Assessment Report.

Groupe CLJ

Report Author

Visit Start Date 05/07/2016

Introduction.

This report has been compiled by and relates to the assessment activity detailed below:

Visit ref/Type/Date/Duration	Certificate/Standard	Site address
8556276 Continuing Assessment (Surveillance) 05/07/2016 1 day(s) Effective no. of employees : 6 Total no. of employees : 6	CE 648248 Healthcare 93/42/EEC Annex II, Sec 3.2 (2007/47) CE MARKING MD 648250 EN ISO 13485:2012 ISO 13485: 2003 ISO 13485	CL Medical 4 rue Dr Pravaz Sainte Foy Les Lyon 69110 France

AUDIT SCOPE AND OBJECTIVES

Assessment Scope
The management system processes at the 4 Avenue du Docteur Pravaz, 69110 Sainte Foy les Lyon, France.

Assessment Objectives

To conduct a surveillance assessment to determine the continued effectiveness of implementation of the company's management system, in accordance with the company objectives, policies and procedures, the management standard(s) & BSI Conditions of Contract and to determine whether a recommendation for continuing certification can be made.
To verify all requirements of ISO 13485:2003 and EN ISO 13485:2012 have been effectively implemented/continue to be effectively implemented.
To determine if the management system continues to meet the requirements of: MDD 93/42/EEC Annex II 3.2

Management Summary.

Overall Conclusion

The objectives of the assessment were not met. Some areas have not been assessed as planned due to the decision of CL medical to stop the audit.

Areas not audited:
Due to cessation of the audit by CL Medical, following processes were not covered as part of this assessment:
Ressources
Product Realization - Production of meshes
Control / Control of non conforming product
Traceability

Suppliers + purchasing /Outsourcing

Identification and Dating
Author of the report:
The report revision 0 was finalized and issued on 11 July, 2016.
The remmendation included in this assessment is based on assessment of:
Groupe CLJ (include CLJ finances, DM Pack, Gyneo (aka J-teck, CL Medical (owner of the CE mark))
4 rue du docteur Pravz, 69110 Sainte Foy les Lyon, France
The report was finalised and issued on 11 July, 2016.
This visit is part of a multi-location assessment. The final recommendation will be contingent on the findings from all assessments.

This report is eligible for submission to US FDA under FDA ISO 13485 Voluntary Audit Report Submission Program.

The management system has not been effectively implemented, addresses the proposed scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract. Further assessment is required prior to a decision regarding a recommendation for certification

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

All Requirements of ISO 13485:2003 and EN ISO 13485:2012 as applicable have not been effectively implemented.
The management system does not meet the requirements of MDD 93/42/EEC Annex II 3.2

There were no outstanding nonconformities to review from previous assessments.

Both major nonconformities and minor nonconformities requiring attention were identified. These, along with other findings, are contained within subsequent sections of the report.

A minor nonconformity relates to a single identified lapse in the management system. 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. The proposed action will be reviewed for effective implementation at the next assessment.

Please submit a plan to BSI detailing the nonconformity, the cause, correction and your proposed corrective action, with responsibilities and timescales allocated. The plan is to be submitted no later than 21/07/2016 by e-mail to msuk.caps@bsigroup.com, referencing the report number.

An additional 1 day visit over and above the continuing assessment plan will be necessary to verify that the planned corrective action has been effectively implemented. This visit will take place on 07/10/2016.

Areas Assessed & Findings.

Quality Management System: 4.0
The quality management system was assessed. The quality manager was interviewed for this part. It is controlled by the SOP CLJ-P-06 issue D which includes the codification, writer responsible, verification and approval activities, diffusion, changes, archiving and follow up of quality manual, procedures, instructions, records, technical file, data backup and external documents. The SOP CLJ-P-07, issue D controls records and defines an archiving time as to be 15 years.
Applicable documents are presented in the form E-02, issue D approved on 10 March 2016 (procedures, instructions and records).
The Quality Manual, issue M approved on 6 January 2016 includes all requirements as the scope of the QMS (no exclusion, no non application), reference to the documented procedure, processes cartography and the structure of the documentation.

