





INDEXPO CERTIFICATION LIMITED

INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME STAGE II AUDIT REPORT – ISO 9001:2015

1. NAME OF ORGANIZATION : New Kuvenitex (Pvt) Ltd
2. ADDRESS OF HEAD OFFICE : Matugama Industrial Estate , Ritiketiya, 5 th Mile Post, Meegama, Darga Town
3. ASSESSMENT SITE/S : Same as 2
4. CONTACT DETAILS :
4.1 Name : Mr. Raja Kulasekera Designation : Managing Director
4.2 Tel : 03422727920 Mobile : 0773083435 Fax : 0342279293
4.3 E-mail : newkuvenitex@gmail.com
5. NO. OF EMPLOYEES : 14
6. APPLICABLE STANDARD : ISO 9001:2015
7. FILE NO. : IMSC-QMS-060
8. NACE CODE / SUBCATEGORY : 21.2 (Manufacture of pharmaceutical preparations)
9. SCOPE OF CERTIFICATION : Activities pertaining to manufacturing of surgical gauze, gauze bandage and crepe bandage
10. CONFIRMATION FOR SCOPE OF CERTIFICATION : The scope is confirmed. NEW KUVENI TEX (PVT) LTD.
Signature <i>[Handwritten Signature]</i> Director Director
11. DATE OF AUDIT & Time : 2019/11/05
12. TYPE OF AUDIT : Stage II
13. AUDIT TEAM :
Mr. D N S Kuruppumullage Team Leader
Mr. Aruna Amaradasa Auditor
Mr. Mohamed Asif Observer

DOC. NO.: QP-06-F-04

Reviewed and approved by : Director

ISSUE NO. : 07 ISSUE DATE : 2016-09-15

Rev No: 01 Rev Date: 2018-04-10

Issued by : Management Representative



IND-EXPO CERTIFICATION LIMITED

INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME

STAGE II AUDIT REPORT

ISO 9001:2015

New Kuvenitex (Pvt) Ltd

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015****14. AUDIT OBJECTIVES:**

The objectives of this audit were:

- to confirm that the management system conforms with all the requirements of the audit standard;
- to confirm that the organization has effectively implemented the planned management system;
- to confirm that the management system is capable of achieving the organization's policy and objectives on quality management

15. ANY DEVIATIONS FROM THE AUDIT PLAN AND REASONS:None

16. ANY SIGNIFICANT ISSUES IMPACTING ON THE AUDIT PROGRAMME:None

17. AUDIT FINDINGS :**17.1 CONTEXT OF THE ORGANIZATION (4 of ISO 9001:2015):****Understanding the organization and its context (4.1 of ISO 9001:2015) :**

Organization has determined the external and internal issues that are relevant to purpose and strategic direction to achieve the expected results from the quality management system. The organization is also having a mechanism to monitor and review those issues.

Understanding the needs and expectations of interested parties(4.2 of ISO 9001:2015):

Organization has identified interested parties that can affect the quality management system. The requirements of these interested parties have been determined by the organization. Organization has a system of monitoring and reviewing information of those interested parties.

Determining the scope of the quality management system(4.3 of ISO 9001:2015):

Organization has determined its scope based on the external and internal issues, the requirement of the interested parties, the product and services offered as well as the requirements of the ISO 9001:2015 standard.

Quality management system and its processes (4.4 of ISO 9001:2015):

Organization has established, implemented and maintained the quality management system including the processes needed and its interaction. Organization has applied all the processes required throughout the organization with required input and expected output. The organization also has established required monitoring and measurement mechanism and assigned responsibilities and authorities for each requirement.

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015**

1. NAME OF ORGANIZATION : New Kuvenitex (Pvt) Ltd	
1. 2. ADDRESS OF HEAD OFFICE : Matugama Industrial Estate , Ritiketiya, 5 th Mile Post, Meegama, Darga Town	
3. ASSESSMENT SITE/S : Same as 2	
4. CONTACT DETAILS :	
4.1 Name : Mr. Raja Kulasekera	Designation : Managing Director
4.2 Tel : 03422722920	Mobile : 0773083485 Fax : 0342279293
4.3 E-mail : newkuvenitex@gmail.com	
5. NO. OF EMPLOYEES : 14	
6. APPLICABLE STANDARD : ISO 9001:2015	
7. FILE NO. : IMSC-QMS-060	
8. NACE CODE / SUBCATEGORY : 21.2 (Manufacture of pharmaceutical preparations)	
9. SCOPE OF CERTIFICATION : Activities pertaining to manufacturing of surgical gauze, gauze bandage and crepe bandage	
10. CONFIRMATION FOR SCOPE OF CERTIFICATION : The scope is confirmed.	
.....	
Signature	
11. DATE OF AUDIT & Time : 2019/11/05	
12. TYPE OF AUDIT : Stage II	
13. AUDIT TEAM :	
Mr. D N S Kuruppumullage	Team Leader
Mr. Aruna Amaradasa	Auditor
Mr. Mohamed Asif	Observer

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015****Resources (7.1 of ISO 9001:2015):****General (7.1.1 of ISO 9001:2015):**

Organization has provided required resources for establish, implement, maintain and continually improve the quality management system by considering capabilities and constrains of existing recourses.

