



IEC System for Conformity Testing and Certification of Electrical Equipment CB Scheme

APPENDIX B (NCB only)

Legal differences

OD-CB 2007

MEMBER NATIONAL CERTIFICATION BODIES (NCBs) INFORMATION SHEETS			
<i>(Use additional forms as necessary.)</i>			
Product categories: TRON , MEAS , MED , OFF ,			
I	CB Scheme Procedure		
II	National Regulatory Requirements for Electrical Products within the Scope of IECEE CB Scheme		
		Yes	No
1	Is compliance with standards mandated by law?	X	
	Comments:		
2	Is product certification or approval mandatory?	X	
	Comments: Standards Mark not mandatory. Testing is mandatory including sample testing from shipments		
3	If approval is mandatory what aspects/characteristics of electrical products require mandatory certification or approval?		
	Electrical safety	X	
	EMC	X	
	Hygiene		
	Energy Efficiency		
	Ergonomics		
	Other (specify):		
4	Does the certification mark of the NCB provide regulatory recognition at National level?	X	



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5	Does the NCB provide certification in all regulated areas listed in item 3 above?	X	
6	If no, specify the body responsible for such certification or approval:		
	Electrical safety:		
	EMC:		
	Hygiene:		
	Energy Efficiency:		
	Other:		
7	Describe the conditions and the processes for obtaining each of the mandatory certifications or approvals in item 3 above, and include a flow chart for each process as necessary. Each description should address as a minimum the following:		See attached power point presentation
7a	Who can submit the application? Manufacturer / Importer	Foreign manufacturer directly/ foreign manufacturer via representative in a country/ commercial agent/ other NCB/ others	
7b	Language of the application:	Hebrew or English	
7c	Need to have a local representative to place a product on the country's market	No (but recommended)	
7d	Additional administrative requirements	<p>samples for re-testing are taken from import lots/ requirements for product liability insurance registration of the manufacturer with the regulatory agency mandatory periodic re-testing requirements</p>	
7e	Can testing/ evaluation be carried out by NCBs in other countries?	No (but we will accept cb test report & certificate and do the deviations in sii)	
7f	Requirements for samples:	Yes	
7g	Documentation required:	Diagrams , technical description, safety and operating instructions and manual .	



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7h	Language of markings, warnings and instructions	Hebrew
7i.	Time needed for processing (?)	With CB from another lab: 1-2 wks



May 30, 2005

Summary of the procedures and conditions for the granting of a license to mark commodities with the Standards Mark

Anyone producing a commodity, for which a Standard applies, is entitled to mark it with the Standards Mark ⁽¹⁾ if he was granted an appropriate license from the Standards Institution of Israel, (SII). A licensee marking his product with the Standards Mark endorses that the product conforms to the requirements of the Israeli Standard.

1. Anyone interested in being granted a license to mark a commodity with the Standards Mark should submit his request, in duplicate, to SII-Quality and Certification Division. To the request should be attached:
 - a. Drawings and/or pictures and/or any other material which describes reliably the product for which the request is submitted.
 - b. The completed "Questionnaire for Initial Recognition of Supplier".
The information supplied in this questionnaire will be confidential and will not be passed on to a third party unless the Manufacturer consents.
2. Based on the questionnaire, SII will draw up a program for preliminary tests and clarifications, outlining the actions which have to be taken by SII so that the requested license may be granted. It will also include a calculation for the price which the Manufacturer should pay for the actions to be taken. After the Manufacturer has accepted the program for the preliminary tests and clarifications, a suitable invoice will be issued.
3. During the time of the preliminary tests and clarifications, SII will carry out the activities detailed in the program which essentially are:
 - 3.1 Tests of the product to verify its conformity to the Standard.
 - 3.2 Audit of the Manufacturer's plant. The purpose of this visit is:
 - 3.2.1 To get to know directly the production process.
 - 3.2.2 To assess the general conditions under which the production is carried out, including sanitation and cleanliness.
 - 3.2.3 To inspect the Quality System at the plant according to the requirements of Procedure SII-005 (attached).
 - 3.2.4 To ascertain that all the activities are actually carried out and to see whether all procedures are applied.