Based upon the objective evidence reviewed, it appears that the QMS does not include all records required by the EN ISO 13485: 2012 (see Major NC, chapter 4.2.1), as for example:

- No record of customer complaints investigation (chapter 8.5.1), example R-1603
- No record of the reason when a customer complaint is not followed by corrective and/or preventive action (chapter 8.5.1), examples R-1603, R-1604
- No record of acceptance under concession (chapter 8.3), seen form E-47-C
- No record of results of the review of changes and any necessary actions (chapter 7.3.7), example NC-1503

Based upon the objective evidence reviewed, it could not be concluded that the QMS was fully compliant with any other documentation specified by national or regional regulations applicable to the company (see Major NC, chapter 4.2.1). Indeed, there is no documented evidence of the regulatory follow up. Only a list of applied standards is included into the annual management review and this list is not complete, as for example:

- No reference to the code de la santé publique for the French market
- No reference to the 21CFR for the US market
- No reference to the MEDDEV and the procedure CLJ-P-21, issue D relatives to materiovigilance is not compliant with MEDDEV2.12.1 and the was not notified to the competent national authority.
- No standards relatives to the controlled area
- Some documented procedure lists the DORS 98-282 as a reference, however this regulation is not listed into the list and appears to be no more followed by the company (examples : P-06 issue D, P-22 issue D, P-24 issue D)
- Quality Manual refers to ISO 9001: 2008, as some documented procedures however this regulation is not more claimed by the company.

Furthermore, according to the SOP CLJ-P-06, a list of applied standards should be included into the QMS (liste norms.xls) and the follow up should be performed monthly and not annually.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Quality Management System were found to be not effective to meet the needs of the business and not compliant with the requirements of ISO 13485:2003 and MDD93/42/CEE.
Two Major non-conformities were therefore raised which require corrective actions.

Management Responsibility: 5.0
The management responsibility process was assessed. The Chairman of the company was interviewed for this part. This process is controlled by the chapter 5 of the Quality Manual, issue M as, for example, the internal communication. It includes weekly and monthly meeting as annually meeting through the management review.
Records of the weekly meeting dated on 01/07/2016, monthly report of May 2016 and record of the last management review performed on 25 January 2016 was reviewed and it includes input and output items required by the EN ISO 13485: 2012.

The SOP CLJ-P-23, issue C describes data analysis and lists all data to be reviewed annually during the management review. Only Four (4) KPIs are followed instead of the fourteen (14) listed in the SOP (see minor NC, chapter 5.4.1)), as for example:

- Qualification and reevaluation of suppliers
- Sales follow up
- Employees training
- Supplier contract conformity

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for management responsibility were found to be generally effective to meet the needs of the business and not fully compliant with the requirements of ISO 13485:2003 and MDD 93/42 EEC.
A minor non-conformity was therefore raised which requires corrective action.

Resource Management: 6.0
This section could not have been audited due to the decision of the client to stop the audit.

Product realization: 7.0
This section could not have been audited due to the decision of the client to stop the audit.

However, based upon the objective evidence reviewed through all audited processes, the documented requirements for risk management throughout product realization was found to be not effective to meet the needs of the business and not compliant with the requirements of ISO 13485:2003 and MDD93/42/CEE (see Major NC, chapter 7.1). For example, the mould for needles was modified according to the NC-1503 action plan, there is no record arising for risk management of this change.

One Major non-conformity was therefore raised which require corrective actions.

Measurement, analysis and improvement: 8.0

Complaints/vigilance/CAPA: 8.2.1/8.5
Complaints, vigilance and CAPA processes were assessed. The Quality Manager was interviewed for these areas. Complaints are controlled by CLJ-P-22, issue C, vigilance controlled by CLJ-P-21, issue D and CAPA by CLJ-P-24, issue D.
From January 2015 to June 2016, there were 22 complaints. Followings were reviewed:

- R-1604: No action
- R-1603: vigilance according to the client and no vigilance by group CLJ
- R-1511: one corrective action undertaken

The review demonstrates that:

- There is no record of customer complaints investigation nor record of the reason when a customer complaint is not followed by corrective and/or preventive action (see Major NC raised against chapter 4.2.1).
- The procedure and the record of CAPA do not include all requirements, as for example, determination of the causes of non conformities, evaluation of the need for action to ensure that non conformities do not recur, determination of action needed (only an action description once implemented), review of actions undertaken and effectiveness. Furthermore, non conformities raised during the transfer audit performed in February 2016 or during the internal audit performed on September 2015 were not recorded according to the CAPA SOP (see Major NC, chapter 8.5)

Internal audit: 8.2.2
The Quality Manager was interviewed for the internal audit process according to the CLJ-P-05, issue C which defines that all areas should be covered every year and that the internal audit is performed by an external consultant due to the company size.
The last internal audit was performed on 12 September 2015 by as lead auditor (CV with IRCA accreditation as the previous one performed on 24 September 2014.

The internal audit report 2015 includes an audit plan which is very general to any company (as example: design if applicable), non conformities raised and audit program. Methods and scope were not defined and the frequency to cover all areas is defined as to be two years into the audit program instead of one year as defined into the procedure (see minor NC, chapter 8.2.2).

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for measurement, analysis and improvement were found to be not effective to meet the needs of the business and not compliant with the requirements of ISO 13485:2003 and MDD 93/42 EEC.
One major and one minor non conformities were therefore raised which require corrective actions.

Minor Nonconformities Raised at Last Assessment.

Ref	Area/Process	Clause
1295742N1	MICRO AUDIT :	8.2.4
Scope	MD 648250	
Statement of non conformance:	The process for ensuring monitoring the characteristics to verify that product requirements have been met. is not entirely effective.	
Requirements:	Monitoring and measurement of product	
Objective Evidence:	1) verification of sterilization report by QA is not documented on available records. 2) A procedure for control of sterilization records and release is not available, so it is not clear which data are verified to support release. Company is to investigate root cause, to define correction (treatment), and to define actions (CA) to prevent re-occurrence.	

Actions:	
Closed?:	No
Justification	

Ref	Area/Process	Clause
1295742N2	MICRO AUDIT :	7.5.2.1
Scope	MD 648250	
Statement of non conformance:	The process for ensuring Validation to demonstrate the ability of processes to achieve planned results is not entirely effective.	
Requirements:	General requirements The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use. Records of validation shall be maintained (see 4.2.4)	
Objective Evidence:	verification of absence of pyrogens on the product was not anymore performed after 2002 Company is to investigate root cause, to define correction (treatment), and to define actions (CA) to prevent re-occurrence.	
Actions:		
Closed?:	No	
Justification		

Ref	Area/Process	Clause

1295742N3	MICRO AUDIT :	6.4
Scope	MD 648250	
Statement of non conformance:	The process for ensuring determination and management of the work environment is not entirely effective.	
Requirements:	Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. The following requirements shall apply. a) The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1). b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1). c) The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)]. d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).	
Objective Evidence:	pest monitoring and control is poorly documented: - A plan / procedure is not available. - Control of positive baits is performed but is not documented. - Monitoring of flying insects is not documented. Company is to investigate root cause, to define correction (treatment), and to define actions (CA) to prevent re-occurrence.	
Actions:		
Closed?:	No	
Justification		

Major Nonconformities Arising from this Assessment.

Ref	Area/Process	Clause
1353979M1	Quality System	4.2.1
Scope	MD 648250	
Statement of non conformance:	The Quality Management System does not include all records required by EN ISO 13485: 2012	

Requirements:	General The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, e) records required by this International Standard (see 4.2.4), and f) any other documentation specified by national or regional regulations. Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained. For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing. NOTE 1 The extent of the quality management system documentation can differ from one organization to another due to a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. NOTE 2 The documentation can be in any form or type of medium.
Objective Evidence:	- No record of customer complaints investigation (chapter 8.5.1), example R-1603 - No record of the reason when a customer complaint is not followed by corrective and/or preventive action (chapter 8.5.1), examples R-1603, R-1604 - No record of acceptance under concession (chapter 8.3), seen form E-47-C - No record of results of the review of changes and any necessary actions (chapter 7.3.7), example NC-1503