People (7.1.2 of ISO 9001:2015):

Organization also has provided personnel required to effectively implement the QMS and the activities related to QMS.

Infrastructure (7.1.3 of ISO 9001:2015):

Company has provided buildings, space for its intended operation with required utilities such as electricity, water, and information and communication technology.

Environment for the operation of processes (7.1.4 of ISO 9001:2015):

Company has provided necessary environment operation intern of both physical and human requirement. Company has provided adequate ventilation and light for the operation. Company also complies with the sanitary requirements for staff and the visitors. General cleanliness of the environment also has been ensured. Similarly, internal audit finding was implemented as a result of higher level of sound in production area for minimizing purpose give ear plugs for workers and provide suitable environment to work.

Monitoring and measuring resources (7.1.5 of ISO 9001:2015):

The equipment used for measurement of processes and products has verified and calibrated.

Organizational knowledge (7.1.6 of ISO 9001:2015):

Available organizational knowledge is sufficient to provide the expected service. Opportunities are given to the staff to acquire required organizational knowledge through experience, failures and successes and also knowledge gained from experiences acquired from education, training and customers.

Competence(7.2 of ISO 9001:2015):

Training need identification and effectiveness of training given have been evaluated.

Awareness (7.3 of ISO 9001:2015):

The organization given awareness to all the staff members on quality policy and objectives.

Communication (7.4 of ISO 9001:2015):

The company has identified and planned internal and external communication relevant to QMS.

Documented information(7.5 of ISO 9001:2008):

Company has identified documented information required by the standard and documents required to be apply for effectiveness of QMS. Company has established a documented information control system

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015****17.2 LEADERSHIP(5 of ISO 9001:2015):****Leadership and commitment (5.1 of ISO 9001:2015):**

The top management has demonstrated the leadership and commitment with respect to quality management system and was aware about their responsibilities to maintain a effective quality system as per the quality policy and quality objective established compatible with company context and the strategic direction of the company.

They also committed to promote risk based thinking throughout the organization and has taken steps to adequately provide recourses required and interested in achieving business objectives with continual improvement of established quality objectives. Director whom we have interviewed during the audit express the necessity of meeting the applicable statutory and regulatory requirements and customer satisfaction.

Policy(5.2 of ISO 9001:2015):

Company has established, implemented and maintained a quality policy that can prove satisfactory application of applicable requirements and achievement of continual improvement.

Organizational roles, responsibilities and authorities (5.3 of ISO 9001:2015):

Top management has delegated responsibility and authority for relevant personals and it is communicated with in the organization. Company has also assign responsibility and authority with regard to requirements of the standard ensuring that the processes are delivering there expected outputs, reporting on performance of the quality management system back to the management including opportunities for improvement.

Managing Director, working director and Marketing Executive are responsible for implementation of quality management system requirement. However, non of their responsibilities indicate requirement to report the performance of QMS and opportunity for improve ment for review. (NCR-01)

17.3 PLANNING(6 of ISO 9001:2015):**Actions to address risks and opportunities(6.1 of ISO 9001:2015):**

Company has determine the risk and opportunities that are arising during the planning of quality management system.

Quality objectives and planning to achieve them (6.2 of ISO 9001:2015):

Quality objectives have been identified

Planning of changes (6.3 of ISO 9001:2015):

Organization has a mechanism to determine the changes required to quality management system and carryout the same by planning, while considering the need for change and its expected results while ensuring the integrity of QMS.

17.4 SUPPORT(7 of ISO 9001:2015):

DOC. NO.: QP-06-F-04

ISSUE NO. : 07 ISSUE DATE : 2016-09-15

Rev No: 01 Rev Date: 2018-04-10

Reviewed and approved by : Director

Issued by : Management Representative

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015****Information for external providers (8.4.3 of ISO 9001:2015):**

Company has mechanism to design the requirements including the quality and level of controls including communication channels and it is being conveyed to the company when the services are obtained. Bleaching process has been outsourced by the company. However, there is no agreement with service provider. (NCR – 02)

Production and service provision (8.5 of ISO 9001:2015):**Control of production and service provision(8.5.1 of ISO 9001:2015):**

Production and service provision is carried out under controlled conditions.

