



May 30, 2005

Assistance for manufacturers in preparation of a product file within the Standards Mark framework

1. General

- 1.1 The purpose of this document is to give instructions and recommendations in preparation of a product file as part of the quality documentation that is to be prepared and presented to The Standards Institution of Israel.
- 1.2 The details in this document are based on the requirements of SII Procedure 005 and the recommendations of ISO – 10013.

2. Product file contents

- 2.1 An opening page that contains the manufacturer's name, the product name, date of the file approval by the manufacturer.

2.2 List of the file contents

This list shall include a list of the documents included in the file: name of the document, document no. and revision no. or the date of the last revision. (The no. of pages may also be noted).

2.3 List of the required product documents (according to the degree of application to the product)

2.3.1 Photographs or drawings of the complete product and its principal dimensions.

2.3.2 Drawings detailing the product in its entirety.

2.3.3 Mechanical drawings of the principal components of the product.

2.3.4 Dimensions and sizes.

2.3.5 List of principal components:

- Differentiation between in – house production and the purchasing of components.
- For purchased components: details of catalog no. and name of manufacturer.

2.3.6 Detailed data on materials such as – metals, polymers (plastic materials), rubber products, plastics, composite materials, insulating materials, foamed and/or slabs of polyurethane
Special reference to inflammable and toxic materials.



- 2.3.7 Alternative components including materials.
- 2.3.8 Indication of the components required to be marked with the Standard Mark.
- 2.3.9 Drawings of the markings of the product / marking labels.
- 2.3.10 Unique packaging instructions, as required.
- 2.3.11 Installation instructions, as required.

3. Quality documents included in the quality plan of the product

The quality plan for the product may be included in the quality procedures, either in the product file or as a separate document. The quality plan shall include:

- 3.1 Detailed flow chart of the manufacturing process from the stage of the incoming raw materials until the finished product, its packaging and delivery to the customer.
- 3.2 Indication of the manufacturing stages, inspection stages by the production workers and / or by the quality inspectors.
- 3.3 For each stage and test point:
 - 3.3.1 Details of the properties to be tested and the required results.
 - 3.3.2 Details of the test equipment for performing the tests.
 - 3.3.3 Details of the required records.
 - 3.3.4 Forms for recording the test results.
 - 3.3.5 Details of sample size and frequency of testing.
 - 3.3.6 Persons responsible for performing the tests.
- 3.4 As required, forms for in – process recording, indicating the test that allows the transfer of the product to the next manufacturing stage.
- 3.5 Required reports, mainly when the test results are negative.



4. Approval of product files by The Standards Institution of Israel

- 4.1 Each drawing and document in the product file shall be approved by a stamp and the signature of the applicable laboratory in The Standards Institution of Israel, or another identifying mark for the approval of SII.
- 4.2 The file as a complete file shall be approved by a stamp and signature of the relevant laboratory in The Standards Institution.
- 4.3 As obligated by the agreement between the manufacturer and SII, "The manufacturer shall not make any changes whatsoever in the products, in their components or in the manufacturing process until notification is given to SII and approval is received in advance and in writing from The standards Institution of Israel".