⁽¹⁾ Everything in this statement referring to Standards Mark, holds also true – with appropriate changes – for SII Specifications.



- 3.2.5 Follow-up of the capabilities of the plant to maintain a constant quality level of its product, including verification of the calibration of the measuring and inspection equipment.
- 3.2.6 To get acquainted with the senior staff at plant and to discuss with them subjects concerning the granting of the license.
- 3.2.7 If required, to take samples of the product for testing in SII's laboratories.
- 3.3 Inspection of the Product File which will be submitted by the Manufacturer (for the Product File requirements see procedure SII – 005 clauses 3.3).
4. At the conclusion of the preliminary tests and clarifications, SII will submit to the appropriate Professional Committee, a report of its activities and its findings.
The Professional Committee's recommendations are submitted to the Licensing Committee for approval.
5. If the Licensing Committee decides to grant the requested license, it will also determine the scope of SII's current supervision of the production and any additional terms for granting the license.
6. Based on the Licensing Committee decision, SII will sign an Agreement with the Manufacturer, outlining in detail the conditions of the supervision, including financial terms.
After signing this Agreement, the manufacturer will fulfill his financial obligations. With the issuance of the license, a notice of issuance will be published accordingly, in the list of issued licenses maintained by SII.
7. SII is entitled to cancel the license any time it is found that the product does not conform to the requirements of the Standard or if the Manufacturer has not fulfilled his other commitments in accordance with the conditions of the Agreement he signed with SII.

⁽²⁾ According to the Standards Mark Regulation, the Technical Committee, after it has examined the report on the activities within framework of the preliminary tests and clarifications, is authorized to recommend to the Licensing Committee the granting of the license. The Licensing Committee is authorized to decide the granting of a license and its calculation.



THE STANDARDS INSTITUTION OF ISRAEL

SII-005

first edition - August 1994

**REQUIREMENTS FOR QUALITY SYSTEMS
OPERATED BY MANUFACTURERS PRODUCING PRODUCTS
BEARING THE STANDARDS MARK**

(In cases of dispute, the Hebrew version is considered the official text)

Ziva Patir
Director General

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1. SCOPE

- 1.1 This documents specifies the quality system requirements for manufacturers who have been certified by Standards Institution of Israel (hereinafter “the Institution”) to mark products with the Standards Mark, or for manufacturers who are interested in obtaining this certification.
- 1.2 The requirements specified in this document apply to manufacturers, in addition to their other to the Institution, as set forth in: the Standards Law – 1953, the Standards Mark, or for manufacturers who are interested in obtaining this certification.
- 1.3 Effective implementation of the requirements specified in this document may ensure long term conformity of the product to the relevant standard; reduce the probability of producing non-conforming producing non-conforming products.
- 1.4 The requirements specified in this document are minimal requirements. Certain products may necessitate setting specific additional requirements, to be determined by the relevant technical committee.
- 1.5 It is emphasized that the use of the Standards Mark by the manufacturer, is a declaration by the manufacturer that the product conforms to the relevant standard. For this reason, the manufacturer must be capable of testing the product he is manufacturing himself, of detecting the incompatible products, of amending the defects that were detected, of determining the reasons for non-conformity, and of taking the necessary action to remove these reasons for non-conformity, so that the defect will not be repeated.
- 1.6 The Institution’s representative shall verify that the quality system requirements set forth in this document are implemented. Nonconformity with these requirements, regardless of whether the product is compatible or incompatible with the Standard, may cause the cancellation of the product’s Standards Mark.

2. DEFINITION

- 2.1 Products – including materials, components, sub-systems, etc. marked with a Standards Mark, or to be marked with a Standards Mark.
- 2.2 Manufacturer – for definition, refer to the Standards Mark Regulations.
- 2.3 Standards – Israel Standards, and Specification, published by the Institution.
- 2.4 Institution Representative – a person who was appointed by the Director of the Quality and Certification Division to represent the Institution regarding a particular issue.

