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1.0 INTRODUCTION

- 1.1 System Advanced Laboratories LTD. operates as an independent certifying body (CB) for products, processes and services. System Labs conforms with Israeli Standard Requirements, International Standards and Normative documents.
- 1.2 System Labs operates as an independent body, with international accreditation, in service to consumer and economic interests for the certification of products, processes and services.
- 1.3 System Labs will monitor the compliance of products in accordance with the requirements document while taking into account the client's quality control capabilities.
- 1.4 System Labs will operate in accordance with the requirements of international standards IEC/ISO 17065 and IEC/ISO 17067.

2.0 SCOPE

- 2.1 This document outlines the certification procedure for products, supervision, marking instructions, manufacturing processes and service provisions.
- 2.2 The purpose of this document is to define the certification process and production surveillance.

3.0 REFERENCES

- 3.1 <u>Documents referred to in this procedure</u>
 - 3.1.1 IEC/ISO 17065: Conformity Assessment Requirements for bodies certifying products, processes and services
 - 3.1.2 IEC/ISO 17067: Conformity Assessment Fundamentals of product certification and guidelines for product certification schemes
 - 3.1.3 Israeli Standard: SI 17025 General Requirements for the competence of testing and calibration laboratories
 - 3.1.4 Israeli Standard: SI 17020 Assessment of Conformity Operation requirements for various examination bodies

4.0 **DEFINITION OF TERMS**

The following terms appear in this document

4.1 Product – Result of a Process

Products fit into one of the following four categories:

- Service includes delivery and maintenance
- Software Computer Software, Translation
- Hardware Mechanical product, engines
- Process Production process, service process, products such as readymix concrete.
- 4.2 Client Organization or Individual responsible for producing or marketing a product for which product certification (by System Labs) is required.

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- 4.3 Subcontractor A manufacturer of parts that are to be included in the client's finished product for which certification is required
- 4.4 Supplier Manufacturer or marketer who provides off-the-shelf products to be included in the final product for certification.
- 4.5 Accredited Laboratory In accordance with section 12.2.a of standards law, an accredited laboratory under Israeli Standard SI 17025 shall be accredited by the Israeli Accreditation Authority or another recognized accreditation body.
- 4.6 Certification Unit A department within System Advanced Laboratories Ltd. responsible for the certification of products, processes and services. System Labs acts as a third party certification body.
- 4.7 Technical Office A unit within the Certification Unit that is responsible for the technical aspects of granting certification approval.
- 4.8 Process Inspection An inspection focused on the production process, production facilities, testing facilities, testing instruments and the client's process control system. The examination shall be performed by a certified Process Inspector.
- 4.9 Document of Requirements Includes: Israeli Standards, International Standards, Foreign National Standards, Normative Documents and Technical Documents.
- 4.10 Initial Stage All the steps and actions required to grant the client certification.
- 4.11 Evaluation Testing the product according to the Document of Requirements, inspecting the production process, approving the Product File and the Product Quality Control Plan.
- 4.12 Review Reviewing the performance of the Evaluation process and providing a certification recommendation and future surveillance program. System Labs shall provide at least one employee to review the performance and results of the Evaluation process. This Review Employee shall not be involved in any part of the Evaluation Processes that they are reviewing.
- 4.13 Decision Decision for granting certification, marking the product and implementing a surveillance program. System Labs shall designate at least one employee to make the decision regarding certification. The decision maker shall not be involved in any part of the Evaluation process.
- 4.14 Certificate Certificate containing the product name, scope of certification, Document of Requirements, client name, date of certificate validity, Certification Mark, System Labs' logo and the Accreditation body's logo.
- 4.15 Surveillance Actions taken by System labs after certification is given to ensure that the certification conditions are maintained.
- 4.16 Certification Mark Mark attesting that the product conforms to the Document of Requirements.
- 4.17 Product File Product specification and technical documents describing the product.
- 4.18 Process Quality Control Plan A document detailing the Quality Control plan during the production process, as implemented by the client.

