

BSI Audit 4017779 2000 APR

BSI Client Ref:

9370214

Certificate No:

FS 28344

CE 01389

Report Number:

4017779

Prepared by:

M.J.BISHOP

Date:

03/04/2000

**VIAMED LIMITED
15 STATION ROAD
CROSS HILLS,KEIGHLEY
WEST YORKSHIRE
BD20 1DT
UK**

ASSESSMENT SUMMARY

This report relates to the continuing assessment for Viamed Ltd., held 03/04/2000. Details of the assessment are contained within this report.

During the assessment 0 nonconformities were identified and, if applicable, these are detailed within Appendix 2. Any opportunities for future improvement are detailed within the body of this report.

CONCLUSIONS

Continued certification is confirmed.

The corrective and preventive actions have been verified for report 4008980 and there are no outstanding NCRs. The details for the close down are fully documented on the (A7) Assessment Detail report.

It is confirmed that:

Certificate No:	Dated
FS 28344	18/10/99
CE 01389	23/08/96

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

OPPORTUNITIES FOR FUTURE IMPROVEMENT

None at this visit

OBSERVATIONS

None at this visit

VISIT DETAILS

THE ASSESSMENT TEAM

The assessment was conducted by:

M.J.BISHOP

on behalf of BSI.

The principal staff involved on behalf of the company were:

Mr.J.LAMB

THE MANAGEMENT STANDARD

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

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THE COMPANY'S DOCUMENTATION

The company's management system documentation forming the basis of assessment was:
Quality Manual iss2 amended 24/02/99

SCOPE OF THIS ASSESSMENT VISIT

The activities assessed in depth are listed in Appendix 1.

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.



Signed for on behalf of BSI

M.J.BISHOP
Client Manager



Signed for on behalf of the client

Mr.J.LAMB
Managing Director

Date: 03/04/2000

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	Management Standard Clause Number																			Nonconformity Summary		
	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		4.20	NCR Ref
Arcs Assessed	✓	✓												✓			✓					
QA		✓					✓	✓				✓	✓		✓	✓						
STORAGE/GOODS-IN		✓														✓						
DOC CONTROL/RECORDS		✓			✓																	
BS EN 46001		✓																				
MDD 93/42/EEC		✓												✓								

APPENDIX 1 – AREAS ASSESSED AND VALIDATION

	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	4.20		
Areas Assessed	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	4.20		
QA	✓	✓						✓				✓	✓		✓	✓		✓				
STORAGE/GOODS-IN		✓						✓				✓	✓		✓	✓						
DOC CONTROL/RECORDS		✓			✓											✓						
BS EN 46001		✓																				
MDD 93/42/EEC		✓												✓								

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

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APPENDIX 2 – NONCONFORMITIES IDENTIFIED DURING THIS VISIT

Area	NCR Ref	Description	Ref Standard
None			

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A218 - Continuing-assessment Plan
Issue 4

Report Number:

Sheet Number : 5 of

Prepared in accordance with ISO10011-1

Client: Viamed Ltd	BS EN ISO 9001,BS EN 46001	BSI Team:	Leader::	M.J.BISHOP
Management Standard:	TBA		Members	
Company Quality Manual ref.	10/2000			
Opening Meeting Date/Time:	10/2000			
Closing Meeting Date/Time:	Mr.J.LAMB			
Company Representative				

Date	Time	Assessor	Area	Clause(s)
10/2000	9.00am	M.J.BISHOP	QA/MDD 93/42/EEC	4.1, 4.2, 4.14, 4.17, 4.19, 4.20
	10.30		TRAINING	4.2, 4.18
	11.15		SALES	4.2, 4.3.
	12.00		lunch	
	12.45pm		DESIGN	4.2, 4.4
	2.15		VANDAGRAPH	4.2, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13
	3.30		REPORT PREP	
	4.30		CLOSE OUT	

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ASSESSMENT DATA SUMMARY

INVOICE DATA

Actual visit date: 03/04/2000
Actual visit days: 1.0
Visit approved site: N

Invoice amount: 505
Person seen: Mr.J.LAMB
Invoice comments: N

VISIT DATA

No. of nonconformities: 0
Corrective action due: N/A
Number of employees: 20

Client Details changed?: N

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