3. REQUIREMENTS

3.1 Management Responsibility

- 3.1.1 The manufacturer's management shall define and document its policy for quality system. This policy shall state the management's commitment to meeting the requirements of the standards relevant to the products and to the requirements specified in this document.
- 3.1.2 The manufacturer's management shall appoint an employee to be responsible for the quality system. This employee shall be at management level, or reporting directly to the management (hereinafter referred to as management Representative).
- 3.1.3 The manufacturer's management shall grant the Management Representative freedom of operation and appropriate authority in order to perform his duties and implement the requirements of this document.
- 3.1.4 The Management Representative shall be the liaison with the Institution on all issues associated with the certification, and especially, in implementation of the requirements specified in this document.
- 3.1.5 The manufacturer's management shall assign appropriate resources and capable manpower, as necessary, to implement the requirements of this document.

3.2 Quality System

- 3.2.1 The manufacturer shall establish and maintain an effective and documented quality system, ensuring that the products conform to the requirements of the Standard. This documented quality system shall incorporate procedures, work instructions, test instructions, and documents consistent with the requirements specified in this document and in the applicable standards.
- 3.2.2 The manufacturer shall prepare a detailed quality plan for each product, to be approved by the Institution's representative. The quality plan shall include, but not be limited to the following details:
 - a. Detailed flow chart of the production process, starting from the acceptance of raw materials and up to the final product, its packaging and storage.
 - b. Indication of the test stations in the production process.

- c. As relevant, details of the stop stations in the process (those test stations from which products are not transferred to the next production phase until tests are run and positive results are obtained).
- d. Details of attributes tested at each test station.
- e. Details of the test equipment and the test procedures used at each test station.
- f. Description of the forms on which the test results are recorded.
- g. Sample size and test frequency at each test station.
- h. Specification of the personnel responsible for carrying out the tests.

3.3 Product File

3.3.1 A product file shall be prepared for each product, specifying, unambiguously, its design.

In general, the product file shall include, as necessary and relevant, the following items:

- a. Product drawing, containing a general description of the product and its major dimensions.
- b. General photographs of the product (from various angles) and photographs of its major components.
- c. In case of electrical appliances, schematic diagrams of the major electrical circuits, where applicable, including wiring diagram indicating wire color marking, terminal marking, etc.
- d. List of major components that details the component type, manufacturer's name, model, name of institutions/laboratories that have approved the component (if any), and the essential technical characteristics of the components.

(note: Major components are those that affect the product's safety, and features that may affect the product's conformity to the Standard).

- e. Specifications of the main materials from which the product is constructed, with special reference to flammable and toxic material.
- f. Catalogs, instruction sheets and any other technical material that may assist in the product specification.

3.3.2 The manufacturer shall maintain the product file. In certain cases, the Institution's representative may request that the product file be retained at the Institution, or that the manufacturer submit the file to the Institution's representative for evaluation and inspection for a short period of time.

3.3.3 The manufacturer shall inform the Institution regarding any essential modification to the product. This modification shall be denoted appropriately in the product file. Changes to the product file shall be approved by the Institution's representative.

3.4 Quality Procedures

3.4.1 The manufacturer shall prepare detailed documented quality procedures that shall describe the quality system maintained by the manufacturer according to the requirements of this document.

3.4.2 The quality procedures shall specify the responsibilities, authorities and mutual relations of all of the manufacturer's functionaries associated with the products.

3.4.3 The quality procedures shall be authorized and signed by the company Director and by the Management Representative.

3.4.4 The quality procedures shall be prepared in accordance with the Israel Standard for writing quality procedures and the Institution's instructions.

(Note: The standard is being prepared concurrent with the publication of this document).

