Assessment Report

Viamed Ltd

Assessment dates	July 15, 2017, and August 07, 2017
Assessment location	Keighley (000)
Report author	Kevin Holochwost
Assessment standards	Healthcare

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Executive summary

The objectives of the assessment were met.
Obstacles, Omissions and Reliability

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.

Areas Not Audited
All areas were covered per the assessment plan.

Identification and Dating
Audit report authors are as per the assessment team listed. The recommendation included in this assessment is based on assessment of July 15, 2017, and August 07, 2017.

The report was finalized and issued on August 14th, 2017.

TECHNICAL FILE ASSESSMENTS
The management system and output technical documentation does not meet the requirements of BSI Conditions of Contract and MDD 93/42/EEC Annex II 3.2.

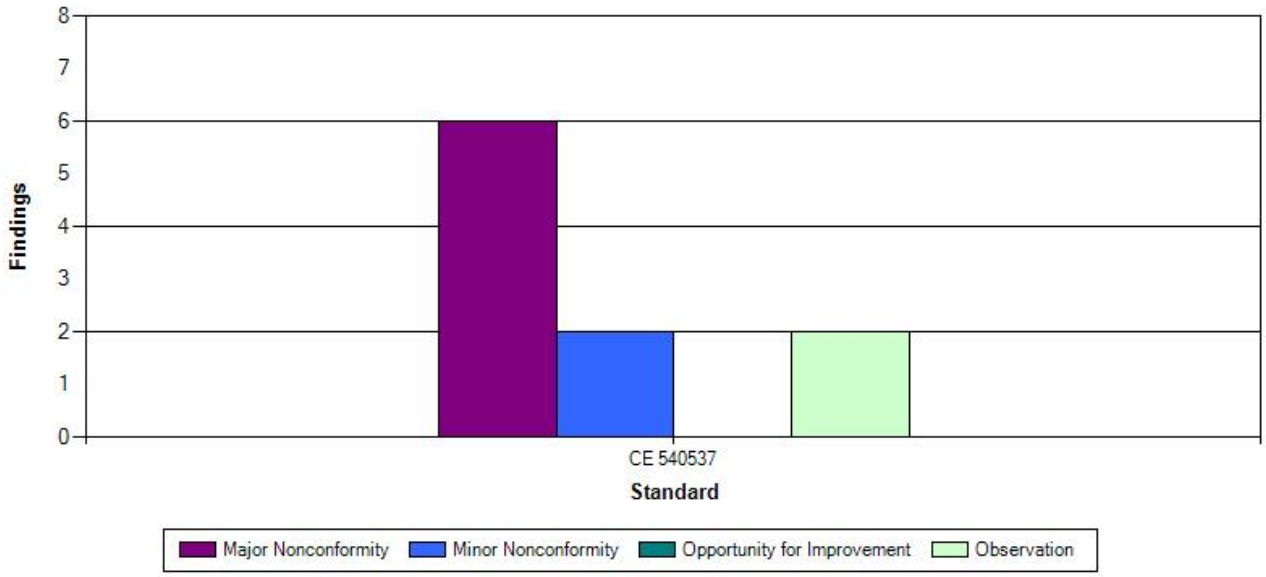
Assessment objective, scope and criteria

TECHNICAL FILE ASSESSMENTS
Continuing TF Assessment
Audit Objective
To conduct a desktop technical documentation audit to assess whether the client's management system and output technical documentation meets the requirements of BSI Conditions of Contract and 93/42/EEC Annex II 3.2.

The scope of the assessment is the documented management system with relation to the requirements of MDD 93/42/EEC Annex II 3.2 and the defined assessment plan provided in terms of locations and areas of the system and organization to be assessed.

NCR summary

Which standard(s) BSI recorded findings against



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 nonconformity in the future.

Assessment participants

Name	Position	Opening meeting	Closing meeting	Interviewed (processes)
Derek Lamb	Management			X

Status of actions from the previous assessment

Ref	Area / process	Clause
1417669N1	Review of Open non-conformities from the last assessment	Annex II 5.4
Scope	CE 540537	
Category	Minor	
Details:	The technical agreement with Bluepoint is not fully effective.	
Objective evidence:	The Bluepoint OEM agreement does not allow for access to their premises in the event of an unannounced visit from a notified body.	
Closed?:	No	
Justification	Not part of technical file review. To be reviewed by QMS Auditor.	

Assessment findings

The assessment was conducted on behalf of BSI by

Name	Position
Kevin Holochwost	Technical expert

Assessment conclusion and recommendation

Audit objectives are met.

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.

The corrective action plan for the non-conformances recorded in this report must include the items listed below. If the plan does not contain the required information, it cannot be accepted. Action plans can be submitted in the company format for the corrective action record process as long as it addresses the action plan requirements as follows:

- Traceability to the relevant BSI non-conformity
- Immediate action to correct the finding
- Details of the investigation and identified cause
- Description of the actions to address the cause
- Timescales and responsibilities for completion of the planned actions

Note that any amendment to the submitted plan and timescales must be accepted by BSI.

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 28/08/2017 by e-mail to msuk.caps@bsigroup.com and kevin.holochowst@bsigroup.com, referencing the report number, or through the BSI Assurance Portal if this is enabled for your account.

Use of certification documents, mark / logo or report

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

Findings

Technical Documentation Assessed: MDD

The assessment was based upon the Quality Management System, reference Quality Manual, 2017:20968 and a review of the Technical Documentation for the Pulse Oximetry (Pulse oximeter probes) Envitec Oxygen Sensors also called Pulse Oximetry Sensors 4000.

Intended Use and Classification: MDD Article 9 and Annex IX

The intended use of the device was verified and confirmed as a medical device. The classification rationale was reviewed. The device was not correctly classified.

