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Second Party Audit

Report for:

Med-I-Pant (UK) Limited

LR reference:	LRQ4009263 / 601908
Assessment dates:	25-October-2017
Reporting date:	25-October-2017
Client address:	Billington Road, Leighton Buzzard, LU7 4AJ
Assessment criteria:	LSAS
Assessment team:	Hamlyn, Coellie
LR Client Facing Office:	LRQ United Kingdom OU

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Attachments:

LRQ4009263_APP_1017_NHS_LSAS_L4.doc

This report was presented to and accepted by:

Name: Yannick Miclo

Job title: Director of Global Sourcing

01. Executive report

Assessment outcome:

This visit was to assess the compliance of the management system of Med-I-Pant (UK) Limited against LSAS as defined in the audit planning documentation. The outcome of the visit is recorded below.

The purpose of the visit was to assess Med-I-Pant (UK) Limited's compliance with the requirements of the NHS LSAS Supply Chain Level 4.

The outcome of the day demonstrated that the client has made significant improvements throughout the last year and so approval to NHS LSAS Level 4 - Progressive, is recommended.

This report is subject to a Technical Review by LRQA and upon that decision being made, Med-I-Pant (UK) Limited will be informed, for them in turn to inform the NHS Supply Chain.

The Assessment Team Leader confirms the contractual arrangements for LSAS are correct. This includes any changes required as a result of the outcome of the Stage 1 visit (including changes to the scope of assessment, duration of the Stage 2 visit, and duration of subsequent surveillance visits).

Continual improvement:

The company continue to demonstrate their commitment to continuous improvement. This was demonstrated in many ways, below a few are listed:

- the appointment of Continuous Improvement manager to review their suppliers manufacturing techniques amongst other things;
- CSR escalation issue report has been developed;
- implementation of the NATLEX legislation update system;
- supply chain map listing country compliance with specific standards
- increasing audit requirement threshold from vendors with >5% of MIP Global Purchase to CAD\$1000,000



Areas for senior management attention:

At this visit no observations of non-conformances were noted. The delivery of the NHS LSAS across the company is a team effort, with clear leadership and ownership of the issues by the Board, Strategic Team and Senior Management Team.



02. Assessment findings

Where scheme requirement differs to the standard definition below, the scheme definition will take preference

Major Nonconformity

The absence of, or the failure to implement and maintain, one or more management system elements, or a situation which would, on the basis of the available objective evidence, raise significant doubt of the management to achieve: The policy, objectives or public commitments of the organisation, compliance with the applicable regulatory requirements, conformance to applicable customer requirements, conformance with the audit criteria deliverables.

Minor Nonconformity

A finding indicative of a weakness in the implemented and maintained system, which has not significantly impacted on the capability of the management system or put at risk the system deliverables, but needs to be addressed to assure the future capability of the system.

Reference number	Assessment Criteria (Clause)	
Grade	Issue Date	
Status	Process / Aspect	
Location(s)		
Statement of Non Conformity		
Requirement		
Evidence		
Proposed correction, corrective action and timescales		
Correction		
Root Cause analysis		
Corrective action		
LR has reviewed and verified the implementation of actions taken.	Date of closure	

03. Assessment summary

Visit generic objective:

This was a Second Party Audit visit, conducted against objectives previously notified to the client. The objectives of the next visit, including any applicable visit specific objective (theme / focus), are confirmed in the audit plan attached to this report.

Client attendees at the opening and closing meeting:

The opening meeting was held with Yannick Miclo, Director of Global Sourcing and Adam Cunningham, Procurement and Logistics Manager UK. The plan and reporting methodology for the day was discussed.

At the closing meeting the client was thanked for their guidance and hospitality throughout the day and the findings of the report discussed. The date for the next visit was agreed for 24th October 2018.

Visit specific objective:

Introduction:

Since the last visit the company have bought another company called Cromptons based in Basingstoke, who work in the same industry. Cromptons' products include one time use patient specific products, slings, slide sheets etc and they are already approved for NHS LSAS Level 2 with SGS and their main customers are NHS Supply Chain and Synergy. The Cromptons' brand will cease to exist in March 2018 and become part of Med-I-Pant (UK) Limited. This will make the company the largest in the UK in their field. There a couple of redundancies, as staff do not wish to locate, but other staff will come across to Leighton Buzzard.

