Audit Report
Primepac Solutions Limited

Audit Reference	3969379, 3969420
Audit type	Verification Audit
Audit Date(s)	15-Nov-2023
Report author	Christian Alexander
Audit Standard(s)	MDD 93/42/EEC, UK MDR 2002

Table of Contents

Identification and Dating

Audit report authors are as per the audit team listed. The recommendation included in this audit is based on the audit of the sites documented in the 'assessed locations' table towards the rear of this report. This table also defines the audit duration. This report was finalised and issued as identified in the table below.

Version No.	Date	Reason
0	17-Nov-2023	First issue

Executive Summary

The objectives of the audit were met.

There were no obstacles encountered during the course of the audit. No factors were encountered during the audit that would affect the reliability of this audit.

All areas were covered per the audit plan.

Witnessing of Testing and Reconciliation

Product testing was not applicable for this audit. Material/ component reconciliation was not applicable for this audit.

Status of findings from previous audits

There were no open nonconformities from previous audits.

Status of findings from this audit

There were nonconformities raised at this audit. These are summarised below. Further details can be found in the sections related to nonconformities raised at this audit later in this report.

No diverging opinions were raised.

Reference	Standard	Clause	Category	Status
2414475-202311-N1	MDD 93/42/EEC	ANNEX II 3.2	Minor	Open

Audit conclusion

Caveats

Please note that all recommendations are subject to independent review.

If this audit is part of a multi-location audit the final recommendation will be contingent on the findings from all audits.

If the objective of this audit report was to conduct a microbiology audit, the conclusions and recommendations only refer to effective implementation from a microbiology/ sterilisation perspective.

If this audit is conducted in support of CE Marking or the UKCA, the recommendation will be subject to review by a scheme manager and certification will be subject to the relevant technical documentation reviews.

Audit conclusion - Healthcare certificate(s):

This conclusion is relevant for the following audit objectives: Verification Audit.

The result of this audit is a recommendation for certification with respect to the verification audit, dependent on submission of a satisfactory corrective action plan.

Use of certification documents, mark / logo or report:

The client does not make use of any BSI or accreditation logos.

Your Next Steps

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 **30- Nov-2023** by email to **christian.alexander@bsigroup.com** and **RSCAPS@bsigroup.com**, referencing the report number: **3969379, 3969420**.

Next audit considerations

The details of your next audit are documented in the Next Visit section of this Report.

Opening Meeting and Changes

The opening meeting was conducted with the client, attendees are documented in the attendee list.

Audit Objective, Criteria and Scope

Objective:

To conduct a verification audit to ensure that the elements of the proposed change and the requirements of the management standard, applicable regulatory requirements from relevant regulatory authorities and BSI Terms of Service are effectively addressed within the organisation's management system.

Criteria:

MDR 2017/745 Article 120 in relation to repealed MDD 93/42/ EEC Annex II, excluding section 4 (2007/47)

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

BSI Conditions of Contract

The client's documented quality management system and associated documents and records

Scope of audit:

The scope of the audit is the documented management system processes, documents and records related to the certificate scope(s) and the location activities at the address(es) defined in the ‘assessed locations table’ towards the rear of this report.

The objective, criteria and scope were confirmed.

Certificate scope:

Please refer to the appendix for the location certificate scope(s) relevant to this audit, which may be a subset of the main certificate scope shown above.

The certificate scope(s) were confirmed.

CE 01455 (2797)

The design and manufacture of chemical disinfectants for use with invasive and non-invasive Medical Devices.

UKCA 781708 (0086)

Design, manufacture and final inspection of chemical disinfectants for use with invasive and non-invasive Medical Devices.

Audit plan and audit language(s):

The audit was performed in English.

There was no requirement for translation.

The audit plan was confirmed.

Required PPE/H&S considerations : Provided by client

Senior Management of the audit location:

ALLAN LOCK – Head of Technology and Projects

Management Representative (including contact details):

Richard Everett, QA & GMP Compliance Manager
E-mail: Richard.everett@lanxess.com
Tel: +44 7562 636140

Changes in the organisation:

There have not been any major or significant changes to the QMS, organisational structure, products or process, subcontractor/ supplier certification status, or locations from where finished product is shipped since the last audit.

