

BSI Audit 4050342 2000 Dec



Management System Assessment Report

BSI Client Ref:
9370214
Certificate No:
FS 28344
CE 01389
Report Number:
4050342
Prepared by:
C E Collins
Date:
6th Dec 00
Continuing
Assessment

Viamed Limited
15 Station Road
Cross Hills
KEIGHLEY
West Yorkshire
BD20 1DT
UK



INTRODUCTION

This report relates to a one day Continuing Assessment of Viamed Limited held on the 6th Dec 00.

During the assessment several pages of hand written notes were taken recording compliance with both the standard and the documented quality management system. As part of this process one nonconformities were identified.

CONCLUSIONS

Continued certification is confirmed, however a corrective and preventive action plan is required.

No nonconformities were raised at the previous visit and therefore there are no outstanding NCRs

The nonconformities identified require corrective and preventive action, firstly to correct the identified nonconformance and secondly to examine the underlying cause 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 20th Jan 00.

The plan should be sent by fax to 0208 996 7988 or by e-mail to caps@bsi.org.uk . Please ensure that your response details each nonconformity and the proposed corrective action with time scales for completions. For administrative reasons please ensure that your response details this report number and your BSI client reference as detailed on page one of this report.

It is confirmed that:

Certificate No: Dated

FS 28344 18th Oct 99
CE 01389 23rd Sept. 96

remain(s) valid for the scope of registration as detailed on the appendix(es).

ASSESSMENT COMMENTARY

EC 1: Design procedures date from a period when this company was involved in the design of simpler products. Because much design work is now more complex and can be speculative in nature, it may be an advantage to differentiate from an original marketing specification, which may include customer inputs (including cosmetic requirements) and a working technical specification which may be subject to change by revision status through the life of the project. This would be an advantage later in the project when the output is evaluated to the input and to any customer specific requirements. This would also assist in the generation of technical file information if the same information could be used.

QC22 is more appropriate to record an outline specification to be agreed at a marketing stage and needs expansion if it is to capture all the design input specifications, legal and regulatory requirements.

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Procedures are not specific in respect of how the objective evidence of design input review would be shown. E.g. signature on QC22

VISIT DETAILS

THE ASSESSMENT TEAM

The assessment was conducted by:

Edward Collins

on behalf of BSI.

The principal staff involved on behalf of the company were:

Mr Lamb – MD

Mr Watmough – Technical Engineer

THE MANAGEMENT STANDARD

The management standard used as the basis for this assessment was ISO 9001, EN 46001 and MDD 93/42/EEC

THE COMPANY'S DOCUMENTATION

The company's management system documentation forming the basis of assessment was:
Issue 2

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

The activities assessed in depth are listed in the 'Areas Assessed this Visit' table attached. 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 organisation, then all pages must be included.

Signed for on behalf of BSI

Edward Collins
Client Manager



Date: 6th Dec 00

Signed for on behalf of the client

Mr Lamb
MD



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AREAS ASSESSED THIS VISIT

Areas Assessed	Management Standard Clause Number															Nonconformity Summary	NCR Ref		
	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19
QA	✓	✓													✓		✓		
Training	✓	✓																	
Sales	✓	✓	✓														✓		
Design	✓	✓	✓														✓		
																			EC 1

Quality Management System Requirements	
4.1	Management Responsibility
4.2	Quality System
4.3	Contract Review
4.4	Design Control
4.5	Document & Data Control
4.6	
4.7	Purchasing
4.8	Control of Customer Supplied Product
4.9	Product Identification & Traceability
4.10	Process Control
	Inspection & Testing
4.11	Control of Inspection, Measuring & Test Equipment
4.12	Inspection & Test Status
4.13	Control of NonConforming Product
4.14	Corrective & Preventive Action
4.15	Handling, Storage, Packaging, Preservation & Delivery
4.16	Control of Quality Records
4.17	Internal Quality Audits
4.18	Training
4.19	Servicing
4.20	Statistical Techniques

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NONCONFORMITIES IDENTIFIED DURING THIS VISIT

Area	Ref	Description	ISO Ref
Design	EC 1	The design input for the quick oxygen analyser is not fully documented and reviewed as detailed in VM/cop/16, Issue 3, QC22. This project was at an early stage but with a working prototype being produced. The design input specification of the 6 th Sept 00 does not specify the battery life expectancy, the accuracy or resolution required of the display or alarm, the alarm setting (which may need to be to a regulatory requirement) or the alarm noise level in dB. The manufacturing price may also be a consideration.	

Plan for Next Visit

Prepared in accordance with ISO10011

Client: Viamed Limited

Opening Meeting Date/Time: _____
Closing Meeting Date/Time: _____
Company Representative _____

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CERTIFICATION DETAILS

REASON FOR ISSUE/REISSUE: Correction of certificate to incorporate RS 28343 and FS 28344 into one certificate (FS 28344) and to include the trading name of Vandagraph Ltd

Client: (as to appear on certificate)

Registered Address:	Invoice Address:
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Trading name (also to appear on certificate): Vandagraph Ltd

Total No of appendices:	one
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Location Address:	
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Approved Site Address:	
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Recommended scope of registration (as to appear on appendices):
Design, manufacture, repair, servicing and supply of ... remaining wording as per FS28344

Accreditation:	Client Tel No: Client Fax No: Client Contact: Alt. Contact: Email:
Best Fit Code(s):	
Certificate Prefix:	
Visit Frequency:	
Start Month:	
Location Client Managers:	
Co-ordinating Client Manager:	

Additional Information:

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Internal BSI Actions

THE FOLLOWING ACTIONS WILL BE IMPLEMENTED BY BSI.

(include actions detailed in the report).

Re issue of certificate

VISIT DATA

Number of employees: 22

Certificate Reissue required: yes

Client CAP due: 20th Jan 01

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