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- 4.19 Full Test A test of a product according to all of the requirements in the Document of Requirements.
- 4.20 Partial Test A test of a product according to some of the requirements in the Document of Requirements.
- 4.21 Family Consisting of several product models. Under the designation of family, the following shall be considered:
 - Singular Design
 - Similar technical specifications
 - Similar nominal dimensions
 - Similar core materials
 - Identical core components
 - Identical manufacturing process
 - Performs the same function
- 4.22 Product Models Categorized as a Family Different versions of a product that differ from one another in certain characteristics. Testing one model in a family is indicative of the acceptability of the other models. Remarks:
 - a) Products that differ from one another in irrelevant or non-critical characteristics (characteristics that have no influence on the functioning of the product or its conformity to the Document of Requirements) shall be considered as identical models.
 - b) Products that are of the same model shall be marked by the manufacturer in such a way that they can be identified with a single value.
- 4.23 Non-Conformity Deviation from the requirements specified in the Document of Requirements.
- 4.24 Corrective & Priventing Action Changes made to prevent further deviations from conformity.
- 4.25 Specific Certification Scheme Certification process requirements for a specific product, process or service.
- 4.26 Certification Requirements All the requirements specified in the Document of Requirements and in the Certification Scheme.

5.0 CERTIFICATION SCHEME

Certification Scheme includes:

Disclosing Information, Submitting the Application, Initial Stage, Evaluation, Review, Decision, Certification and Surveillance

- 5.1 Disclosing Information
 - 5.1.1 A client that is interested in undergoing the certification process must first address the Certification Unit verbally or in writing and indicate the product, process or service that is to undergo the certification process.
 - 5.1.2 The Certification Unit shall check if there is any existing Document of Requirements applicable to the product. If there is no Document of Requirements applicable to the product, the Certification Unit

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shall examine the possibility of preparing the Document. If it is not possible, the Certification Unit shall inform the client that it is not possible for this product to undergo certification.

- 5.1.3 Once there is an appropriate Document of Requirements, the Certification Unit shall send detailed information to the client including:
 - a) Certification Scheme (This Document)
 - b) Application
 - c) Document of Requirements
 - d) Agreement
 - e) Specific Certification Scheme

5.2 <u>Submitting the Application</u>

- 5.2.1 The client shall provide the following documents to the Certification Unit:
 - a) Application Form The client shall reference the Document of Requirements associated with the application.
 - b) Product Details Technical documents (Data sheets, technical drawings, assemblies, catalogs)
 - c) Process Quality Control Plan
 - d) Client Information Details about the organizational system, key personnel, location of production sites and company offices. If the client has a quality manual it should also be included.
 - e) Subcontractor details If a subcontractor is included in the production process this should be noted.

Note: If necessary, the Certification Unit may assist the client in providing all of the necessary information.

5.2.2 Application Review

- a) The Certification Unit of System Advanced Laboratories will review the application and all of the attached documents to verify that all of the necessary information is provided.
- b) System Labs will verify that it has the capability to perform the Certification Scheme as requested in the application.
- c) If the application is incomplete or additional information is required, System Labs shall inform the client regarding which details are missing in order to complete the application form.

5.3 Initial Stage

The Initial Stage is conducted according to the certification scheme based on IEC/ISO 17067.

5.3.1 Evaluation

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The evaluation includes all of the steps required to demonstrate compliance with the Certification Scheme.

Steps of compliance include:

Product testing according to the Document of Requirements, approval of the Product File, Process Quality Control Plan, inspection at the client and subcontractor's manufacturing facilities.

5.3.2 Review

Review of the successful evaluation shall be performed by a reviewer who was not involved in the evaluation process. At the end of the process, the reviewer shall prepare a recommendation stating whether it is possible to grant certification to the client and their surveillance plan. During the review, consultation is permitted with individuals who did not take part in the evaluation process.

