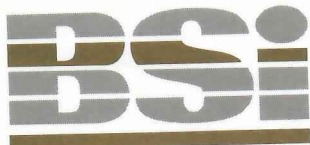


BSI AUDIT 327574 1997 DEC



Assessment Report

INCLUDES BIENNIAL REVIEW.

236736
Report no. 236735
Sheet no. 1 of

Client: VIANAD LTD.

Address: 15 STATION ROAD

CROSBILLS.

KEIGHLEY

Postcode B20 7DT.

Ref documents:

Client: QUALITY MANUAL. PK 2.

PRODUCES

BSI:

Management standard: BS EN ISO 9002:1994.

Scheme requirement: REG. FIRM + DISTRIBUTOR.

Product standard: —

Type of assessment: CONTINUING.

Commencement date: 14 NOV 96.

NCR ref numbers raised this visit: NIL.

Outstanding NCR

From Report: 201675/6 Y/N

Corrective action letter N/A.

Required by: —

Client reference No: 9376214.

Cert/Licence No: RS 28343/FS 28344.

No. of employees: ± 17.

Scope: —

Verified as correct ☒ Y/N?

(if no, changes to be detailed on A368)

UPDATED ON FS CERT TO

STATE AM 46002: 1994.

Visit Duration (Mandays): 1.0.

BSI contacts:

Client manager: M. J. BRYANT

Client administrator: SARINA BARK

Client administrator DDI: 07908 228047

Coordinating client manager: M. J. BRYANT

Team members: —

Signed for BSI:

Name: M. J. BRYANT

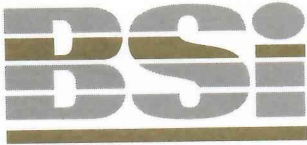
Signed for client,
(acknowledging receipt of report)

Name: J. Lamb

Date: 14 NOV 96.

Where it is found on a subsequent visit that corrective actions have not been implemented, in accordance with the agreed programme, then BSI QA may take steps to withdraw certification.

Where the client wishes to distribute copies of this report, all pages must be included.



Assessment summary

Report no. 236 736
236 735
Sheet no. 2.

Management Standard Clause no.	This visit*	Specify areas assessed Indicate with tick															Nonconformity Summary
	Clauses Covered																Quantity of NCR's
4.1	✓	✓															
4.2	✓	✓	✓														
4.3																	
4.4	N/A.																
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	N/A.																

* Indicate either: ✓ = Assessed or: - = not applicable to this scheme

Comments

ASSESSMENT.
14.11.96
NO PROBLEMS !!



Biennial Review

236736
Report no. 236735
Sheet 1 of 6.

Client: VIA MND LTD.
Address: 15 STATION ROAD.
CROOK HILLS.
WIDGBURY
W. YORKS.

Postcode B20 4DT

Date of visit: 14 Nov 96.

Reference No. 9370214
Certificate No(s). FS 28344
RS 28343.

No of Locations: 1.

Client Representative: Mr J. LAMB (M.D.)

BSI Representative: M.J. DUNN

Review period from 18 Oct 94. to 14 Nov 96.
Planned visits 2/4 Achieved 2/4.

REFERENCE DOCUMENTATION

Management Standard BS DIN ISO 9002: 1994.
Scheme requirements BS EN 46002: 1994.
MDD 93/42/EEC. ANNEX V.

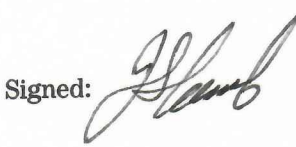
CLIENT REFERENCE DOCUMENTS

QUALITY MANUAL. 1992.
PROCEDURES.

SCOPE OF CURRENT REGISTRATION - Confirmed/Amended, see Certification Details sheet A368.
(Refer to Certificate of Registration and Appendix)

Original certificate issue date: 15 JUNE 94.
Amended certificate issue date: 1 FEB 95.
Current appendix issue date: 15 JUNE 94.

