Andhra Pradesh MedTech Zone Ltd (AMTZ)

Healthcare Textiles Processing Facility Certification (HEALTEXPROF) Scheme

(Certification Process)

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Contents

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Foreword

There is a rising concern about the risk of spreading infections from Healthcare textiles (Scrubs, jackets, lab coats, bed sheets and towels etc.) to patient, staff and the public, if not washed under a monitored environment. Textiles used in healthcare settings are the components in the chain of infection transmission. The risk is greater when contaminated healthcare textiles are not handled properly. Such textiles are the source of microbes, if the laundry process fails to eliminate contamination and spreads to the other items in the laundry load. For example, if laundry is left damp, this encourages microbial survival and residual microorganisms could grow. A healthcare facility can avert this risk by having these textiles professionally processed by a certified service provider.

The aim of the Scheme is to provide for optimum performance levels in the processing of multiple-use healthcare textiles and is mainly targeted for the healthcare textile processing facilities.

1.0 Scope

This document describes the requirements, the Certification body (CB) has to follow for carrying out evaluations of "Processing of multiple-use healthcare textiles" at organization premise under this Scheme. The HEALTEXPROF Scheme is developed based on Type 3 as per ISO/IEC 17067: 2013 standards (Refer Annexure 1).

This document shall be read with the document titled "**Technical Document- Healthcare Textiles Processing Facility Certification Scheme (AMTZ/HEALTEXPROF/TD /R00)**".

2.0 Normative References

- ISO/IEC 17065:2012: Conformity assessment — Requirements for the operation of various types of bodies performing certifying products, processes and services
- ISO/IEC 17067:2013: Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes
- ISO/IEC TR 17032:2019: Conformity assessment — Guidelines and example of a scheme for the certification of processes
- Technical Criteria documents for Processing of Multiple-use Healthcare Textiles Certification Scheme

3.0 Terms and definitions

3.1 Appeal

request by the provider of the item of evaluation to the Certification body (CB) for reconsideration by that body of a decision it has made relating to that item

NOTE 1 Adapted from ISO/IEC 17000:2004, definition 6.4.

3.2 Complaint

expression of dissatisfaction, other than appeal, by any person or organization to an certification body (CB), relating to the activities of that body, where a response is expected

NOTE 1 Adapted from ISO/IEC 17000:2004, definition 6.5.

3.3 Evaluation

combination of the selection and determination functions of conformity assessment activities

NOTE 1 The selection and determination functions are specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

3.4 Certification requirement

specified requirement, including product requirements, that is fulfilled by the client as a condition of establishing or maintaining certification

3.5 Client

organization responsible to a certification body (CB) for ensuring that certification requirements, including applicable service requirements, are fulfilled

Organization includes healthcare establishment owned/ operated or third party operated, on-premise or off-site facilities, or standalone commercial facilities who are engaged in processing of multiple-use healthcare textiles.

NOTE: Service includes laundering, mending, packaging, disinfection and sterilization

3.6 Healthcare Textile

Constitute clothing material requiring care and hygiene used for the patients such as but not limited to:

- Used in critical areas like operation theatres, ICU and emergency department etc.
- Used in hospital wards and patient care facilities such as bedsheets, pillow covers etc.
- Used in patient handling activities such as trolley covers including the mattresses, pillows, blankets, sheets, and towels etc.
- Used in hospital furnishings like curtains, bedside screen etc.

3.7 Organization

person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives

NOTE 1 In the context of scheme, the organization includes, but is not limited to, sole proprietorship, partnership firm, incorporated company, enterprise, association, charity or institution, or part or combination thereof, whether government or non-government, related to the processing of multiple use healthcare textile as defined above.

For example, this can be a Laundry Operator, hospital, or an individual clinic etc.

4.0 Pre-Certification process:

4.1. Requirements for the applicant

4.1.1 The applicant organization shall complete the prescribed application with detailed information in the application form (AF/HEALTEXPROF/00) and submit to CB along with the prescribed fee.

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

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

4.2. Application Processing

4.2.1 The application form and the process of evaluation shall be made publicly available by the approved CB.

4.2.2 CB shall respond to all queries of applicant w.r.t application/evaluation process on this Scheme before accepting the application.

4.2.3 The application received must be reviewed for its adequacy and availability of resources to perform the evaluation by a competent person of the CB.

4.2.4 The applications received with complete details along with the required application fee shall be processed further for evaluation. The data to be submitted with the application is as listed in Section-IV of application form (AF/HEALTEXPROF/00).

4.2.5 Based on the scope of certification, the CB shall constitute an evaluation team (if required, more than one evaluator) to carry out the evaluation. If required, CB may include technical expert in the team to make the team competent enough to conduct onsite evaluation based on

the scope of certification. In such case, the details of the expert shall be informed to applicant/organization sufficient in advance.

4.2.6 The certificate shall be issued by CB only against the current revision/issue of the Scheme criteria documents.

4.2.7 CB may close or reject the applications under the following circumstances.

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

5.0 Evaluation duration/man-days

5.1 The CB shall have 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 also based on the number of location/sites considering risks involved.

5.2 The CB shall maintain records with justification on time allocation/planning for each organization.

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

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

5.5 The CB shall 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 shall meet the applicable requirements of ISO/IEC 17025 for testing and ISO/IEC 17020 for inspection, considering the applicable impartiality requirements.

5.6 Sampling Process: 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.

6.0 On-site Evaluation process

6.1 CB shall decide a competent team, to perform the evaluation and review the relevant document.

6.2 Evaluation shall be conducted in two stages.

6.2.1 Stage 1 to check the readiness of the applicant and fulfilling the legal obligations if any. The review shall include, 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.