Identification and traceability (8.5.2 of ISO 9001:2015):

Company has a mechanism to identify the output whenever it is required to measure and monitor the conformity to the required specification. The deficient activities during the production process can be trace back through the batch code given in final packages to take necessary corrections and corrective actions.

Property belonging to customers or external providers (8.5.3 of ISO 9001:2015):

Any item that is brought from outside by the customer will be recorded, preserve (if required) and kept with required identification and traceability until it is being used and handed over to the customer after completion of the function.

Preservation (8.5.4 of ISO 9001:2015):

Company has storing and preservation system of products until it is dispatch to the customer. Identification and prevention of contamination, packing as per the customer requirements and storage and transportation is carried out as per the customer requirements ensuring the product quality. By contrasting, preservation of product is not adequate to ensure the cleanliness and contamination. Ex: Opening of the stores to external environment. (NCR – 03)

Post-delivery activities (8.5.5 of ISO 9001:2015):

Any post-delivery activities requested by the customer is handles as per the contractual obligation, regulatory and statutory requirements, etc. any customer feed backs whether it is positive or negative will be recorded and appropriate corrective action is taken for improvements.

Control of changes (8.5.6 of ISO 9001:2015):

When changes required for production and services, company has reviewed requirement of the same and documented information has been retained under controlled condition.

Release of products and services (8.6 of ISO 9001:2015):

The company has a mechanism to release its products as per the customer request and in accordance with the agreement with the customer.

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015**

for both documents and records. Including distribution, retrieval, storage and preservation, control of changes, retention and disposition. All external documents required has been identified and controlled.

17.5 OPERATION (8 of ISO 9001:2015):**Operational planning and control (8.1 of ISO 9001:2015):**

Company has planned, implemented and controlled the processes required to control the service and product provision. Company has established relevant criteria for the processes and the acceptance of service and products. As well as organization has controlled planned changes and it has noticed they have been reviewed the consequences of unintended changes and actions has taken to mitigate the same.

Requirements for products and services (8.2 of ISO 9001:2015):**Customer communication(8.2.1 of ISO 9001:2015):**

Company has been adequately addressed customer communication as it is important to their activities. Company provides information to their customers regarding to their products. Customer complain register was maintained.

Determining the requirements for products and services (8.2.2 of ISO 9001:2015):

Company has considered about statutory and regulatory requirements when defining the requirements for product and services.

Review of the requirements for products and services (8.2.3 of ISO 9001:2015):

The customer's requirement has confirmed by the company before acceptance of the customer order and conducts review prior to committed supply product to customers.

Changes to requirements for products and services (8.2.4 of ISO 9001:2015):

Organization is having a mechanism to collect documented information that has been intimate by the client for any changes required and communicate the same to the relevant personnel responsible for operation.

Design and development of products and services (8.3 of ISO 9001:2015):

Company has being developing new products with their product development team and get the approval from the team of experts prior to launch the products.

Control of externally provided processes, products and services (8.4 of ISO 9001:2015):**General (8.4.1 of ISO 9001:2015):**

Company purchases materials for registered suppliers Evaluation of supplies and communication of any requirements of the company to suppliers is been done as per the purchasing procedure. Only one supplier is available for yarn purchase.

Type and extent of control (8.4.2 of ISO 9001:2015):

Externally provided processes are included in the quality management system and appropriate control have been implemented for both services provided and for intended output.

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015**

protective equipments are replaced newly and maintained

Continual improvement (10.3 of ISO 9001:2015):

Company is committed to continually improve the effectiveness of the management system through the use of quality policy, quality objectives, audit results, analysis of data, management review, and corrective implementation.

18. APPLICABLE LEGAL REQUIREMENTS:

Company has obligations to comply with both the shop and office act and the factory ordinance. In addition company comply with other labour laws applicable such as EPF, ETF and Gratuity act., National medicines Regulations...etc

19. ANY UNRESOLVED ISSUES: None

20. OVERALL CONCLUSION OF THE AUDIT:

Audit is based on a sampling process of the available information at the point of auditing and the audit methods used were interviews, observation of activities and review of documentation and records. With consideration to the findings identified on the report the overall conclusions of the audit are as follow:

- The management system documentation demonstrated conformity with the Requirements of the audit standard and provided sufficient structure to support implementation and maintenance of the management system. YES NO
- The organization has demonstrated effective implementation and maintenance /improvement of its management system. YES NO
- The organization has demonstrated the establishment and tracking of Appropriate key performance objectives and targets and monitored progress towards their achievement. YES NO
- The internal audit program has been fully implemented and demonstrates Effectiveness as a tool for maintaining and improving the management system. YES NO
- The management review process demonstrated capability to ensure the Continuity, suitability, adequacy and effectiveness of the management system. YES NO
- Throughout the audit process, the management system demonstrated overall conformance with the requirements of the audit standard. YES NO

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015****Control of nonconforming outputs (8.7 of ISO 9001:2015):**

When company has detected any product which do not conform the requirements of customer it is identified and if possible appropriate correction will be carried out prior to release of the products. If the product can not be corrected it will be segregated from the good product and prevented reaching the customers. Any delays on delivery of products will be informed to the customer and necessary concurrence will be taken if required including acceptance under the concessions.

