Unannounced Visit Assessment Report.

Viamed Ltd

Report Author **Michael Ford**

Visit Start Date 26/11/2014

Introduction.

This report has been compiled by Michael Ford and relates to the assessment activity detailed below:

Visit ref/Type/Date/Duration	Certificate/Standard	Site address
8192916 26/11/2014 2 day(s) No. Employees: 14	CE 01389 Healthcare 93/42/EEC Annex II, Sec 3.2 (2007/47) CE MARKING Richard Tully	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of this unannounced assessment was to ensure that products at:

Viamed Ltd
15/17 Station Road
Cross Hills
Keighley
BD20 7DT
United Kingdom

were being manufactured in accordance with product specifications and the requirements of the Medical Devices Directives 93/42/EEC.
Audit Criteria to be used, Directive / Annex, e.g. MDD 93/42/EEC Annex II.3 & Commission Recommendation 2013/473/EU

Management Summary.

Overall Conclusion

The objectives of this assessment have been achieved.

I would like to thank all the audit participants for their assistance and co-operation which enabled the audit to run smoothly and to schedule.

Based on the objective evidence detailed within this report, the areas assessed during the course of the visit were generally found to be effective.

This report is eligible for submission to the US FDA under the FDA ISO 13485 Voluntary Audit Report Submission Program.

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 per the assessment team listed. The report was finalised and issued on 28th November 2014.

There were no outstanding nonconformities to review from previous assessments.

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

Areas Assessed & Findings.

Opening Meeting :

Assessment team were received promptly on arrival and commenced the opening meeting immediately without undue delay. Staff understood the protocol to follow for unannounced visits.

Opening meeting with the Managing Director.

Current Number of employees 14

There have been no vigilance reports since the last surveillance visit.

There have been no major changes to the QMS

The company is moving from manufacturing their own equipment to either Own Brand labelling or selling other companies equipment.

Production :

Tom Thumb Infant resuscitator was in production during the visit, most other product has been moved to bought in product and is either covered by .their OBL certificates or sold with original branding.

Review of production for the Tom Thumb Infant Resuscitator, part No 0310030. 25 off being manufactured. All components items are identified with a unique barcoded ID which is then scanned in against the top level job number for traceability. All top level assemblies are given a barcoded ID.
Sample with Barcode 813934, serial No 0401203 sampled and witnessed operator assembling the unit, on completion the unit was witnessed tested to set up the pressure settings. Two manometers are used in tandem to ensure good readings are obtained, set up to 42mbar.
Instruction VM3-Cop50.02 rev 1 used to manufacture and set up product, document control No 9230.

On completion the unit is tested by an independent operator and the results recorded into the QA system on the network, The system also records the equipment used to carry out the testing and and records the actual values.
Completed product Barcode ID 802362 reviewed and and results recorded along with pass fail criteria for non quantifiable tests/inspections. Calibrated Manometer 674700 used.

Witness electrical safety test on Ceramtherm radiant Warmer, serial No 10071-0411 and passed OK.

Review of finished product SP02 Sensor in stock, lot Number 0141237, cross checked to receipt record, supplied 31 Oct 2012, use by date shown as 09-2017, record cross references to manufacturers lot No 1020131126. System shows log off all deliveries of the product for traceability.

The company is moving towards a greater number of devices being OBL'ed and less being manufactured on-site. It was noted that the nerve stimulator is manufactured by Healthcare Technology, but subjected to full inspection and test as part of incoming inspection, when the next batch is manufactured the Scheme Manager should be contacted to determine if Healthcare Technology should be added as a significant subcontractor on the CE certificate.

No products requiring electrical safety testing were being manufactured but the operation of the electrical safety tester was observed on a dummy product. The Fluke Electrical Safety Analyser, ID CE 182, was calibrated, calibration due 6 February 2015, the device was fully automated. After entering the details of the device to be tested the device is started and runs through an automated series of tests (manual operation is required to attached a lead for measuring earth resistance at various locations), the device can then out put a full PDF report with product details, pass/fail indications and measurements.

Observations.

Type	Area/Process	Clause
Observations	Production	7.5.1.1
Scope	CE 01389	
Details:	The system automatically populates answers into the batch record, it would prompt the operators to conciously check the record if the boxes were blank and they had to enter the result	

Technical File :

The device accuracy was tested and calibrated against the QA Form requirements used in production. The QA form required that the output of the fixed pressure was 42-48 cmH2O, the operator controlled output was 2-4 cmH2O above the fixed pressure with a maximum of 51 cmH2O, and the pressure gauge should read 30 +/- 1 cmH2O.