3.5 Customer Order Review

When the products are to be manufactured in accordance with a customer's specific order, the manufacturer shall review the customer's requirements to ensure, among other issues, that these requirements do not conflict with the product's applicable Standard. When any such conflict is found, the manufacturer shall reject the order unless he receives prior approval from the Standard's Mark Board.

3.6 Documentation

3.6.1 The manufacturer shall have in his possession all updated documentation necessary for the production of the products and testing thereof, including standards applicable to the products, drawings, production instructions, test instructions, etc.

3.6.2 The manufacturer shall establish and maintain documented procedures for documentation control. This control shall include, but not be limited to:

- A. Assurance that the pertinent documents are available at all locations where necessary to conduct operations connected to product manufacturing and testing.

- B. Method for updating documentations as necessary.
- C. Appropriate arrangements for prompt removal of obsolete documents, their destruction or unequivocal identification.

3.7 Purchase Control

3.7.1 All purchase orders from suppliers and sub-contractors shall be prepared in writing and contain precise specification of the ordered materials, components, sub-assemblies, processes, etc. (hereinafter referred to as Materials). The purchase order shall also specify the tests to be carried out by the supplier/sub-contractor and the records accompanying the deliverables.

(Note: Supplier: An organization supplying off-the-shelf items;
Sub-contractor: An organization producing the Material, specifically for the Customer, in accordance with the Customer's specifications).

3.7.2 To the extent necessary, the manufacturer shall specify the quality requirements for sub-contractors and the quality systems they should maintain. In these events, the manufacturer shall verify that the sub-contractor actually meets these requirements. The manufacturer shall set procedures for choosing a sub-contractor, on the basis of their quality of work, and shall verify this through follow-up inspection. The manufacturer shall reject any sub-contractor whose quality of work does not meet his requirements.

3.7.3 The manufacturer shall take all steps necessary to assure that purchased Material shall not cause the final product to deviate from the Standard. When the standard specifies requirements for Materials, it is the manufacturer's responsibility to verify their compliance.

3.8 Product Identification and Traceability

The manufacturer shall establish, set and operate a documented method for identifying the products during all stages of productions, delivery and installation. This identification shall include, to the extent applicable:

- a. Identification of the production batch.
- b. Identification of all production phases, the production phase date and the person responsible.
- c. Identification of the materials and components comprising the product.
- d. Quantity of products in the production batch.
- e. Identifications number for each individual product, provided it is required by the Standard.

3.9 Inspection and Testing

3.9.1 General

- 3.9.1.1 The inspections shall be carried out according to drawings, specifications and test instructions, detailed and valid.
- 3.9.1.2 The inspection results shall be documented on forms approved for this purpose, and signed by the person who actually conducted the tests.
- 3.9.1.3 Sampling inspections shall be based on commonly accepted statistical sampling programs.
- 3.9.1.4 The manufacturer shall ensure that the environmental conditions at the test location are suitable for the inspections and tests being carried out, taking into consideration the product, the test accuracy and the Standard's requirements.

3.9.2 Receiving Inspection

- 3.9.2.1 The manufacturer shall carry out receiving inspections for incoming Material from suppliers or sub-contractors. The inspections shall be carried out according to documented specifications that shall specify, among other things, the size of the test sample, the features to be inspected, the inspection/test methods, and the acceptance and rejection criteria.
- 3.9.2.2 The sample size and features to be inspected shall be determined according to the nature of the Material, the supplier's or the sub-contractor's reliability, historical quality records of the Material received from the same source, test reports accompanying the shipment, etc.
- 3.9.2.3 As minimum requirements, the manufacturer shall carry out visual inspections to detect any apparent defect, verify the incoming quantity, and inspect the test reports of the supplier/sub-contractor.

3.9.3 In Process Tests

- 3.9.3.1 The manufacturer shall inspect and test the product at the test stations specified in the product's quality plan.
- 3.9.3.2 At stop stations specified in the product's quality plan, a positive result of the test carried out at the station shall be required for the dispatch of the Material to the next production phase.