17.6 PERFORMANCE EVALUATION (9 of ISO 9001:2015):**Monitoring, measurement, analysis and evaluation (9.1 of ISO 9001:2015):****General (9.1.1 of ISO 9001:2015):**

Company has determined what needs to be monitored and measured, the methods for monitoring, measurement, analysis.

Customer satisfaction (9.1.2 of ISO 9001:2015):

Customer survey, customer feedback and meeting with customer have been identified as essential requirements for the evaluation of customer satisfaction. Non of customer complaints were received at the time of audit.

Analysis and evaluation (9.1.3 of ISO 9001:2015):

Organization has implemented a process to analyse and evaluate the data and evaluation obtains from monitoring and measurement activities. Such as customer complain, customer satisfaction, performance of external providers, risk analysis.

Internal audit (9.2 of ISO 9001:2015):

Internal audit has been conducted as per the requirements defined in the procedures. During the Internal audit two NCRs found, higher sounds of machines is not suitable for provide good environment for workers and the fire protective equipments are expired.

Management review (9.3 of ISO 9001:2015):

Management review has been conducted as per the requirements defined in the procedures. Internal audit results were not specifically discussed under MR. (OB-01)

17.7 IMPROVEMENT (10 of ISO 9001:2015):**General (10.1 of ISO 9001:2015):**

Company has determined and selected opportunities for improvement and implemented necessary actions to meet customer requirements and to increase customer satisfaction.

Nonconformity and corrective action (10.2 of ISO 9001:2015):

Company has taken necessary actions to addressed nonconformities and corrective actions have been implemented for such nonconformities. Company has retained documented information as evidence of the nature of the NC and any subsequent action taken and results of corrective action taken. Although company has addressed customer complaint after discussing at production meeting. Corrective actions taken for internal audit findings. As ear plugs are wear by workers during the production and fire



INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015

- This page is for internal purposes only.

24. RECOMMENDATION BY AUDIT TEAM :

Recommended for certification subjected to submission of evidence for corrective action and time period for submission of evidence will be given two months from the date of Stage 2 audit.

..... Signature of Team Leader2019-11-05..... Date
..... Signature of Team Member -12019-11-05..... Date
..... Signature of Team Member - 2 Date

25. RECOMMENDATION BY CERTIFICATION MANAGER:

All NCRs are closed, & recommended for certification.

..... Signature of Certification Manager <i>2019-11-21</i> Date
---	---------------------------------------

26. APPROVAL FOR SUBMISSION TO THE CERTIFICATION COMMITTEE:

<i>Approved</i> Signature of Director <i>2019-11-21</i> Date
---	---------------------------------------

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 9001:2015**

21. MAJOR NON-CONFORMITIES: None

22. MINOR NON-CONFORMITIES:

1. Managing Director, working director and Marketing Executive are responsible for implementation of quality management system requirement. However, non of their responsibilities indicate requirement to report the performance of QMS and opportunity for improvement for review. (NCR-01)
2. Bleaching process has been outsourced by the company. However, there is no agreement with service provider. (NCR – 02)
3. Preservation of product is not adequate to ensure the cleanliness and contamination. Ex: Opening of the stores to external environment. (NCR – 03)

OBSERVATIONS:

1. Internal audit results were not specifically discussed under MR. (OB-01)

23. RECOMENDATION FROM AUDIT TEAM:

(Strike off which is not relevant)

The audit team concludes that the organization has / has not established and maintained its management system in line with the requirements of the standard and demonstrated the ability of the system to systematically achieve agreed requirements for products / services within the scope and the organization's policy and objectives.

Therefore the audit team recommends that, based on the results of this audit and the system's demonstrated state of development and maturity, management system certification be:

Granted / continued the certification subjected to the completion and subsequent verification of corrective action for all major/minor non conformities raised / Suspended until satisfactory corrective action is completed.

ANY OTHER COMENTS:

Mr. D.N.S. Kuruppumullage
LEAD AUDITOR

2019-11-05
DATE