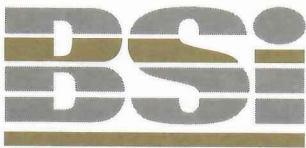
Signed: 
BSI QA

Signed: 
Client

Signed:

Reviewing Manager

Date:



Biennial Review
Assessment Summary

236736
Report no. 236735
Sheet no. 2,

Management Standard Clause no.	Visit*	Brief Numbers																Nonconformity Summary
	Clauses Covered																	Quantity of NCR's
4.1	/	✓	✓	✓	✓	✓												1
4.2	/	✓	✓	✓	✓	✓												
4.3	/	✓	✓	✓	✓	✓												
4.4	N/A	.	.	.	.	.												
4.5	/	.	✓	.	.	✓												
4.6	/	.	✓	.	✓	✓												2
4.7	/	✓	✓	✓	✓	.												
4.8	/	✓	✓	✓	✓	.												
4.9	/	.	✓	✓	✓	.												
4.10	/	.	✓	✓	✓	.												1
4.11	/	.	✓	✓	.	.												
4.12	/	.	✓	✓	✓	.												
4.13	/	.	✓	✓	✓	.												
4.14	/	✓	✓	✓	✓	✓												
4.15	/	.	✓	✓	✓													
4.16	/	.	✓	✓	✓	✓												
4.17	/	✓	✓	✓	✓	✓												3
4.18	✓	.	✓	.	✓	.												
4.19	✓	✓	✓	.	.	✓												
4.20	N/A	.	.	.	.	.												

* Indicate either: ✓ = Assessed or: - = not applicable to this scheme

Summary

Quality System

7 Nonconformities noted in the period of review - all minor. Vianed are a small organisation operating both Registered Firm solely for repair and installation of medical electronic and mechanical equipment and Registered Firm: Distribution for distribution of similar equipment. The procedures have recently been updated to meet the requirements of BS EN ISO 9001:1994 and BS EN 46001:1994. And the Company have successfully gained CE Certification for the manufacture of Heart Stimulators, Thoracic Resuscitator, Resuscitator and VNI 202 Oxygen Monitor.

The Quality System is working well with few complaints received. There have all been connected with equipment supplied via other manufacturers. Since Jan '96 the business activity has increased considerably, and several new ventures have been established within the Vianed umbrella (these are to be included in the current negotiation at the next continuing assessment visit). Few problems have been experienced in this period thus demonstrating the effectiveness of the system.

Audits

Currently up to date however management review and audit of the audit have been delayed due to extensive overseas travel by the M.D. Areas of nonconformance identified have been closed out by effective corrective/preventive actions.

Future Developments

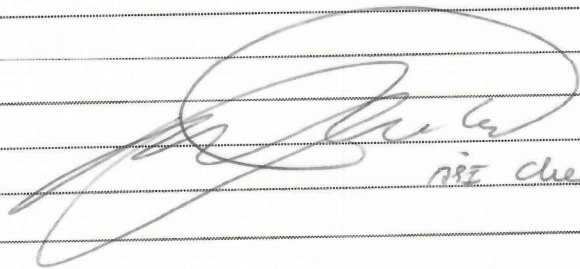
Mr J. Lamb M.D. has expressed a desire to include the new business activities, that have been identified and are currently under development, within the Visited Registration. However it is felt that the Distributor scheme no longer has any viability within the association and it is intended that this registration be rescinded.

Currently the premium rate being extended to accommodate increased activity and it is hoped that upgrade to PR IN 190 9001:1994 will be possible in 1997.

Recommendation

Registration Form FS 28344 to continue at the current rate of 2 visits per annum of 0.5 days duration following cancellation of the PR 28343 Certificate.

The assessment rate for CB Mark is set at 1 visit per annum of 0.5 days duration in addition to the above. This will be combined with the Registration Form continuing visits due April 97.



District Manager.