



Kalam Institute of Health Technology
(Operating Certification Services
through KIHT Certification Services)

**Certification Procedure
HEALTEXPROF Certification
Scheme**

KIHT Certification Services (KCS)
KCS/SCHEME/PR01b/R00
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1. Purpose

The purpose of the procedure is to detail the Certification process for HEALTEXPROF Scheme at the KIHT Certification Services (KCS). This document lists and describes the activities that would be performed by KCS in the certification process at the client site.

2. Scope

KIHT Certification Services (KCS) is carrying out evaluations of “Processing of multiple-use healthcare textiles” at organization premises under the HEALTEXPROF Scheme which is based/operated on ISO/IEC 17065:2012 standards.

3. Reference Documents/Standards

- ISO/IEC 17065 - Conformity assessment — Requirements for bodies certifying products, processes and services.
- HEALTEXPROF Scheme Documents:
 1. Technical Criteria document (AMTZ/ HEALTEXPROF /TD/R00)
 2. Annexures for Technical Criteria document (AMTZ/ HEALTEXPROF /ATD/R00)
 3. Certification Process document (AMTZ/ HEALTEXPROF /CP/R00)
 4. CB & AB Requirements document (AMTZ/ HEALTEXPROF /CBAB/R00)
 5. Provisional approval for CBs document (AMTZ/ HEALTEXPROF /PA/R00)
 6. Rules for Use of Scheme Mark document (AMTZ/HEALTEXPROF/RM/R00)

4. Responsibilities

All certification processes will be conducted by a person designated by the Certification Manager and the Certification Manager will oversee the execution of this process.

5. Procedures

5.1 Pre-certification process

5.1.1 Applicant Requirement

The application form, along with the application processing fee (as decided by KCS) needs to be submitted by the applicant organization. The application can be submitted either in person at the KCS office at Kalam Convention Centre or via email (kcs@kiht.in)

If any activities of processing of multiple use healthcare textiles are carried out by the applicant organization other than the main address, those additional premises are to be mentioned in the application along with the equipment details/activities.



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The applicant organization must declare at the time of application submission regarding any legal proceedings relating to its operation by any regulatory body.

5.1.2 Application processing

Upon a written or oral request for Certification from an applicant organization, KCS will contact an authorized representative from the organization (via phone or email kcs@kiht.in).

KCS shall made available the application form and the process of evaluation on its website (<https://kiht.in>).

The application form can be downloaded from the KCS website (<https://kiht.in>).

Before accepting the application form, KCS is responding to all queries of the applicant organization w.r.t application/evaluation process on this Scheme.

The applicant organizations has to submit the duly completed application form with applicable processing fee (as decided by KCS) along with the initial information required to commence the certification process.

The application which is received from the applicant organization is reviewed for its adequacy and availability of resources to perform the evaluation by a Client Manager.

The applications received from the applicant organization with complete details along with the required application fee will be processed further for evaluation.

Based on the scope of certification, the KCS will constitute an evaluation team (if required, more than one evaluator) to carry out the evaluation. If required, KCS may include technical experts in the team to make the team competent enough to conduct onsite evaluation based on the scope of certification. In such a case, the details of the expert will be informed to the applicant organization sufficiently in advance.

The certificate will be issued by KCS only against the current revision/issue of the Scheme criteria documents.

KCS may close or reject the applications under the following circumstances.

- a) No actions are being taken from the applicant organization on identified issues during the evaluation within 3 months-time.
- b) The applicant organization, if found to be misusing the Scheme logo while their application is being processed, will be rejected after a due notice of 15 days. Fresh applications may be considered from the same applicant organization after one year of cooling period.
- c) Voluntary withdrawal of application. In such cases, the application fee paid is forfeited.

5.2 Evaluation Duration/ man-days

The KCS has a defined process to allocate sufficient time for the evaluation considering the factors like laundry process, mending process, disinfection/sterilization as may be applicable and based on the number of locations/sites considering risks involved.



The KCS will maintain records with justification on time allocation/planning for each organization.