5.3.3 Decision

The decision regarding approval shall be made by the decision maker. The following decisions shall be made:

- Surveillance program
- Certification Mark
- Confirmation that the evaluation and review were carried out by an unbiased individual with no conflict of interest.
- This decision shall be reported to the certification Unit. Note: The Review and Decision stages may be performed by the same employee.

5.4 Evaluation

- 5.4.1 Prior to the evaluation, the Certification Unit shall conduct a visit to the client's facilities.
 - a) The purpose of said visit is for the Certification Unit to become familiar with the client's team, product, production process and process controls that are present within the client's facilities.
 - b) The head of the Certification Unit may decide to forgo the visit to the client's facilities.
- 5.4.2 Based on the application form, the Certification Unit shall send the client a proposal for the initial stage.
 - a) The proposal shall include details of the activities that will be carried out within the framework of the initial stage, the schedule for the certification process and the price of certification.
 - b) This proposal shall include an agreement for the client to sign and return to the Certification Unit.
- 5.4.3 The proposal shall be sent within 2 working days of the application, however, if the proposal requires a Document of Requirements to be prepared it shall be sent within 14 working days.

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5.5 <u>Initial Stage Plan</u>

The Initial stage plan shall include:

5.5.1 Product testing by an accredited laboratory according to the Document of Requirements

Note:

- a) If a valid test report has already been attained by an accredited laboratory, the head of the Certification Unit may take this into account.
- b) If the client has no information about the product's compliance, it must first be tested prior to beginning the Initial Stage.
- 5.5.2 The Product File and the Process Quality Control Plan shall be prepared by the Certification Unit's technical office for the client's approval.
- 5.5.3 Inspection shall be carried out by accredited personnel.
- 5.5.4 After receiving a signed agreement from the client, the Certification Unit shall provide an invoice for the cost of the Initial Stage.
- 5.5.5 According to the decision of the Head of the Certification Unit, testing may be carried out by:
 - a) System Advanced Laboratories Ltd.
 - b) An accredited laboratory
 - c) The client's lab
- 5.5.6 If the client has a valid test report indicating that the product is in compliance with the Document of Requirements, the product may be sampled during inspection. When this occurs, only the product's safety components shall be tested.
- 5.5.7 During Inspection, the implementation of a Process Quality Control Plan for the product shall be examined and the product shall be compared to the Product File for compliance. After inspection, an inspection report shall be provided to the client.
- 5.5.8 If critical components are produced by a subcontractor, the Certification Unit shall also inspect the components at the subcontractor's facility. When this is the case, a Process Quality Control Plan shall also be implemented for the subcontractor.
- 5.5.9 If there is a non-conformity with the product, the client shall be instructed to take corrective action. If a non-conformity is found with the product's safety components, System Labs shall perform additional tests on the product.
- 5.5.10 If the client requests to expand the certification for new models, the head of the Certification Unit shall create a specialized plan for the initial stage.

The program shall include:

- a) An updated Product File
- b) An updated Process Quality Control Plan

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c) A partial test focusing on the differences between the product models.

5.5.11 Schedule

- a) The initial stage period shall be completed within 60 working days of receiving a signed agreement, unless the product test requires more than 45 days, in which case the period may be extended.
 - If the initial stage is not completed on time, the head of the Certification Unit shall conduct a meeting with the client to redefine the schedule.
 - The schedule for the initial stage when the manufacturing facilities are abroad shall be determined in conjunction with the client in order to minimize the costs involved in the certification process.
- b) Preparation of the Product File and the Process Quality Control Plan shall be completed within 14 working days of the agreement being signed.
- c) Inspection shall be completed within 14 working days of receiving the test results.
- d) Testing may be carried out simultaneously with the preparation of the Product File and the Process Quality Control Plan. Where possible, the product should be sampled from the production line or from the client's warehouse.
- e) The Review and Decision period may take up to 7 working days from the completion of the Evaluation period.
- f) Certification shall be provided within 1 additional working day after the Decision for certification has been made.