3.9.4 Final Inspection

- 3.9.4.1 The manufacturer shall carry out final inspections according to, but not limited to, the quality plan, to complete the evidence of conformity to the finished product to the Standard. When the Standard requires certain tests of the finished product, the manufacturer shall carry out these tests as required.
- 3.9.4.2 The final inspection shall verify that all tests specified for the production process were carried out as required.

3.10 Inspection, Measuring and Test Equipment

- 3.10.1 The manufacturer shall ensure the availability of all inspection, measuring and test equipment (hereinafter referred to as Test Equipment) required for the specified test, in the specified accuracy and in accordance with the product's quality plan. Specifically, the manufacturer shall provide Test Equipment that allows the manufacturer to determine the product's conformity to the standard.

(Note: In order to reach conformance and uniformity between the manufacturer tests and the Institution tests, it is recommended that the manufacturer consult with the Institution representative prior to purchasing new Test Equipment).

- 3.10.2 When expensive Test Equipment is not in the possession of the manufacturer, the manufacturer shall make appropriate arrangements acceptable to the Institution to carry out the required test, at the required frequency, by a laboratory acceptable to the Institution.
- 3.10.3 The Test Equipment shall be calibrated against certified equipment having a known valid relationship to nationally recognized standards. The calibration frequency shall be determined according to the circumstances, and in general annually, unless it has been proved that this frequency may be reduced or must be increased.
- 3.10.4 Where jigs, fixtures, patterns, etc. are used to determine the conformance of the product with the requirements, they are considered to be Test Equipment.
- 3.10.5 The calibration shall be carried out by a laboratory certified by the Institution.

- 3.10.6 The Test Equipment shall be identified by suitable indicators to identify its calibration status. This identification shall include, at least, the following details:
 - a. Last calibration date.
 - b. Next calibration.
 - c. Calibrating laboratory and person names.
- 3.10.7 The manufacturer shall verify that faulty or uncelebrated Test Equipment are neither used by nor accessible to the manufacturer's workers.
- 3.10.8 The manufacturer shall ensure that handling, preservation and storage of Test Equipment are such that their accuracy and fitness for use are maintained.
- 3.10.9 The manufacturer shall maintain an orderly cardfile for Test Equipment listing the Test Equipment technical data, the calibration information and the complete history of repairs and rework to which they were subjected.
- 3.10.10 Despite the aforementioned, it is permissible that Test Equipment used for general purposes only and not for measurement purposes, is not periodically calibrated, provided that each Test Equipment item carries readily apparent indicators indicating that this equipment is not to be used for measurement purposes.

3.11 Inspection and Test Status

- 3.11.1 The inspection and test status shall specify the status of the products according to two criteria:
 - a. The products are pre- or post-test.
 - b. The products have been approved (conforming products) or rejected in the tests.
- 3.11.2 The marking shall be performed by means appropriate to the product and production process, such as, stamping the product itself, a tag attached to the product, a symbol on the accompanying card, etc.
- 3.11.3 In the event that, for technical reasons, the product itself cannot be marked, the marking shall be done by other appropriate means, such as, physical location, color of the storage facilities, etc.
- 3.11.4 Non-conforming products shall be conspicuously marked.

- 3.11.5 The inspection and test status records shall provide identification of the person who determined that status of the product.
- 3.11.6 The manufacturer's procedures shall identify which personnel are authorized to change the status of the non-conforming product.

3.12 Control of Non-conforming Products

- 3.12.1 Products found to be non-conforming to the requirements at any phase of the production process, shall be physically segregated from other production process products and stored in a designated storage area, identified appropriately. When this requirement cannot be met for objective reasons, other extreme measures shall be taken to ensure that no use shall be made of these products unless approved by an authorized person.
- 3.12.2 The manufacturer shall establish procedures to handle non-conforming products, which shall explicitly determine who is authorized to decide what shall be done with them.
- 3.12.3 The manufacturer shall establish and maintain orderly records of non-conforming products discovered during the receiving inspection, the production process, the final inspection, or are found defective by the customers (either as a result of complaints or during the warranty period).
- 3.12.4 Repaired or reworked non-conforming product shall be re-inspected after the completion of the repair/rework.