Vigilance

There have been no adverse incidents, recalls, or requirement for field safety corrective actions or vigilance/mandatory problem reports since the last audit.

The client stated that there has been no engagement with any global regulatory bodies in respect of legal compliance or other issues since the last audit.

Device Registration

The client stated that they have NO Class I, IVD self-certified, Article 12 / 22 or custom made

devices.

The client stated that they have NO devices which require registration with the MHRA.

There has been no change to the EU Authorised Representative or UK Responsible Person since the last audit. The current details are: N/A

Manufacturing

There is no manufacturing at this location during this audit. It is not possible to witness any testing.

Quality Management System

There are no exclusions or non-applications documented.

Staffing and audit duration

Site Reference	Total Employees	Effective Employees	Justification
0009138360-002	8	8	None

The shifts are identical in terms of process outputs and as a result it has been determined that the effectiveness of all shifts can be seen from outputs and records within the normal assessment times. 8 hour 6am to 2pm shift and afternoon shift 10 hour Mon - Thursday 2pm to 12am

Critical Subcontractors / Suppliers

Critical Subcontractors

Name	Address	Role	Certificate(s)
Primepac Solutions Limited	36 Rassau Industrial Estate, Rasssau, Ebbw Vale, NP23 5SD United Kingdom	Packaging and Labeling	CE 01455 (2797) , UKCA 781708 (0086)

Crucial Suppliers

There are no Crucial Suppliers for certificate(s) in this audit

Summary of Subcontractors

Subcontractors relevant to these certificates were confirmed. Refer to Suitability of the agreement between the manufacturer and the subcontractor for further details.

Corporate identity of the organisation

PrimePac Solutions Ltd. are an Employee- Owned co- packers who were formed in the Summer of 2005 following the closure of the Budelpack Rhymney factory.

Description of the organisation

PrimePac Solutions LTd. offers packaging and labelling services to customers who require filling of a liquid / powder / gel etc.

PrimePac are acting as a critical subcontractor for Antec International Ltd where PrimePac are packaging and labeling Antec's PeraSafe powder into sachets on an automated packaging and labelling machine in a room purposed for Antec. There are warehouse facilities at the location and areas for other customers, including non-medical device and food products, which are out of scope of this location.

The audit team

Name	Position
Christian Alexander	Team Leader

Attendees

Name	Position	Inter-viewed	Opening Meeting	Closing Meeting
Caroline Spencer	Manufacturing Director	-	X	X
Glyn Jones	Technical Director	X	X	X
Rose Burridge	Quality Manager	X	X	X
Rianne Bundy	Quality Administrator	X	X	X
Chloe Horton	Purchasing Administrator	-	X	X
Hannah Pitts	Sales Administrator	-	X	X
Richard Everett	GMP & QA Compliance Manager	X	X	X

Processes Audited

Suitability of the agreement between the manufacturer and the subcontractor

ISO 13485:2016, 4.1.5

Description of the audited process or activity

Christian Alexander

The suitability of the quality agreement was assessed in the meeting room at the Primepac location in the presence of those listed below.

The Quality Agreement between Primepac Solutions Ltd and Antec International Ltd signed on 23 Jun 2023 was reviewed and used to complete BSI's internal CE subcontractor checklist. The scope of the agreement included the packaging and labelling of Antec's PeraSafe product to specifications provided with the agreement.

There was also a separate agreement between the two parties allowing BSI to perform an unannounced inspection of the Primepac facility in relation to PeraSafe.

A minor non-conformance was raised however as there were items missing from the quality agreement required by NBOG-BPG-2010-1 and BSI's internal CE subcontractor quality agreement checklist as follows:
- Procedures governing collaboration between the supplier and manufacturer in the case of incidents / mandatory notifications / recalls.
- Procedures for collaboration in case of complaints / post-market issues and corrective and/or preventive actions
- Obligations for the supplier to notify the manufacturer where there are changes to the status of the supplier certificates that affect the status of the device.
- Procedures by which changes to the device or activities; and manufacturing processes are initiated, released, implemented, documented and communicated between the legal manufacturer and the subcontractor.
- Provisions to allow access to information (i.e. technical documentation and records of the supplier), including the relevant competent authority if required.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Suitability of the agreement between the manufacturer and the subcontractor were found to be generally effective to meet the needs of the organisation but not fully compliant with the requirements of the audit criteria. 1 minor nonconformity was raised.

