Audit2	Audit3
Business area/location	**Date (mm/yy):**	09/16	09/17	07/18
	Duration (days):	1	1	2.5
Core QA processes - Including: The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, corrective action processes, and complaints.		X	X	X
General objectives for quality and improvement		X	X	X
Scheme requirements for vigilance and feedback		X	X	X
Design and risk				X
Manufacture and test, monitoring and measuring, control of NC product and process validation:		X	X	X
Purchasing and supplier controls		X		X
Sales and order processing			X	X
Reassessment visit				X
Discussion with Top Management				X
Transition to ISO 13485:2016 and ISO 9001:2015 - 1 additional day over the visit cycle required.			X	X

Certificate number - FM 607767
Location reference - 0009370214-001

		Audit1	Audit2	Audit3
Business area/location	**Date (mm/yy):**	07/18	07/19	07/20
	Duration (days):			
Recommendation to incorporate this certificate in the contract to align the visit cycles between Viamed and Vandagraph Sensor Technologies				

Justified exclusions / non applicable clauses

There are no justified exclusions / non applicable clauses of the standard for certificate : FS 28344

Exclusions of the standard are not permitted for certificate : CE 01389

Justified exclusions / non applicable clauses have been confirmed for certificate : MD 78787

details:

No exclusions. Contamination control, Sterile and implantable products are identified to be non applicable with justification.

Exclusions of the standard are not permitted for certificate : CE 97289

Exclusions of the standard are not permitted for certificate : CE 540537

Justified exclusions / non applicable clauses have been confirmed for certificate : FM 540797

details:

No exclusions, contamination control, sterile and implantable clauses are identified to be non-applicable with justification.

There are no justified exclusions / non applicable clauses of the standard for certificate : FM 607767

Mandatory requirements – recertification

Review of assessment finding regarding conformity, effectiveness and relevance of the management system:
The recertification pack for certificate FM 607767 was reviewed (for Vandagraph Sensor Technologies Ltd)
- Since initial assessment in 20/5/2014 a total of 3 days assessment (including this audit) have been completed.
- This was not in line with the recertification plan. The Stage 2 assessment recommended including the visits for Vandagraph Sensor Technologies within the current contract for Viamed, but this did not occur. As a consequence visit cycles have been missed. The action taken was to include this recertification with the surveillance assessment for Viamed (due to using the same common procedures) over a period of three total days. Unfortunately the visit planned for September 12-14th was aborted after the first day. This visit was re-scheduled for two days to allow completion of the originally planned assessment. over the visits in September and October the planned three days of assessment were delivered.

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.

- Major non-conformities have been identified during this visit in Management Review, Internal Audit and design and development which will need to be resolved prior to a positive recommendation being made.

Management Review, internal audit and design and development are not considered to be effectively implemented due to the identified major nonconformities.

Management system strategy and objectives:

The management system strategy and objectives were assessed. Please refer to the relevant part of the findings section of the last report (references: 8580193, 8778185, 8789316, 8789318, 8789319).

Review of progress in relation to the organization's objectives:

The management system objectives for Vandagraph Sensor technologies were demonstrated to be met. The Vandagraph Sensor Technologies business runs alongside Viamed and uses common procedures.

Review of assessment progress and the recertification plan:

With the exception of the major nonconformities identified and their impact on Viamed and Vandagraph Sensor Technologies, the common procedures in use across both businesses demonstrate that the recertification plan has been appropriate and the future recertification plan has been developed on the understanding that both businesses Viamed and Vandagraph Sensor Technologies will be assessed together under a common contract.

BSI client management impartiality and surveillance strategy:

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.

Expected outcomes for accredited certification

What accredited certification to ISO 9001 means

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

What accredited certification to ISO 9001 does not mean

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

Notes

This report and related documents are prepared for and only for BSI's client and for no other purpose. As such, BSI does not accept or assume any responsibility (legal or otherwise) or accept any liability for or in connection with any other purpose for which the Report may be used, or to any other person to whom the Report is shown or in to whose hands it may come, and no other persons shall be entitled to rely on the Report.If you wish to distribute copies of this report external to your organization, then all pages must be included.

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This audit was conducted on-site through document reviews, interviews and observation of activities. The audit method used was based on sampling the organization's activities and it was aimed to evaluate the fulfilment of the audited requirements of the relevant management system standard or other normative document and confirm the conformity and effectiveness of the management system and its continued relevance and applicability for the scope of certification.

As this audit was based on a sample of the organization's activities, the findings reported do not imply to include all issues within the system.

Regulatory compliance

BSI conditions of contract for this visit require that BSI be informed of all relevant regulatory non-compliance or incidents that require notification to any regulatory authority. Acceptance of this report by the client signifies that all such issues have been disclosed as part of the assessment process and agreement that any such non-compliance or incidents occurring after this visit will be notified to the BSI client manager as soon as practical after the event.