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

6.2.3 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 CB. Corrective actions shall be provided by organization within 15 days for major NC or as agreed with CB. Major nonconformities if any shall result in onsite follow-up evaluation at the discretion of the CB.

6.2.4 Where there are multiple types of healthcare textiles to be covered in the Scheme based on the complexity of the service process, the CB shall have a plan for evaluation activities to allow for the necessary arrangements to be managed.

6.3 CB shall follow 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 Technical criteria as specified in Technical document (AMTZ/HEALTEXPROF/TD/R00).

6.4 CB shall uniquely identify the processing of multiple use healthcare textile offered by the organization for witnessing the applicable processes. In case of any abnormalities are observed during witnessing, the same shall be documented and the organization informed.

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

6.6 Textile submitted by the organization for processing shall be safeguarded during the evaluation process in such a manner to avoid any damage or deterioration affecting its service integrity.

6.7 CB shall ensure the calculations and data transfer are subject to appropriate checks in a systematic manner, to avoid errors if applicable.

6.8 The evaluation report shall be prepared and submitted to organization along with the findings.

6.9 Evaluation report shall include at least the following:

a) identification of the organization
b) identification of the issuing body (CB)
c) unique identification of report and date of issue
d) date(s) of evaluation
e) identification of the textile (s) inspected/evaluated
f) signature or other indication of approval, by authorized personnel
g) a statement of conformity where applicable
h) name and calibration status of the instruments used during the evaluation.

7.0 Review and Certification decision

7.1 The CB shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person (s) who have not been involved in the evaluation process.

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

7.3 The CB shall assign at least one person to make the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision shall be carried out by a person or group of persons [e.g. a committee] that has not been involved in the process for evaluation.

7.4 It is desirable to have an agreement detailing the terms and conditions of certification between the CB and organization.

7.5 Certificate shall include at least the following:

a) Identification of the organization providing the services
b) Identification of the issuing body (CB)
c) Reference to the healthcare textile Scheme doc of the organization

d) Scope of certification
e) Scheme name and version
f) Logo of AB and Scheme, as applicable
g) Certificate number
h) Date of certification
i) expiry date
j) signature, by authorized personnel

7.6 The certificate shall be valid for 3 years from the date of issuance.

8.0 Surveillance

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

9.0 Termination, reduction, suspension, or withdrawal of certification

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

a) continuation of certification under conditions specified by the CB (e.g. increase in the frequency of the surveillances);
b) reduction in the scope of certification;
c) suspension of the certification pending remedial action by the organization;
d) withdrawal of the certification.

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

9.3 If certification is terminated (by request of the organization), suspended or withdrawn, the CB shall 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 service process continues to be certified in the organization.

9.4 If a scope of certification is reduced, the CB shall take actions which includes 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.

9.5 If certification is suspended, the CB shall communicate the actions needed to end suspension and restore certification based on the certification decisions.

9.6 If certification is reinstated after suspension, the CB shall 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.

9.7 If a decision to reduce the scope of certification is made as a condition of reinstatement, the CB shall 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.

10.0 Records

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

10.2 The CB shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained.

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

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

NOTE: Records may include but are not limited to:

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

11.0 Complaints and Appeals

11.1 The CB shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The CB shall record and track complaints and appeals, as well as actions undertaken to resolve them.

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

11.3 The CB shall acknowledge receipt of a formal complaint or appeal.

11.4 The CB shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

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

11.6 Whenever possible, the CB shall give formal notice of the outcome and the end of the complaint process to the complainant.

11.7 The CB shall give formal notice of the outcome and the end of the appeal process to the appellant.

11.8 The CB shall take any subsequent action needed to resolve the complaint or appeal.

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

12.0 Application Fee

12.1 A fee to be charged to the organization for various activities of the certification under the Scheme, should be based upon units, geographical location, scope of certification etc.

12.2 The CBs fee structure shall be publicly accessible and be provided on request.

12.3 CB shall notify and obtain consent to its fee structure from the organizations prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the certified organization under this Scheme of certification for their acceptance.

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Annexure I

Table 1 — Building a product certification scheme

Conformity assessment functions and activities[a] within product certification schemes		Types of product certification schemes[b]							
		1a	1b	2	3	4	5	6	*N*[c,d]
I	**Selection**, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II	**Determination of characteristics**, as applicable, by: a) testing b) inspection c) design appraisal d) assessment of services or processes e) other determination activities, e.g. verification	x	x	x	x	x	x	x	x
III	**Review** Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	x
IV	**Decision on certification** Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V	**Attestation, licensing**								
	a) issuing a certificate of conformity or other statement of conformity (attestation)	x	x	x	x	x	x	x	x
	b) granting the right to use certificates or other statements of conformity	x	x	x	x	x	x	x	
	c) issuing a certificate of conformity for a batch of products		x						
	d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.		x	x	x	x	x	x	
VI	**Surveillance**, as applicable by:								
	a) testing or inspection of samples from the open market			x		x	x		
	b) testing or inspection of samples from the factory				x	x	x		
	c) assessment of the production, the delivery of the service or the operation of the process				x	x	x	x	
	d) management system audits combined with random tests or inspections						x	x	

a. Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.

b. An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.

c. A product certification scheme includes at least the activities I, II, III, IV and V a).

d. The symbol *N* has been added to show an undefined number of possible other schemes, which can be based on different activities.

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Amendment Sheet

The history of changes is as below:

Sl. No	Date of Amendment	Page No./Clause No.	Amendment details