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7649340

**Date:**
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**Prepared by:**
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**BSI reference:**
VIAMED-0009370214-000

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# BSI Technical Assessment Visit Report

## Introduction

This report relates to the Directive 93/42/EEC Technical Assessment Visit for Viamed Ltd held on 22 March 2011.

The assessment was based upon the Client's Management System, reference Quality Manual, Rev 22/03/11, and a review of the Technical Documentation, Microstim Technical File, and associated documentation.

During the assessment 3 minor nonconformities were identified.

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.

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.

This visit report forms part of BSI's partnership approach in the assessment of your Management System.

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

If you wish to distribute copies of this report external to the organization, then all pages must be included.

## Conclusion

Continued certification is confirmed and the EC certificates listed below remain valid. However, a corrective action plan is required.

The non-conformities identified require corrective action, firstly to correct the identified non-conformance and secondly to examine the underlying causes and implement the changes necessary to prevent recurrence. The investigation and resulting actions may take time, and therefore require the preparation of an action plan.

Please submit a plan to determine action, timescales and responsibilities for review, no later than the date specified in the section below **(Non-Conformities – Summary)**. Please send to ben.wall@bsigroup.com or +44 (0) 1442 278575

## EC Certificates

Certificate Number: CE 01389
Annex: Annex II, Section 3.2
Scope: The design and manufacture of microstim nerve stimulators, tom thumb resuscitator, thermacot, oxygen monitors, pulse oximeter probes, temperature probes, breathing monitors, headboxes, oxygen tents, gas respiratory adapters, gas respiratory valves and phototherapy light shields

Device Technical Audit Visit Review History

| Review Date | Product Reviewed |
|---|---|
| 24 May 2005 | Tee Adapter |

## Areas Assessed

The following areas have been assessed in this assessment

- Classification rationale, Declaration of Conformity and general technical file construction
- Description of product and family, intended use and accessories
- Location of responsibilities for the device and significant sub-contractors used
- Compliance with essential requirements
- Specifications and testing
- Risk management
- Clinical evidence
- Labels and instructions for use

## Observations and Commentary

- The standard EN 14971 was mistakenly entered into the ER checklist as EN 13471
- Neither of the harmonised standards for usability, EN 62366:2008 or EN 60601-1-6:2004 were utilised as the device was originally designed prior to their release. It is recommended that these standards are reviewed and considered for any future design changes or developments to ensure compliance with the Essential Requirements
- The 'product life' document that came to light during the review was not referenced against ER 4 in the checklist

- It would be beneficial if a statement was included in the technical file regarding the use of human blood derivatives
- The risk analysis document was referenced against ER 7.6. yet contained no corresponding risk. Compliance with this requirement was however demonstrate by alternate means
- ER 9.1. was not addressed in the checklist although verbally explained as not being applicable
- Relevant standards were not always filled out in the ER checklist, e.g. in ER 9.2, risk and EMC documents were referenced, but without the corresponding standards
- The harmonised standards for programmable electrical medical systems (EN 60601-1-4:1997) and software lifecycle processes (EN 62304:2006) were not applied as the device was designed prior to their release. However, the software function is reasonably limited and the device has a long history of safe use. To ensure future compliance with the essential requirements these standards should be given due consideration for any future modifications or developments
- The label for the electrode accessory incorrectly included the BSI Notified Body number. As this is a class I device, it is outside the scope of the Annex II certificate

## Non-Conformities (Summary)

- 3 minor non-conformities have been identified. A corrective action plan is required by 22 April 2011

## Non-Conformities (Detail)

| Area | NCR Ref. | Description | Clause/Annex |
|---|---|---|---|
| Clinical Evaluation | BW1 | NONCONFORMITY<br>The clinical evaluation process is inadequate to provide an evaluation meeting the current state of the art<br>REQUIREMENT<br>Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X<br>OBJECTIVE EVIDENCE<br>The clinical evaluation documentation for the device consisted of a statement from Dr Nigel Harper regarding the satisfactory clinical performance of the device and a selection of articles. No analysis or overriding report was provided. The approach taken was not in line with that detailed in Annex X or MEDDEV 2.7.1., for example with regard to having an objective, selection criteria, critical review of documents, etc. In addition, there was no evidence of post-market clinical follow as required in Annex X, 1.1c. | Annex I, 6a<br><br>Annex X |
| Harmonised Standards | BW2 | NONCONFORMITY (Annex I, ER 2)<br>Harmonised standards have not been applied or only applied in part; compliance with the essential requirements by other means has not been adequately demonstrated<br>REQUIREMENT<br>The solutions adopted by the manufacturer for the design and construction of the device must conform to safety principles, taking account of the generally acknowledged state of the art<br>OBJECTIVE EVIDENCE<br>Compliance with the harmonised standard, EN 60601-1, general requirements for safety for medical electrical equipment, has not been demonstrated for the device. No rationale has been provided to support the non-use of the various elements of this standard as is required in | Annex I, ER2<br><br>Annex II, 3.2c |

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|---|---|---|---|
| | | Annex II, 3.2c. | |
| Declaration of Conformity | BW3 | NONCONFORMITY<br>The Declaration of Conformity is incomplete<br>REQUIREMENT<br>The manufacturer must.....and draw up a written declaration of conformity<br>OBJECTIVE EVIDENCE<br>The conformity assessment route (Annex II) was not included on the declaration. In addition, it is recommended that the device classification rule is included in the declaration | Annex II, 2 |

## Assessment Team

| On behalf of BSI the assessment was conducted by: | The principal staff involved on behalf of the company were: |
|---|---|
| Ben Wall<br>David Adams | Derek Lamb<br>John Lamb |

## Visit Details

Number of Employees (covered by Registration at site visited): approx 15
Actual visit days: 1
Other sites visited: none

Signed for on behalf of BSI

**Ben Wall**
22 March 2011

Signed for on behalf of the client

**Derek Lamb**
22 March 2011