The evaluation duration planned will be informed to the organization sufficiently in advance along with evaluation team composition and their CVs to identify any conflict-of-interest (Col) issues.

When a KCS performs evaluation activities, either with its internal resources or with other resources under its direct control, it meets the applicable requirements of the relevant International Standards and, as specified in the Scheme. Where appropriate, it meets the applicable requirements of ISO/IEC 17025 for testing and ISO/IEC 17020 for inspection, considering the applicable impartiality requirements.

If required, KCS may outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and as specified in the Scheme. Where appropriate, it will meet the applicable requirements of ISO/IEC 17025 for testing and ISO/IEC 17020 for inspection, considering the applicable impartiality requirements. However, as on date KCS is not outsourcing any of the evaluation activities.

5.3 On-site evaluation Process

KCS decides on a competent team, to perform the evaluation and review the relevant document.

Evaluation will be conducted in two stages.

Stage 1 to check the readiness of the applicant and fulfilling the legal obligations if any. The review includes, but is not limited to the following:

- a) Verification of the facts/details submitted in the application form
- b) Review of the competencies of the personnel involved in reprocessing of healthcare textiles process.
- c) Review of the applicable procedures established for the reprocessing of healthcare textiles process.

Subject to satisfactory completion of stage 1, the KCS will conduct stage 2 (witnessing the service process) within 3 months from the said date.

In case there are non-conformities (major and minor), the applicant organization is given 30 days to resolve minor NC and provide evidence to the KCS. Corrective actions should be provided by the organization within 15 days for major NC or as agreed with KCS. Major nonconformities if any will result in onsite follow-up evaluation at the discretion of the KCS.

If there are multiple types of healthcare textiles to be covered in the Scheme based on the complexity of the service process, KCS has a plan for evaluation activities which allow for the necessary arrangements to be managed. (Annex 1. Sampling Criteria)

KCS follows evaluation methods and procedures as documented under clause 5.0 of the CB and AB requirement document (AMTZ/HEALTEXPROF/CBAB/R00) of the Scheme along with the KCS checklist (F12b)



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KCS will uniquely identify the processing of multiple use healthcare textiles offered by the organization for witnessing the applicable processes. In case any abnormalities are observed during witnessing, the same is documented and then informed to the organization.

The KCS will conduct the evaluation in a manner to ensure all the compliance applicable to health and safety are followed as per the local regulations.

Textiles submitted by the organization for processing will be safeguarded during the process in such a manner to avoid any damage or deterioration affecting its maintenance integrity.

KCS ensures the calculations and data transfer are subject to appropriate checks in a systematic manner, to avoid errors.

The evaluation report will be prepared and submitted to the client organization along with the findings.

Evaluation report includes:

- i. identification of the organization
- ii. identification of the issuing body (CB)
- iii. unique identification of report and date of issue
- iv. date(s) of evaluation
- v. identification of the equipment (s) inspected/evaluated.
- vi. signature or other indication of approval, by authorized personnel
- vii. a statement of conformity where applicable
- viii. name and calibration status of the instruments used during the evaluation.

KCS will seek feedback on the conduct of the evaluation from the client organization.

5.4 Review and Certification decision

The KCS assigned one person to review all information and results related to the evaluation. The review is carried out by person (s) who have not been involved in the evaluation process.

Recommendations for a certification decision based on the review will be documented unless the review and the certification decision are completed concurrently by the same person.

The Certification manager makes the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision will be carried out by a CM.

We have an agreement detailing the terms and conditions of certification between the KCS and Client organization. (F03).

The certificate is valid for 3 years from the date of issuance. (Attached Certificate Copy)

5.5 Surveillance



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The first surveillance evaluation will take place within 9 months from the date of issuance of certificate. The second surveillance will be unannounced and will take place within 4 to 6 months prior to the date of expiry of certificate.

5.6 Termination, reduction, suspension or withdrawal of certification

When a non-conformity with certification requirements is substantiated, either as a result of surveillance or otherwise, the KCS will consider and decide upon the appropriate action which can include the following:

- a) continuation of certification under conditions specified by the CB
- b) reduction in the scope of certification.
- c) suspension of the certification pending remedial action by the organization.
- d) withdrawal of the certification

When the appropriate action includes evaluation, review or a certification decision, the requirements in evaluation, review or certification decision, respectively, will be fulfilled.