The company are in the process of corporate re-organisation across the whole group. An organisation chart was seen for the Strategic Team, showing two senior positions have been identified for Senior VP Supply Chain, Eric Turcotte and Senior VP Sales and Marketing, Francois Pilon. Aviyam Friedman's role has now changed to be Executive Vice President of Change and Innovation. The company have hired a member of staff to drive continuous improvement, starting in their suppliers' factories. The addition of new expertise has not led to any job losses. The Senior Management Team organogram has also been revised showing the reporting lines.

The Supply Chain organogram is headed by Tor Lund President and CEO, Eric Turcott Senior VP Supply Chain with direct reports Yannick Miclo, Director of Global Sourcing and Yvan Chabot - Vice President Manufacturing. Chris Goodchild - Regional Sourcing Director UK (who has joined from Cromptons) and Adam Cunnigham Procurement and Logistics Manager UK report into Yannick Miclo.

Med-I-Pant (UK) Limited will remain in Leighton Buzzard but the office will expand to incorporate the additional staff coming across. In addition they will take more space at another warehouse (owned by their landlord Mini-clipper) in Houghton Regis.

The company have updated their IT particularly for finance migrating their data from Sage to Microsoft Great plains. The company are also in the process of moving towards ISO9001:2015 with QMS. Supply Chain England and NHS Scotland are the company's main clients.



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Going forward it was agreed that the company need to change their LSAS scope to include the new products made by Cromptons as currently they reflect the Frameworks they are already assessed against.



Assessment of: NHS LSAS Level 4	Auditee(s): Yannick Miclo Adam Cunningham	Assessor: Hamlyn, Coellie
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Audit trails and sources of evidence:

Work Instruction - Corporate Social Responsibility Doc MIP-WI7.4.1-E revision 13/10/17
This covers documentation, objectives, responsibilities in terms of intent and instruction.

Evaluation and conclusions:

Refer to NHS LSAS Matrix for further detail.

Areas for attention:

Refer to NHS LSAS Matrix for further detail.



04. Next visit details

Standard(s) / Scheme(s)	LSAS	Visit type	Second Party Audit		
Activity codes	090814	Audit days	1.00	Visit start / end dates	24-October-2018 / 24-October-2018
Team	Coellie Hamlyn				
Site					Audit days
Billington Road,Leighton Buzzard					1.00



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05. Appendix

1. Audit Programme/Plan

Both the audit plan and the programme are dynamic and must be in line with the client's developments. Any (last minute) changes are possible with valid reasons e.g. organisational changes, processes, management review results etc. Prior to the closing meeting the audit team should (re)confirm the programme and identify any changes, e.g. to the management system, extent, time or dates of the audit, competences ...

Visit Type	Gap	Level 2 implementation	Level 2 review	Level 3 implementation	Level 3 review	Level 4 implementation	Level 4 review	
Due Date	21/05/15	19/08/15		Aug 2016		Oct 2017	Oct 2018	
Start Date	21/05/15	19/08/15		20/10/16		25/10/17	24/10/18	
End Date	21/05/15	19/08/15		20/10/16		25/10/17	24/10/18	
Audit Days	1	1		1		1	1	
Separate assessment plan?	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
Any change in workforce numbers that may impact visit duration (if yes add new number)	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
Where identified above see separate current assessment plan for further detail.								
Process / aspect / theme / location								
<i>Final selection will be determined after review of management elements and actual performance</i>								
Opening meeting	✓	✓	✓	✓	✓	✓	✓	✓
Closing meeting	✓	✓	✓	✓	✓	✓	✓	✓
Gap Analysis NHS LSAS Level 2	✓							
Level 2 Assessment Confirmation of implementation		✓						
Level 2 review of implementation								
Level 3 Assessment Confirmation of implementation				✓				
Level 3 review of implementation								
Level 4 Assessment Confirmation of implementation						✓	✓	

- 1: Complete the list of organisation (parts), departments and/or processes of the different locations
 2: Required for Annex SL based Standards
 3: Not required for Annex SL based Standards

Scope

Any revised scope will be as agreed in formal correspondence between LRQA and the client or defined in section 4 of the previous LRQA visit report.