3.13 Handling, Storage, Packaging and Delivery

- 3.13.1 The manufacturer shall provide appropriate handling equipment so as to prevent damage to the products being handled, or to other products located on the handling route. Personnel associated with mechanized handling shall be qualified for this method of handling, and if required by law, shall have the appropriate certifications.
- 3.13.2 The manufacturer shall provide suitable storage facilities, taking into consideration conditions appropriate to the stored products, to prevent damage or deterioration. Materials shall be separated from final products.
- 3.13.3 Materials shall be properly marked in order to ensure their full and unambiguous identification. In general, Materials that may deteriorate during storage shall be removed from the storage using the "first-in first-out" method.
- 3.13.4 The manufacturer shall ensure that only products that meet all the requirements are stored in the final products storage area. Products shall not be marked with a standards Mark if they do not conform with the Standard.

- 3.13.5 The manufacturer shall inspect the stored materials and products for identification of possible deterioration at appropriate intervals.
- 3.13.6 The manufacturer shall establish and maintain special control procedures for Materials with Limited storage time, and shall dispose of these Materials when their usability has expired.
- 3.13.7 The packaging of the final products shall provide appropriate protection against damage during handling in the production plant, during delivery to the customer, and shall also anticipate the customer's storage conditions. These requirements shall be met even when the Standard does not set forth packaging requirements. Packaging shall verify that all accompanying materials, such as operating instructions and installation accessories, are contained in the package.

3.14 Corrective Action

- 3.14.1 The manufacturer shall make corrective actions in the event of reoccurring quality problems, especially those associated with the conformance of the product to the Standard. These quality problems may be detected at the manufacturer's (at various phases of the production process), following customer complaints, or following tests that were carried out by the Institution.
- 3.14.2 The corrective action shall include investigation to identify the causes for the quality problem, shall set forth the method to remove these causes, and shall take all necessary steps to prevent recurrence of the problem.

3.15 Quality Records

- 3.15.1 All inspection and test activities, starting with the Material inspections and up to the final product inspection, shall be accompanied by appropriate records.
- 3.15.2 The manufacturer shall maintain the test and inspection reports in such a way that they are readily retrievable according to various data elements, such as: date, number of production batch, type of product, etc. The records shall be stored in an appropriate location, taking care that damage, deterioration or loss is prevented.
- 3.15.3 The manufacturer shall establish and maintain a special file for customer complaints, indicting the corrective actions taken consequent to these complaints.

- 3.15.4 The quality records shall be maintained for a minimum period of one year, unless otherwise required by the customer, the Standard, the law, or the Institution.
- 3.15.5 The quality records shall be accessible for inspection and control by the Institution's representative.
- 3.15.6 The requirements of this clause are in addition to the special instructions regarding records that are included in other clauses of this document.

3.16. Personnel Training and Certification

- 3.16.1 The manufacturer shall provide training for those personnel whose activities may affect the product's quality. The training shall cover, as relevant, the manufacturer's quality procedures, production methods, test and inspection methods, the Standard's requirements, the requirements of this document etc.
- 3.16.2 The manufacturer shall provide certification of the personnel associated with activities for which the Standard, or the law, requires certification.
- 3.16.3 The manufacturer shall specify the special activities that strongly affect the product's quality, and shall provide certification of the personnel associated with these activities.
- 3.16.4 The manufacturer shall maintain appropriate records concerning the training and certification of his personnel.
- 3.16.5 When certain physical characteristics of the personnel may adversely affect the product quality, and these personnel are employed in production, these personnel shall be subject to medical tests at appropriate intervals. The manufacturer shall take all precautions in order to prevent personnel having such limitations from being employed in types of work that may result in the production of non-conforming products.