The following NCs were raised in this section

Reference	Standard	Clause	Category	Status
2414475-202311-N1	MDD 93/42/EEC	ANNEX II 3.2	Minor	Open

The following people were interviewed

Christian Alexander

Rose Burridge / Quality Manager
Rianne Bundy / Quality Administrator

The following documents and records were sampled

Christian Alexander

Labeling and Packing Agreement between Antec International Ltd. and Primepac Solutions Ltd effective on 01 Oct 2023

Implementation of the agreement at the subcontractors' facility

ISO 13485:2016, 4.1, 6.3, 6.4, 7.1, 7.5, 7.5.1, 7.5.10, 7.5.11, 7.5.2, 7.5.8, 7.5.9, 7.6

Description of the audited process or activity

Christian Alexander

The implementation of the quality agreement was assessed in the meeting room at the Primepac location in the presence of those listed below.

PeraSafe is manufactured by Antec at Sudbury and transported to PrimePac in bulk drums. The drums are received into Unit 33 and booked into the business system Sage 50. The drums are then transported to Unit 36 for production and initially stored in the warehouse section. During production, the bulk powder is fed into the Holler packaging and labelling machine which adds 16.2g of powder into a sachet and heat seals. During production, there are periodic weighing checks as specified by the quality agreement. There is an online printer that will print the variable information onto the sachet. The operators then manually add the sachets into a shipper carton and will be shipped back to Anetc at Sudbury.

There was no production at the time of the assessment. The area where the Antec product would be packaged and labelled was visited however the room was empty and the Holler machine was being used for another customer product at the time of the assessment. The warehousing section of the site was also visited. There are no specific environmental controls for PeraSafe except the requirement to store in a cool dry place. There are no special shipping requirements for PeraSafe when sending the sachets back to Antec.

Primepac has packaged and labelled two lots of PeraSafe being a test run, and a commercial batch destined for Korea. The Job Pack Master Records were reviewed and were seen to be complete and accurate and captured the quantity of sachets produced and were traceable to the bulk lot of PeraSafe used to fill the sachets. The records captured a copy of the sachet with the printed batch- specific artwork which corresponded to the packaging record.

Antec triggers a production run using a purchase order and the two purchase orders for the two batches were reviewed showing appropriate purchasing information.

The Master Packaging Specification specifies the cleaning procedure before and after each run. The completed cleaning documents were reviewed as part of the Job Pack Master Record. Procedures and policies relating to work environment and gowning were also reviewed where the packaging area of PeraSafe is in scope.

Pest control is outsourced to EcoLabs and the previous 3 pest controls reports were reviewed for the site.

There is an in-line balance on the Holler machine and a separate balance for periodic weighing checks. The calibration certificates were reviewed to ensure the balances were in a state of calibration.

The monthly maintenance records covering the time the two batches were manufactured were reviewed showing the equipment had been maintained appropriately.

The training records for staff working on the PeraSafe project were reviewed showing they were trained to operate the Holler machine.

The organization had documented a procedure with high- level manufacturing requirements for the Perasafe product, based on the product specification document provided with the quality agreement.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Implementation of the agreement at the subcontractors' facility were found to be effective to meet the needs of the organisation and compliant with the requirements of the audit criteria.