Scope	LSAS Level 3 assessment, supply of textiles to the NHS.
Exclusion	Anything supplied outside of MIP UK Ltd's contract with the NHS.

Visit start time (approximate)	09:30	Visit end time (approximate)	15:00
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The actual start and finish times for the visit will be agreed at the pre-visit contact with the assessor and recorded in the report introduction.

Additional information

Opportunities for improvement

If we identify opportunities to improve your already compliant system, we will either record them in the process table applicable to the area being assessed or in the Executive summary of the report if they can deliver improvement at a strategic level.

Confidentiality

We will treat the contents of this report, together with any notes made during the visit, in the strictest confidence and will not disclose them to any third party without written client consent, except as required by the accreditation authorities.

Sampling

The assessment process relies on taking a sample of the activities of the business. This is not statistically based but uses representative examples. Not all of the detailed nature of a business may be sampled so, if no issues are raised in a particular process, it does not necessarily mean that there are no issues, and if issues are raised, it does not necessarily mean that these are the only issues.

Legal entity

The accredited legal entity and client facing office that has provided the assessment service in this report is referenced in the applicable agreement for this service.

Generic audit objectives and team responsibilities

The generic audit objectives and team responsibilities are included in the Client Information Note 'Assessment Process'. Any visit specific objectives for the next visit will be recorded in the report of the previous visit and will be addressed through the visit plan for that visit. The assessment standard and roles of the audit team are defined in the assessment visit confirmation sent to the client.

Audit Criteria

The audit criteria consist of the assessment standard and the client's management system processes and documentation.

Additional observers

Any additional observers will be as formally communicated to the client.

2. Separate Assessment Plan

Note: if the visit involves more than one team member and/or is more than one day duration, an additional plan detailing the activities of each member of the team on each day will be required.

(Date Day 1) Not Required for LSAS

Introductory meeting with management to explain the scope of the visit, assessment methodology, method of reporting and to discuss the company's organisation (approximately 30 minutes). The Team Leader will agree a time to meet with top management to discuss policy and objectives for the management system.

LRQA team briefing for a team of two or more assessors or (experts).

<Name> (Team Leader)

<Name>

Discussion of all outstanding issues from previous visits.

Lunch.

Lunch.

Report writing.

Report writing.

Close.

Close.

(Date Day 2)

Review of findings from previous day. Review of the assessment plan for the day.

Lunch

Lunch

Report writing.

Report writing.

Close

Close

(Date Day 3)

Review of findings from previous day. Review of the assessment plan for the day.

Lunch

Lunch

Review of day's findings

Review of day's findings

Preparation of final report

Preparation of final report

Closing meeting with management to present a summary of findings and recommendations.

3. Report Considerations

LRQA Report considerations		
Have there been any deviation from the original assessment plan:	No	If yes detail these in the introduction section of the report along with the reasons for the deviations
Have there been any significant issues impacting on the audit programme:	No	If yes detail these in the introduction of the report and amend the APP
Have there been any significant changes that affect the management system of the client since the last audit took place:	No	If yes detail these within the executive summary section of the report
Have any unresolved issues been identified during the assessment:	No	If yes detail these within the executive summary section of the report
Was the audit undertaken a combined or integrated audit:	No	If yes confirm what type of audit and the standards covered in the introduction to the report.
Was the organisation effectively controlling the use of the certification documents and marks:	No – N/A	If no document within the reporting table covering the mandatory elements
If applicable has the organisation taken effective corrective action regarding previously identified nonconformities:,	Yes	Record outcome in the findings log against the relevant findings.
Does the management system of the organisation continue to meet the applicable requirements and meet the expected outcomes:	Yes	If no details reasons within the executive summary of the report
Does the scope of certification continue to be appropriate to the activities/products/services of organisation:	Yes	If no then document the actions necessary in relation to the scope in the executive summary of the report and amend the APP as required.
Were the objectives of the visit as defined in the APP fulfilled during the visit:	Yes	If no detail the reasons and any necessary actions in the executive summary of the report and amend/update the APP