Ref	Area/Process	Clause
1353979M2	Quality System	4.2.1
Scope	MD 648250	
Statement of non conformance:	The Quality Management System does not include all documentations required by national or regional regulations.	
Requirements:	General The quality management system documentation shall include a) documented statements of a quality policy and quality objectives,	

	b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, e) records required by this International Standard (see 4.2.4), and f) any other documentation specified by national or regional regulations. Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained. For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing. NOTE 1 The extent of the quality management system documentation can differ from one organization to another due to a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. NOTE 2 The documentation can be in any form or type of medium.
Objective Evidence:	There is no documented evidence of the regulatory follow up. Only a list of applied standards is included into the annual management review and this list is not complete, as for example: - No reference to the code de la santé publique for the French market - No reference to the 21CFR for the US market - No reference to the MEDDEV and the procedure CLJ-P-21, issue D relatives to materiovigilance is not compliant with MEDDEV2.12.1 and the was not notified to the competent national authority. - No standards relatives to the controlled area - Some documented procedure lists the DORS 98-282 as a reference, however this regulation is not listed into the list and appears to be no more followed by the company (examples : P-06 issue D, P-22 issue D, P-24 issue D) - Quality Manual refers to ISO 9001: 2008, as some documented procedures however this regulation is not more claimed by the company. Furthermore, according to the SOP CLJ-P-06, a list of applied standards should be included into the QMS (liste norms.xls) and the follow up should be performed monthly and not annually.

Ref	Area/Process	Clause
1353979M3	Quality System	7.1
Scope	MD 648250	
Statement of non conformance:	There is no documented evidence that the organization has established documented requirements for risk management throughout product realization and many records were not available.	
Requirements:		

	Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations. The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4). NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes. NOTE 3 See ISO 14971 for guidance related to risk management.
Objective Evidence:	Mould for needles was modified according to the NC-1503 action plan, there is no record arising for risk management of this change.

Ref	Area/Process	Clause
1353979M4	Quality System	8.5.2
Scope	MD 648250	
Statement of non conformance:	The process for ensuring corrective and preventive actions is not compliant.	
Requirements:	Corrective action The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, including, if appropriate, updating documentation (see 4.2), e) recording of the results of any investigation and of action taken (see 4.2.4), and f) reviewing the corrective action taken and its effectiveness.	

Objective Evidence:	The procedure and the record of corrective and preventive actions do not include all requirements, as for example, determination of the causes of non conformities, evaluation of the need for action to ensure that non conformities do not recur, determination of action needed (only an action description once implemented), review of actions undertaken and effectiveness. Furthermore, non conformities raised during the transfer audit performed in February 2016 or during the internal audit performed on September 2015 were not recorded according to the CAPA SOP

Minor Nonconformities Arising from this Assessment.

Ref	Area/Process	Clause
1353979N1	Quality System	5.4.1
Scope	MD 648250	
Statement of non conformance:	Quality objectives are established but not followed.	
Requirements:	Quality objectives Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	
Objective Evidence:	Only Four (4) KPIs are followed instead of the fourteen (14) listed in the SOP CLJ-P-23, issue C (data analysis), as for example: - Qualification and reevaluation of suppliers - Sales follow up - Employees training - Supplier contract conformity	

Ref	Area/Process	Clause
1353979N2	Quality System	8.2.2
Scope	MD 648250	
Statement of non conformance:	The process for ensuring internal audit is not entirely effective.	
Requirements:	Internal audit The organization shall conduct internal audits at planned intervals to determine whether the quality management system	

	a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that 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 (see 8.5.2). NOTE See ISO 19011 for guidance related to quality auditing.
Objective Evidence:	The internal audit report 2015 includes an audit plan which is very general to any company (as example: design if applicable), non conformities raised and audit program. Methods and scope were not defined and the frequency to cover all areas is defined as to be two years into the audit program instead of one year as defined into the procedure

Assessment Participants.

On behalf of the organisation:

Name	Position
	Chariman
	Quality Manager

The assessment was conducted on behalf of BSI by:

Name	Position
	Team Leader
	Observer

Continuing Assessment.

The programme of continuing assessment is detailed below.