If certification is terminated (by request of the organization), suspended or withdrawn, the KCS will take actions which include modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the maintenance process continues to be certified in the organization.

If a scope of certification is reduced, the KCS will take actions which include modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the organization and clearly specified in certification documentation and public information.

If certification is suspended, the KCS will communicate the actions needed to end suspension and restore certification based on the certification decisions.

If certification is reinstated after suspension, the KCS will make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the process continues to be certified.

If a decision to reduce the scope of certification is made as a condition of reinstatement, the KCS will make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the organization and clearly specified in certification documentation and public information.

5.7 Records

The KCS retains records to demonstrate that all certification process requirements (those in ISO/IEC 17065 Standard and those of the Certification Scheme) have been effectively fulfilled.

The KCS keeps records confidential. Records are transported, transmitted and transferred in such a way that confidentiality is maintained.

If the Scheme involves complete re-evaluation of the process within a 3-year cycle, records will be retained at least for the current and the previous cycle.



All the records related to evaluation and testing will be maintained to establish traceability and appropriately safeguarded.

NOTE: Records may include:

- a) Raw data sheets
- b) Evaluation reports
- c) Checklists
- d) Any relevant instructions

5.8 Complaints and appeals.

The KCS has a documented process to receive, evaluate and make decisions on complaints and appeals. The KCS will record and track complaints and appeals, as well as actions undertaken to resolve them.

Upon receipt of a complaint or appeal, the KCS will confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, KCS will address it.

The KCS will acknowledge receipt of a formal complaint or appeal.

The KCS is responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

The decision resolving the complaint or appeal is made by, or reviewed and approved by, person (s) not involved in the certification activities related to the complaint or appeal.

Whenever possible, the KCS will give formal notice of the outcome and the end of the complaint process to the complainant.

The KCS will give formal notice of the outcome and the end of the appeal process to the appellant.

The KCS will take any subsequent action needed to resolve the complaint or appeal.

The complaints regarding the activity carried out by the certified organization, the KCS review the complaints received and evaluate the complaints by doing a short visit to the certified organization, if required and report the findings to the organization and the complainant.

6.0 Records - Other Applicable Document

- 1) Application Form (F01b)
- 2) KCS Personnel Agreement (F02)
- 3) Certification Agreement (F03)
- 4) Technical Expert Mapping with Scheme Product Category for BEMC Scheme (F09b)
- 5) Audit Plan (F10)
- 6) Audit Report (F11)
- 7) Checklist for BEMC Scheme (Medical Equipment) (F12b)
- 8) Certificate for BEMC Scheme (F13b)



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- 9) Non-Disclosure Agreement for Auditor/Technical Expert (F14)
- 10) Audit Attendance Sheet (F20)
- 11) Non-Conformity Report (F21)
- 12) Concern Report (F22)
- 13) Technical Review of Reports for Decision Making (F23)
- 14) Complaint Register (F24)
- 15) Appeal Register (F25)
- 16) Customer Feedback (F26)

(Annex 1. Sampling Criteria)

The AQL for a batch of less critical healthcare shall be 2.5%, which means that no more than 2.5% of the scrub suits in the batch can have defects such as loose threads or seams. If the actual number of defects in the batch exceeds the AQL, the entire batch may be rejected or subject to additional testing or inspection. AQL sampling plan for less critical healthcare textiles shall be in accordance with IS/ISO 3951 (part-1, part-2, part-3) or any equivalent national/ international sampling plan/standard.

AQL for critical healthcare textiles classified as medical devices shall be in accordance with the barrier efficacy level as per the relevant product standard/ regulatory requirements. AQL sampling plan for critical healthcare textiles classified as medical devices shall be as per the relevant product standard/regulatory requirements.



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Revision Status

Date of approval	Clause/Para under change	Reason of Change

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K. Udayabhaskar

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