



IND-EXPO CERTIFICATION LIMITED

INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME

STAGE I AUDIT REPORT

ISO 9001:2015

New Kuvenitex (Pvt) Ltd





INDEXPO CERTIFICATION LIMITED
MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE I AUDIT REPORT – ISO 9001 : 2015

1. **NAME OF ORGANIZATION :** New Kuvenitex (Pvt) Ltd
2. **REGISTERED ADDRESS :** Matugama Industrial Estate Ritiketiya, 5th Mile Post.
Meegama, Darga Town
3. **FACTORY/OUTLET/ LOCATIONS/SITES:** Same as 2
4. **CONTACT DETAILS :**
 - 4.1 **Name:** Mr. Raja Kulasekara
 - 4.2 **Designation:** Managing Director
 - 4.3 **Telephone :** 03422722920 **Mobile :** 0773083435 **Fax :** 0342279293
E-mail: newkuvenitex@gmail.com
5. **APPLICABLE STANDARD :** ISO 9001:2015
6. **FILE NO. :** IMSC-QMS-060
7. **APPLICABLE SECTOR :** Manufacturing of pharmaceutical preparations
8. **NACE CODE :** 21.2
9. **SCOPE OF CERTIFICATION :** Activities pertaining to manufacturing of surgical gauze, bandages and crepe bandages
10. **NO. OF EMPLOYEES :** 14
11. **DATE OF AUDIT:** 2019-10-18
12. **TYPE OF AUDIT:** Stage I
13. **AUDIT TEAM :**
D.N.S. Kuruppumullage Lead Auditor

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14. AUDIT OBJECTIVES:

The objectives of this audit were:

- to confirm that the management system has been planned to conform with all the requirements of the audit standard including availability of documented information required;
- to understand the scope of the management system of the client with regards to operational sites, processes, equipment and the complexity of the operation (levels of controls established particularly in case of multiple site), applicable statutory, regulatory and contractual requirements;
- to confirm the readiness and planned arrangements for the Stage 2 audit.

15. AUDIT FINDINGS :

Serial No.	Relevant Clause of ISO 9001 :2015	Finding	Remarks
1.	6.1	Yarn supplier risk is not identified	<i>Corrected as appropriate.</i>
2.	9.1.2	Customer feedback is not monitored and reviewed	
3.	9.1.3	Product conformity is not analysis	
4.	7.5.3	External documents are not conformed	
5.	9.3.2.c	Internal audit results are not discussed under management review meetings	
6.	7.2.c	Conducted trainings were not evaluated	
7.	9.2	Internal audit findings effectiveness was not monitored	

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

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

18. OVERALL CONCLUSIONS:

- The Stage 1 audit was successful in meeting the stated objectives: YES NO
- If NO please mention the reasons:

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Audit has been carried out on sample basis and the available information, consideration to the findings identified on the report the overall conclusions of the audit are as follow:

- | | | | | |
|--|-----|-------------------------------------|----|-------------------------------------|
| • The management system has been planned to conform with all the requirements of the audit standard: | YES | <input checked="" type="checkbox"/> | NO | <input type="checkbox"/> |
| • The management system is designed to achieve the organization's policy and quality objectives: | YES | <input checked="" type="checkbox"/> | NO | <input type="checkbox"/> |
| • Based on the information provided, the system is designed to identify and manage compliance with statutory, regulatory and contractual requirements: | YES | <input checked="" type="checkbox"/> | NO | <input type="checkbox"/> |
| • Verification, validation of appropriate controls have been done: | YES | <input checked="" type="checkbox"/> | NO | <input type="checkbox"/> |
| • The internal audit and management review planning assure appropriate coverage prior to the Stage 2 Audit: | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |
| • Appropriateness of the certification scope. | YES | <input checked="" type="checkbox"/> | NO | <input type="checkbox"/> |

Team Leader : D.N.S. Kuruppumullage


Date:18/10/2019



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- Page 04 of 04 is for internal purposes only.

1. RECOMMENDATION BY AUDIT TEAM :


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Signature of Team Leader

2019-10-18
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Date

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Signature of Team Member -1

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Date

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Signature of Team Member - 2

.....
Date

2. RECOMMENDATION BY CERTIFICATION MANAGER :

Recommend for stage II audit.


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Signature of Certification Manager

2019/10/19
.....

Date