Site Address	Certificate Reference/Visit Cycle	
CL Medical 4 rue Dr Pravaz Sainte Foy Les Lyon 69110 France	Contract 200653534	
	Visit interval:	12 months
	Visit duration:	1 Days
	Next re-certification:	01/06/2020

Re-certification will be conducted on completion of the cycle, or sooner as required. An entire system re-assessment visit will be required.

Next Visit Plan.

Visit objectives:

NC Closeout

To conduct a NC closeout audit in order to determine the possibility to recommend the maintain of certificates according to the relevant standards.

ISO 13485 surveillance

To verify all requirements of ISO 13485 :2012 continue to be effectively implemented

MDD surveillance

To verify if the management system continues to meet the requirements of MDD 93/42/CEE Annex II 3.2

Visit Criteria

NC closeout audit and finalise the continuing assessment

Visit Scope

The management system processes at the 4 Avenue du Docteur Pravaz, 69110 Sainte Foy les Lyon, France.

Date	Assessor	Time	Area/Process	Clause
October 2016	Assessor 1	8.30	Opening meeting	
		9.00	Review of CAPA plan and evidences following previous major NCs report SMO 8526276	8.5.2
		13.00	Ressources	6.0
		13.30	Product Realization - Production of	7.1/7.5

			meshes Control / Control of non conforming product Traceability Suppliers + purchasing /Outsourcing	8.2.4/8.3 7.5.3 7.4
		16.30	Report preparation	
		17.00	Closing meeting	

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the organisation within 30 days of an agreed visit date. It is a condition of Registration that a deputy management representative be nominated. It is expected that the deputy would stand in should the management representative find themselves unavailable to attend an agreed visit within 30 days of its conduct.

Scope of Certificate CE 648248 (Healthcare).

Main Scope

Design, manufacture and final inspection of meshes for treatment of male and female urinary incontinence, genito-urinary prolapse and cervical cerclage; polyester meshes for the treatment of genito-urinary prolapse by laparotomy and laparoscopy; and hernia surgical meshes.

Location	Scope
CL Medical 4 rue Dr Pravaz Sainte Foy Les Lyon 69110 France CL MED-0047588805-000	Main Certificate Scope applies.

Scope of Certificate MD 648250 (EN ISO 13485:2012).

Main Scope

Design, manufacturing and sales of implantable meshes for the treatment of male and female incontinence, treatment of prolapse and cervical stitching. Manufacturing of medical device components. cleaning, disinfection and packaging of medical devices.

Location	Scope
CL Medical 4 rue Dr Pravaz Sainte Foy Les Lyon 69110 France CL MED-0047588805-000	Design, manufacturing and sales of implantable meshes for the treatment of male and female incontinence, treatment of prolapse and cervical stitching.

Scope of Certificate Contract 200653534 ().

Main Scope

Location	Scope
CL Medical 4 rue Dr Pravaz Sainte Foy Les Lyon 69110 France CL MED-0047588805-000	Main Certificate Scope applies.

Notes.

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

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

BSI, its staff and agents shall keep confidential all information relating to your organisation and shall not disclose any such information to any third party, except that in the public domain or required by law or relevant accreditation bodies. BSI staff, agents and accreditation bodies have signed individual confidentiality undertakings and will only receive confidential information on a 'need to know' basis.

'Just for Customers' is the website that we are pleased to offer our clients following successful registration, designed to support you in maximising the benefits of your BSI registration - please go to www.bsigroup.com/j4c to register. When registering for the first time you will need your client reference number and your certificate number (47588805/CE 648248).

This report and related documents is prepared for and only for BSI's client and for no other purpose. As such, BSI does not accept or assume any responsibility (legal or otherwise) or accept any liability for or in connection with any other purpose for which the Report may be used, or to any other person to whom the Report is shown or in to whose hands it may come, and no other persons shall be entitled to rely on the Report.

Should you wish to speak with BSI in relation to your registration, please contact our Customer Engagement and Planning:

Customer Services
BSI
Kitemark Court,
Davy Avenue, Knowlhill
Milton Keynes
MK5 8PP

Tel: +44 (0)845 080 9000

Email: MK.Customerservices@bsigroup.com

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 assessment 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.