Essential Requirements: MDD Article 3 and Annex I

The validity of the Essential Requirements checklist was reviewed. The responses were generally found to be acceptable except as noted elsewhere in the report.

Machinery Directive 2006/42/EC: MDD Article 3

The device did not fall within the definition of a machine defined in the above directive.

Observations

Ref. no	1515871-201705-O1
Area/process	Machinery Directive 2006/42/EC
Clause	
Scope	CE 540537
Details	No assessment of the applicability for the machinery directive was provided.

Personal Protective Equipment Directive 89/686/EEC: MDD Article 1 Section 6

The device did not fall within the definition of personal protective equipment.

Observations

Ref. no	1515871-201705-O2
Area/process	Personal Protective Equipment Directive 89/686/EEC
Clause	
Scope	CE 540537
Details	No assessment of the applicability for the PPE directive was provided.

Risk Management File: MDD Annex I and II

The risk management file was reviewed. The risk documentation was generally found to be unacceptable and failed to follow the processes of EN ISO 14971.

Design Inputs: MDD Annex II

The design inputs were generally found to be inappropriate. Despite the function specification, evidence of design verification tied to these design inputs was not provided. Furthermore design inputs by the manufacturer through which the components were selected IE. Requirements which these components must meet were not provided.
Evidence for this non conformity is logged against the Major Non conformity with Design verification in the pre-clinical section as part of a single major against ER 3.

Pre-Clinical Data: MDD Annex II

The pre-clinical testing data was sampled, including safety and performance testing, and was not generally found to be appropriate.

Clinical Evaluation: MDD Annex X

The clinical evaluation was in accordance with Annex X of the MDD and followed the guidance in MEDDEV 2.7.1 except where otherwise identified in this report.

Information Supplied by the Manufacturer: MDD Annex I

The labeling and instructions for use sampled met the Essential Requirements of Annex I of the MDD except where otherwise identified in this report.

Declaration of Conformity: MDD Annex II

An appropriate declaration of conformity was available for the device.

Major (6) nonconformities arising from this assessment.

Ref. no	1515871-201705-M1
Area/process	Intended Use and Classification
Clause	Annex IX, Section II
Scope	CE 540537
Category	Major
Statement of non-conformance:	The process to ensure that devices are correctly classified is not effective.
Clause requirements	“Application of the classification rules shall be governed by the intended purpose of the devices. If the device is intended...”
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.

Ref. no	1515871-201705-M2
Area/process	Essential Requirements
Clause	Annex I
Scope	CE 540537
Category	Major

Statement of non-conformance:	Solutions adopted to fulfil Annex I are incomplete.
Clause requirements	"The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons..."
Objective evidence	[ER 4] - While the risk management files 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 anesthetic 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.

Ref. no	1515871-201705-M3
Area / process	Risk Management File
Clause	ER2
Scope	CE 540537
Category	Major
Statement of non-conformance:	The solutions adopted to fulfill the essential requirements are incomplete.
Clause requirements	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art
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.

Ref. no	1515871-201705-M4
Area / process	Pre-Clinical Data
Clause	ER 3
Scope	CE 540537
Category	Major
Statement of non-conformance:	The solution adopted to fulfil the Essential Requirements is not complete
Clause requirements	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are...”
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 not provided - Testing against design inputs was not provided beyond standards assessments.

Ref. no	1515871-201705-M5
Area / process	Clinical Evaluation
Clause	Annex X 1.1.c
Scope	CE 540537
Category	Major
Statement of non-conformance:	The system for post-market clinical follow-up is inadequate.
Clause requirements	The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not

	deemed necessary, this must be duly justified and documented
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.

Ref. no	1515871-201705-M6
Area / process	Declaration of Conformity
Clause	Annex II
Scope	CE 540537
Category	Major
Statement of non-conformance:	The EC declaration of conformity does not fully meet the requirements of Annex II
Clause requirements	The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1...
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...”

Minor (2) nonconformities arising from this assessment.

Ref. no	1515871-201705-N1
Area / process	Pre-Clinical Data
Clause	Annex I ER 1
Scope	CE 540537
Category	Minor
Statement of non-conformance:	The solutions adopted to fulfill the essential requirements are incomplete
Clause requirements	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety...

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.

Ref. no	1515871-201705-N2
Area / process	Information Supplied by the Manufacturer
Clause	Annex I, ER 13
Scope	CE 540537
Category	Minor
Statement of non-conformance:	The information supplied by the manufacturer does not fully meet the essential requirements.
Clause requirements	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training
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.

Our next steps

Next visit plan

The date of the next visit will be based on the corrective action plan and will be scheduled in conjunction with scheme manager.

Next visit objectives, scope and criteria

MAJOR NONCONFORMITY (SPECIAL VISIT)
To conduct an onsite or remote follow up assessment to determine whether the effective implementation of agreed corrective action(s) to address Major nonconformities identified during the previous continuing assessment, report No 8536454 has occurred, and to determine whether a recommendation for continued certification can be made.

The scope of the assessment is the documented management system with relation to the requirements of MDD 93/42/EEC Annex II.3 and the defined assessment plan provided in terms of locations and areas of the system and organization to be assessed.

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.

Your next steps

NCR close out process

Both major nonconformities and minor nonconformities requiring attention were identified. These, along with other findings, are contained within other 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.

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 (47527482/CE 540537).

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

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

Assessed location(s)

The audit has been performed remotely.

Keighley / CE 540537 (Healthcare)

Location reference	0009370214-000
Address	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom
Visit type	Product certification
Assessment reference	8536454
Assessment dates	30/05/2017
Deviation from audit plan	No
No. of full time equivalent employees	17
Total no. of effective employees at the site	17
Scope of activities at the site	Main certificate scope applies.
Assessment duration	1 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.

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

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

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.