These requirements have developed over time and following some changes to the product design, it was noted that the product specification stated that the output of the fixed pressure should be 45 cmH2O, the operator controlled output should be 45 cmH2O, and the pressure gauge should read 30 +/- 1 cmH2O. These values did not correspond and the product specification should be updated. The biocompatibility of the gas pathway was verified, the product specification required that the pathway should be nickel chromed brass or stainless steel.

The purchase order for the chrome plating did not include a specification for the plating or reference to plating standards such as BS 12540.

During the course of the visit logos were found to be used correctly.

Minor Nonconformities Raised at Last Assessment.

Ref	Area/Process	Clause
984873N1	Risk Management	

Scope	CE 01389
Details:	Annex I, ER 2
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. ISO 14971 requires a review of the risk management process to be documented in the Risk Management Report and to include results ensuring the risk management plan has been appropriately implemented, the overall residual risk is acceptable
Objective Evidence:	The manufacturer has not fully evaluated and addressed the impact of the EN ISO 14971:2012 Annex Zs: • All risks, regardless of their dimension, need to be reduced as much as possible • All risks, regardless of any "acceptability" assessment, need to be balanced, together with all other risks, against the benefit of the device • Residual risks have been incorrectly reduced by warnings placed on IFUs or provided in training.
Actions:	
Closed?:	No
Justification	To be closed by a technical expert

Ref	Area/Process	Clause
984873N2	Clinical Evaluation	Annex X, Section 1.1c, MedDev 2.7.1
Scope	CE 01389	
Details:	The process for clinical evaluation did not meet the requirements of Annex X.	
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. The evaluation of clinical data, hereinafter referred to as clinical evaluation must follow a defined and methodologically sound procedure. One option is a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where: — there is demonstration of equivalence of the device to the device to which the data relates, and — the data adequately demonstrate compliance with the relevant essential requirements.	
Objective Evidence:	There was no evidence that the Clinical Evaluation and its documentation are actively updated with data obtained from post-market surveillance. The lack of Post Market Clinical Follow up studies was not duly justified and documented The Clinical Evaluation Report does not currently meet the state of the art regarding clinical literature reviews, as detailed in the MEDDEV 2.7.1.	
Actions:		
Closed?:	No	

Justification	To be closed by a technical expert

Ref	Area/Process	Clause
984873N3	Information Supplied by the Manufacturer	Annex I, Section 13.6
Scope	CE 01389	
Details:	Information for the user is not complete.	
Requirements:	…the instructions for use must contain the following particulars: 13.6 b: the performances referred to in Section 3 and any undesirable side-effects; 13.6 n: precautions to be taken against any special, unusual risks related to the disposal of the device;	
Objective Evidence:	13.6 b: There is no evidence of performance for the device in the ifu. 13.6 n: There is no evidence in the ifu for precautions to be taken against any special, unusual risks related to the disposal of the device	
Actions:		
Closed?:	No	
Justification	To be closed by a technical expert	

Minor Nonconformities Arising from this Assessment.

Ref	Area/Process	Clause
1122953N1	Production	7.5.1.1.
Scope	CE 01389	
Details:	The production test requirements did not correspond to the specification in the technical file for the Tom thumb.	
Requirements:	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, f) the implementation of release, delivery and post-delivery activities, and g) the implementation of defined operations for labelling and packaging. The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.	

	NOTE A batch can be a single medical device.
Objective Evidence:	The product specification stated that the output at the fixed pressure should be 45 cmH2O, the operator controlled output should be 45 cmH2O, and the pressure gauge should read 30 +/- 1 cmH2O. These values did not correspond to the QA Form and the product specification should be updated. The manufacturing QA Form stated 42-48 cmH2O, the operator controlled output should be 2-4 cmH2O above the fixed pressure with a maximum of 51 cmH2O, and the pressure gauge should read 30 +/- 1 cmH2O.

Ref	Area/Process	Clause
1122953N2	Production	7.4.2
Scope	CE 01389	
Details:	The purchase order for chrome plating did not include sufficient detail.	
Requirements:	Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).	
Objective Evidence:	The biocompatibility of the gas pathway relies on the pathway being nickel chromed brass or stainless steel. Purchase order POR 09700 for chrome plating did not include a specification for the plating or reference any plating standards, e.g. BS 12540.	

Assessment Participants.

On behalf of the organisation:

Name	Position
Derek Lamb	

The assessment was conducted on behalf of BSI by:

Name	Position
Michael Ford	Team Leader
Alan Barker	Technical Expert

Next Visit Plan.

As per your latest on going surveillance visit report

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

Notes.

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

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