5.6 Review

5.6.1 Once the Evaluation phase has been successfully completed, the reviewer shall prepare a recommendation stating whether it is possible to grant the customer product certification, a certification mark and a surveillance plan. This shall be performed by an employee who was not involved in the Evaluation process. The reviewer may consult with professionals who have not participated in the Evaluation process.

5.7 Certification Decision

5.7.1 At the end of the Review phase, the Decision maker shall indicate whether Certification may be granted to the Client or not. The Decision maker shall also decide on the scope of the Certificate and the Surveillance plan. This shall be performed by a Decision maker that was not involved in the Evaluation process. The Decision maker

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- may consult with professionals who have not participated in the Evaluation process.
- 5.7.2 If a decision was made not to grant the client Certification, a report shall be sent and include the reasons why Certification may not be granted. If the client wishes to continue with the Certification process, the process must begin again with the Evaluation Phase.
- 5.7.3 The Decision maker must be a direct employee of System Advanced Laboratories Ltd., in a working contract with System Labs or an Employee of a department that is controlled by System Labs.

6.0 **DOCUMENTATION**

6.1 Agreement

- 6.1.1 The Agreement includes all of the stages of the Certification Scheme (Initial and Surveillance) and shall ensure:
 - a) The client will comply with the stipulated requirements of the Certificate.
 - b) The Product will conform to the Document of Requirements
- 6.1.2 The Agreement shall be signed during the Initial Stage and remain valid after Certification is acquired.
- 6.1.3 The Client shall agree to cooperate with System Labs during the Initial Stage and in Surveillance (including visits to subcontractors).
- 6.1.4 Extending the Certification to additional models does not require the drafting and signature of a new Agreement.
- 6.1.5 The client shall handle and keep track of their customer's complaints regarding the Product under Certification.

6.2 <u>Certificate</u>

- 6.2.1 The Certificate shall be valid for 12 months from the date of initial approval. Provided that the client meets all of the certification requirements the Certificate may be renewed for an additional 36 months continuously.
- 6.2.2 The Certificate shall include:

 Details of the Certification Body, Certification Date, Client Details,
 Scope of Certification, Expiry date and additional information as required.
- 6.2.3 The Certificate shall be signed by the C.E.O. of System Advanced Laboratories Ltd.

7.0 CONTINUED SURVEILLANCE

- 7.1 Surveillance shall be carried out in accordance with the Specific Certification Scheme for the Certified Product.
- 7.2 The Specific Certification Scheme shall be prepared by the Certification Unit in accordance with IEC/ISO 17067.
- 7.3 The Specific Certification Scheme shall ensure that:
 - 7.3.1 The Product conforms with the Document of Requirements

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- 7.3.2 There have been no significant changes to the Product's design
- 7.3.3 The Process Quality Control Plan is being implemented
- 7.3.4 The client performs Corrective Actions when required
- 7.3.5 The client performs regular testing according to the Process Quality Control Plan
- 7.3.6 The client will handle and keep track of their customer's complaints regarding the Certified Product and perform corrective actions as necessary.
- 7.4 Surveillance shall include monitoring the Certification Mark.

8.0 CHANGES THAT AFFECT CERTIFICATION

- 8.1 The Certification Unit shall inform the clients of any changes made by the Certification Unit that have an effect on the clients' responsibilities. This may include changes to the Document of Requirements, the Specific Certification Scheme, the Process Quality Control Plan, the Certification Scope or the Certificate itself.
- 8.2 Client-related Changes These changes may include changes to the product, production process, quality control, company ownership or any other change that relate to the Certificate or Agreement with System Advanced Laboratories Ltd.
- 8.3 The Certification Unit shall review the changes affecting the Certification and determine a method to re-establish the conditions required for Certification. Such methods may include one or more of the following: Evaluation (Testing and/or Inspection as needed), Review and/or Decision.

