Assessment Report.

Viamed Ltd

Report Author	**Richard Tully**
Visit Start Date	23/10/2013

Introduction.

This report has been compiled by Richard Tully and relates to the assessment activity detailed below:

Visit ref / Type / Date / Duration	Certificate / Standard	Site address
7841750 Technical Visit by PS 23/10/2013 1 day(s) No. Employees: 15	CE 01389 Healthcare 93/42/EEC Annex II, Section 3.2 CE MARKING Richard Tully	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom

The objective of this assessment was to conduct a technical documentation audit / desktop technical documentation audit to assess whether the client's management system and output technical documentation meets the requirements of 93/42/EEC Annex II 3.2 and BSI Conditions of Contract.

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 found to be effective.

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 author Richard Tully. The report was finalised and issued on 23rd October 2013.

Corrective actions with respect to nonconformities raised at the last assessment have been reviewed and found to be effectively implemented.

4 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.

Please submit a plan to BSI detailing the nonconformity, the cause and your proposed corrective action, with responsibilities and timescales allocated. The plan is to be submitted no later than 23/11/2013 by e-mail to msuk.caps@bsigroup.com or by fax to +44 (0)1908 228123, referencing the report number.

Areas Assessed & Findings.

Details of Technical Documentation Assessed : Annex II

The assessment was based upon the client's quality management system and a review of the technical documentation for the Microstim device.

Intended use / Classification : Article 9, Annex IX

Unless otherwise identified within this report the documentation reviewed is considered to be compliant with the requirements of the MDD.

Essential Requirements : Article 3, Annex I

Unless otherwise identified within this report the documentation reviewed is considered to be compliant with the requirements of the MDD.

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

The manufacturer must determine whether or not the device is also a machine, as defined in the Machinery Directive 2006/42/EC as Article 3 of the 2007/47/EC amendment to the MDD states that devices which are also machinery shall also meet the essential requirements of the Machinery Directive 2006/42/EC as laid out in Annex I of that directive. The manufacturer must document the solutions adopted to fulfil these essential requirements.

Observation:
Consideration has not been given however it is accepted that the device is not a PPE.

Observation:
The manufacturer should consider applying EN 60601-1-6 or, ideally, EN 62366, concerning usability. If either of these standards is not to be applied or to be applied in part, a justification should be provided in the technical file.

Observation:
The manufacturer should consider mentioning standards which are used to show that the device conforms to the state of the art such as 60601-2-10.

Observation:
Packaging instructions are evidently designed to preserve the level of cleanliness. It would be useful if the level of cleanliness required was stated under ER 8.6

Risk Management : Annex I, ERs 1, 2 and 6

Unless otherwise identified within this report the documentation reviewed is considered to be compliant with the requirements of the MDD.

Design Inputs : Annex II

Unless otherwise identified within this report the documentation reviewed is considered to be compliant with the requirements of the MDD.

Pre-Clinical : Annex II or VII

Unless otherwise identified within this report the documentation reviewed is considered to be compliant with the requirements of the MDD.

Clinical Evaluation : Annex X

Unless otherwise identified within this report the documentation reviewed is considered to be compliant with the requirements of the MDD.

Information Supplied by the Manufacturer : Annex I, ER 13

Unless otherwise identified within this report the documentation reviewed is considered to be compliant with the requirements of the MDD.

Observation:
13.6 f: The accompanying documents did not include the tables of guidance and manufacturer's declaration regarding electromagnetic emissions and immunity as required by EN 60601-1-2:2007 (clauses 5.2.2.1 and 5.2.2.2). This is because it is not possible to carry out EMC tests on this device.

Minor Nonconformities Arising from this Assessment.

Ref	Area/Process	Clause
984873N0	Essential Requirements	Annex I, ER 7.1
Scope	CE 01389 at VIAMED-0009370214-000	
Details:	The solutions adopted to fulfil the essential requirement are incomplete.	
Requirements:	Attention should be paid to the choice of material with regards to toxicity and flammability... and compatibility between the material used and biological tissue.	
Objective Evidence:	The manufacturer was unable to provide biocompatibility test reports for materials utilised, The applied part is the electrode. Viamed do not sell these. They do send a pair out in the box. These are a class 1 medical device which is being sent as a courtesy but without labelling.	
Actions:	The electrodes are now supplied in their original CE marked packaging.	
Closed?:	Yes	

Ref	Area/Process	Clause
984873N1	Risk Management	
Scope	CE 01389 at VIAMED-0009370214-000	
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.	

Ref	Area/Process	Clause
984873N2	Clinical Evaluation	Annex X, Section 1.1c, MedDev 2.7.1
Scope	CE 01389 at VIAMED-0009370214-000	
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.	

Ref	Area / Process	Clause
984873N3	Information Supplied by the Manufacturer	Annex I, Section 13.6
Scope	CE 01389 at VIAMED-0009370214-000	
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	

Assessment Participants.

On behalf of the organisation:

Name	Position
John Lamb	Chairman
Derek Lamb	Managing Director

The assessment was conducted on behalf of BSI by:

Name	Position
Richard Tully	Technical Expert

Next Visit Plan.

Visit objectives:

A continuing assessment visit for technical documentation.

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the 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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