Nonconformity Report
Viamed Ltd

Audit Reference	30133042
Audit type	Continuing Assessment (Surveillance)
Audit Date(s)	10-Sep-2025
Report author	Jun Wai Kow
Audit Standard(s)	ISO 13485:2016 & EN ISO 13485

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Summary

Thank you for your cooperation during this audit. The full audit report will follow, this report details the nonconformities raised at this audit and the actions you need to take.

No diverging opinions were raised.

This report was printed on 11-Sep-2025

Findings raised at this audit

2 minor non-conformities requiring attention were identified

Finding Reference	**2700663-202509-N1**	**Certificate Reference**	**MD 78787**
Certificate Standard	**ISO 13485:2016 & EN ISO 13485**	**Clause**	**8.2.4**
Location Reference	0009370214-000		
System NC	No		
Authorised to close	QMS Auditor		
Remote closeout	No		
Category	Minor		
Area/process	Core QMS		
Details	The internal audit process is not fully effective as raised issues within audit records do not clearly differentiate between observations and non-conformities.		
Clause requirements	**8.2.4** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope,		

	interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.
Objective Evidence	Audit records reviewed (Audit 15 and Audit 06) highlighted issues and were raised within the Intrastat (eQMS system). The issues raised did not highlight or state if the issues were an observation or non-conformance. No investigation or CAPA related actions were seen and the issues were cleared/completed with note comment only. # Audit 06 – Performed 30 May 2025 – Issues 365729 Raised 26 June 2025; Issue 367474 Raised 18 June 2025 – Closed 26 June 2025 # Audit 15 – Performed 21 July 2025 – Issues 370409, 370410 – Raised 21 July 2025 – Closed 22 July 2025
Status	Open

Finding Reference	**2700663-202509-N2**	**Certificate Reference**	**MD 78787**
Certificate Standard	**ISO 13485:2016 & EN ISO 13485 ISO 13485:2016**	**Clause**	**4.2.3 7.5.11**
Location Reference	0009370214-000		
System NC	No		
Authorised to close	QMS Auditor		
Remote closeout	No		
Category	Minor		
Area/process	Risk Management and Medical Design File		
Details	The medical devices files process of the organisation is not fully effective, as the organisation has not established requirements to		

	ensure that product labelling is up to date and viable.
Clause requirements	**4.2.3** For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements. The content of the file(s) shall include, but is not limited to: a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use; b) specifications for product; c) specifications or procedures for manufacturing, packaging, storage, handling and distribution; d) procedures for measuring and monitoring; e) as appropriate, requirements for installation; f) as appropriate, procedures for servicing. **7.5.11** The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).
Objective Evidence	The organisation has not documented labelling requirements as a distributor to verify or maintain product labels implemented and placed by the legal manufacturers are current, compliant and remain legible throughout distribution. Technical files were seen historic, predating the sampled product and existing labels on product was seen not recorded. The product sampled was in relation to Temperature Probe – Skin Contact – Ref 1010132021V – SN 210114478 – Type 0212921 – Viamed Ltd – Produced Oct 2021 – Barcode ID 1856344 – Manufacturer Bluepoint Medical Gmbh # Interface Agreement – Bluepoint medical GmbH & Co KG – 21/12/2016
Status	Open

Actions required from you

A corrective action plan is required to define the action to address the non-conformities identified during this audit. The corrective action plan must include the correction (containment), root cause, corrective action, timescales and person responsible for implementation.

The plan is to be submitted no later than **25-Sep-2025** by email to **Jun.Kow@bsigroup.com** and **RSCAPS@bsigroup.com**, referencing the report number: **30133042**.

It is essential that the CAP includes the following elements:

1. **The unique identifier** (the Finding Reference as detailed in this report and where applicable, any internal identifier assigned within your organisation).

2. **Statement of non-conformity**.

3. **Root Cause Analysis**. You must clearly indicate if this is a single site issue, or exists across all or other named sites as applicable.

4. **Relevant Immediate Correction** (where applicable). Please clearly indicate where the corrections are across single or all or other named sites.

5. **Relevant and Proportionate Corrective Action**. Please clearly indicate where the corrective actions are across single or all or other named sites.

6. **Person/s responsible**.

7. **Time for completion of all identified actions**, and where necessary, across all affected sites.

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.

How to contact BSI

Appeals
An Appeal is defined as a request for reconsideration of any decision made by BSI related to the certification process, for example an appeal against a nonconformity raised by an auditor during an audit.

If you wish to contest a decision made *or* a nonconformity raised during this audit that you have been unable to resolve through your Client Manager/ Auditor, you may appeal in writing within 21 calendar days of the closing meeting of the audit to the Head of Compliance & Risk using RSComplianceandRisk@bsigroup.com.
Please provide the audit report reference number, date of the audit, or the nonconformity reference number and the technical details supporting your disagreement.

Complaints
A Complaint is defined as an expression of dissatisfaction, other than an appeal, by any person or organisation, to BSI, relating to the activities or behaviour of someone working on behalf of BSI or the products or services of BSI.

If you wish to raise a complaint related to the activities or behaviour of your auditor, or other aspects of the products and services provided by BSI, that you have been unable to resolve through your Client Manager/Auditor then you may submit a complaint in writing at any time to the Head of Compliance & Risk using RSComplianceandRisk@bsigroup.com.
Please provide the audit report reference number or date of the audit and the details of your complaint.

Notes

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This audit was conducted 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 audit 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.