9.0 CHANGES TO THE SPECIFIC CERTIFICATION SCHEME

- 9.1 Changes may include the termination of the Agreement, Withdrawal or Suspension of the Certificate and/or reduction of the Certification Scope.
 - 9.1.1 The client or System Labs may terminate the Certification Agreement provided that they give advanced notice of 14 working days.
 - 9.1.2 When a non-conformity is detected in relation to the Document of Requirements, one of the following steps must be taken:
 - a) Continuation of Certification on condition that the nonconformity is rectified and corrective actions are taken.
 System Labs may perform additional tests and inspections to approve the Corrective Actions.
 - b) Reduction of the Certification Scope such that the parts with the non-conformities are not included within the Certificate.
 - c) A temporary suspension of Certification until Corrective Action is implemented.
 - d) Certification withdrawal
 - 9.1.3 Client side Certification Cancellation Where a client decides to withdraw, suspend or reduce the scope of Certification, System Labs

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shall publish the changes to the Certification website in order to prevent misleading the public.

9.1.4 When the Client announces a temporary pause in the production of a product, provided that the pause does not exceed 12 months, System Labs shall determine the conditions for the renewal of Certification when production is scheduled to resume.

10.0 PUBLICATION

- 10.1 Once the Client is granted Certification, System Advanced Laboratories shall publish the following information to their Website (updated once per working day):
 - 10.1.1 Client name, address, product, process or service name, scope, Document of Requirements, product or services models, Certificate number.
 - 10.1.2 All certificates granted to clients and service providers.
- 10.2 The client may publish their Certificate to the public.
- 10.3 A list of all certificate withdrawals within the last 12 months shall be published by System Labs to their website.
- 10.4 A public warning shall be published by System Labs to their website whenever Certificate withdrawal is the result of a severe non-conformity with the Document of Requirements and where the non-conformity may pose a safety concern with the client's customers.

11.0 MAINTAINING IMPARTIALITY AND NON-CONFLICT OF INTEREST

- 11.1 All employees and subcontractors of System Advanced Laboratories Ltd. shall maintain the confidentiality of any client information they were subject to during the course of their duties. Such information may be related to or include the client's products, production, services, quality control system and any other confidential information related to the client.
- 11.2 In a situation where a suspected conflict of interest arises, System Labs shall prevent the suspected cause from taking part in the Certification Scheme.
- 11.3 System Labs employees and CB Subcontractors that take part in the certification process shall sign a non-conflict of interest document and disclose to the head of the Certification Unit any affinity that they have with outside businesses or family members that could pose a conflict of interest with the Certification Scheme.
- 11.4 System Labs shall implement a permanent set of controls to monitor and maintain impartiality and to prevent conflicts of interest in the Certification Scheme.

12.0 CB SUBCONTRACTORS

12.1 Within the process of the Certification Scheme, System Labs is permitted to use Subcontractors. CB Subcontractors shall follow System's guidelines and maintain non-conflict of interest, impartiality and confidentiality.

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12.2 CB Subcontractor Requirements:

- 12.2.1 Product testing shall be carried out by accredited laboratories in accordance with SI 17025 and be accredited in the applicable testing method.
- 12.2.2 Inspection shall be performed by personnel trained and certified by the head of the Certification Unit. Personnel shall be accredited according to SI 17020.

13.0 APPEALS AND COMPLAINTS

- 13.1 System Labs shall publish a procedure for inquiries and complaints on the company website. System shall ensure that complaints are handled objectively and impartially by employees who were not involved in the certification process and who have had no connection with the complaint applicant within the last 2 years.
- 13.2 Submissions shall be responded to within 7 working days.

14.0 APPENDICES

- 14.1 CB100 Appendix A Application Form
- 14.2 CB100 Appendix B Certification Agreement