The following people were interviewed

Christian Alexander

Glyn Jones / Technical Director
Rose Burridge / Quality Manager
Rianne Bundy / Quality Administrator
Richard Everett / GMP & QA Compliance Manager

The following documents and records were sampled

Christian Alexander

BUY-4-12 (Lanxess: Perasafe 16.2g Sachets Supplier Specification Agreement) version 7 issued on Jul 2022
F006/2 (Mater Packaging Specification for 7787/1) version 1 approved on 02 Mar 2023
Job Pack Master Record for PeraSafe Sachet 16.95g Batch 2301BH0000, Works Order 5467, MPS 7787/1 manufactured on 29 Mar 2023 – 23,962 units
Calibration Certificate for Balance CS1401A242 by Mettler Toledo on 27 Jan 2023 and due on 31 Jan 2024 (Cert. No.: UK0208-013-012723-ACC)
Purchase Order: 312318693 raised on 23 Nov 2022 for a Test Run of PeraSafe Sachets
Rely+On PeraSafe Shipper Label 57782610/Psafe/500x16.2g/UK/27.07.20/Z
Job Pack Master Record for Perasafe Korea Sachet 16.96g Batch 2308BH0000 and 2308BH0001, Works Order5608, MPS 7852/1 manufactured on 31 Aug 2023 – 51,640 unit
Calibration Certificate for Balance B543605241 by Mettler Toledo on 27 Jan 2023 and due on 31 Jan 2024 (Cert. No.: UK0208-006-012723-ACC)
Number 10 (Primepac Solutions – Cleaning Procedure – Dry Powders) dated 05 Sep 2023
Purchase Order: 312356159 raised on 22 Jun 2023 for PeraSafe Korea 500x16.2GR CTN
PRC050 (PrimePac Solutions Gowning Illustration) version 1 issued on Apr 2023
Workwear and hygiene Policy version 2 issued on 28 Sep 2023
PRC006 (General Health and Reporting of Illness) version 2 issued on 28 Jul 2023
Hygiene Policy version 2 issued on 28 Sep 2023
Jewellary / Make Up Policy issued on 12 Oct 2019
PRC029 Food Safety Manual (Site Plan Pest Control) version 1 issued on 26 Oct 2023
EcoLabs Customer Service Report 730408/3835303 dated 27 Feb 2023

EcoLabs Customer Service Report 589413/3820180 dated 14 Feb 2023
EcoLabs Customer Service Report 730408/3799007 dated 31 Jan 2023
F052 (Supplement Montly Inspection Checklist) version 1 dated 26 Oct 2023
Monthly Maintenance Plan for Holler (Machine 2) dated 24 Mar 2023
Monthly Maintenance Plan for Holler (Machine 2) dated 28 Aug 223
Monthly Maintenance Plan for Holler (Machine 2) dated 31 Mar 2023
Monthly Maintenance Plan for Holler (Machine 2) dated 01 Sep 2023
Training Record for CB dated 21 Nov 2022 (Includes training on Hoeller packaging machines)
Training Record for JC dated 02 Nov 2023 (Includes training on Hoeller packaging machines)
Training Record for JC dated 02 Nov 2022 (Includes training on Hoeller packaging machines)
Training Record for GC dated 02 Nov 2022 (Packer only)
Training Record for GC dated 03 Nov 2023 (Packer only)
Training Record for AP dated 02 Nov 2022 (Includes training on Hoeller packaging machines)
Training Record for AP dated 3 Nov 2022 (Includes training on Hoeller packaging machines)
PRC052 (Procedure for the completion of Quality Control Checks on Medical Devices) version 1 issued on 02 Nov 2023
QC-3-239 (Sampling and Testing Regime for Perasafe intended for 16.2g Sachets Percarbonate (PCS)) issued Sep 202

Minor (1) nonconformities arising from this audit

Finding Reference	**2414475-202311-N1**	**Certificate Reference**	**CE 01455**
Certificate Standard	**MDD 93/42/EEC ISO 13485:2016**	**Clause**	**ANNEX II 3.2 4.1.5**
Location Reference	0009138360-002		
System NC	No		
Authorised to close	QMS Auditor		
Remote closeout	No		
Category	Minor		
Area/process	Suitability of the agreement between the manufacturer and the subcontractor		
Details	The process for controlling the critical subcontractor is not fully effective as there were items missing from the quality agreement required by NBOG-BPG-2010-1 and BSI's internal CE subcontractor quality agreement checklist as follows: - Procedures governing collaboration between the supplier and manufacturer in the case of incidents / mandatory notifications / recalls. - Procedures for collaboration in case of complaints / post-market issues and corrective and/or preventive actions - Obligations for the supplier to notify the manufacturer where there are changes to the status of the supplier certificates that affect the status of the device. - Procedures by which changes to the device or activities; and manufacturing processes are initiated, released, implemented, documented and communicated between the legal manufacturer and the subcontractor. - Provisions to allow access to information (i.e. technical documentation and records of the supplier), including the relevant competent authority if required.		
Clause requirements	**ANNEX II 3.2** Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly		

	manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c). It shall include in particular an adequate description of: (a) the manufacturers quality objectives; (b) the organization of the business and in particular: the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned, the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform, where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party; (c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular: a general description of the product, including any variants planned, and its intended use(s), the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full, the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed, if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer, a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device, a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC (1), the solutions adopted as referred to in Annex I, Chapter I, Section 2, the pre-clinical

	evaluation, the clinical evaluation referred to in Annex X, the draft label and, where appropriate, instructions for use. (d) the inspection and quality assurance techniques at the manufacturing stage and in particular: the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents, the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture; (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately. **4.1.5** When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.
Objective Evidence	Labeling and Packing Agreement between Antec International Ltd. and Primepac Solutions Ltd effective on 01 Oct 2023 and signed on 23 Jun 2023
Status	Open

Next visit plan

There is no next visit plan required following this audit.

Appendix: Your certification structure & ongoing audit programme

Scope of certification

CE 01455 (2797)

The design and manufacture of chemical disinfectants for use with invasive and non-invasive Medical Devices.
Accreditation:
Certificate scheme: MDR 2017/745 Article 120 in relation to repealed MDD 93/42/EEC Annex II, excluding section 4 (2007/47)
Scheme manager: Senthilkumar Thirumal

UKCA 781708 (0086)

Design, manufacture and final inspection of chemical disinfectants for use with invasive and non-invasive Medical Devices.
Accreditation:
Certificate scheme: Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]
Scheme manager: Senthilkumar Thirumal

Audited location(s)

CE 01455 (MDD 93/42/EEC) (2797)

Location reference	0009138360-002
Address	Primepac Solutions Limited 36 Rassau Industrial Estate Rasssau Ebbw Vale NP23 5SD United Kingdom
Visit type	Verification Audit
Assessment reference	3969379
Assessment dates	15-Nov-2023
Audit plan (revision date)	01-Nov-2023
Deviation from audit plan	No
Total number of Employees	8

Effective number of Employees	8
Scope of activities at the site	Main certificate scope applies
Audit duration	0.5 day(s)

UKCA 781708 (UK MDR 2002) (0086)

Location reference	0009138360-002
Address	Primepac Solutions Limited 36 Rassau Industrial Estate Rasssau Ebbw Vale NP23 5SD United Kingdom
Visit type	Verification Audit
Assessment reference	3969420
Assessment dates	15-Nov-2023
Audit plan (revision date)	01-Nov-2023
Deviation from audit plan	No
Total number of Employees	8
Effective number of Employees	8
Scope of activities at the site	Main certificate scope applies
Audit duration	0.5 day(s)

Certification assessment programme

		SubCon Ver
Business Area / Location	**Date (mm/yy)**	**11/23**
	Duration (days)	1
Subcontractor Verification Assessment		X
Review and Implementation of the Quality Agreement at the subcontractors location		X

Justified exclusions / non applicable clauses

CE 01455 (2797)

Not applicable for this certificate.

UKCA 781708 (0086)

Not applicable for this certificate.

Definitions of findings

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

'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 (43203216/CE 01455).

Should you wish to speak with BSI in relation to your certification, please contact your local BSI office – contact details available from the BSI website:

https://www.bsigroup.com/en-GB/contact-us/

https://www.bsigroup.com/en-GB/global-contact-details/

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 MedDevComplianceandRisk@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 MedDevComplianceandRisk@bsigroup.com . Please provide the audit report reference number or date of the audit and the details of your complaint.

Notes

This report and related documents are 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. If you wish to distribute copies of this report external to your organization, then all pages must be included.

BSI, its staff and agents shall keep confidential all information relating to your organization 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.

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.