

## ANNEX II

### PROCEDURE FOR CERTIFICATION OF CONFORMITY

#### 5. EC VERIFICATION

- 5.1. EC verification is the procedure whereby the manufacturer or his authorised representative established within the Community ensures and declares that the appliances subject to the provisions of point 3 are in conformity to the type as described in the EC type-examination certification and satisfy the requirements of this Directive that apply to them.
- 5.2. The manufacturer or his authorised representative established within the Community must take all measures necessary in order that the manufacturing process ensures conformity of the appliances to the type as described in the EC type-examination certification and to the requirements of this Directive that apply to them. The manufacturer or his authorised representative established within the Community must affix the CE marking to each appliance and draw up a written declaration of conformity. The declaration of conformity may cover one or more appliances and must be kept by the manufacturer or his authorised representative established within the Community.
- 5.3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the appliance to the requirements of this Directive by examination and testing of every appliance, as specified in point 5.4, or by examination and testing of appliances on a statistical basis, as specified in point 5.5, at the choice of the manufacturer.
- 5.4. Verification by checking and testing of each appliance
  - 5.4.1. All appliances must be individually examined and appropriate tests, as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, must be carried out in order to verify their conformity with the type as described in the EC type-examination certificate and the requirements of this Directive that apply to them.
  - 5.4.2. The notified body must affix, or cause to be affixed, its identification number on each appliance and draw up a written certificate of conformity relating to the tests carried out. The certificate of conformity may cover one or more appliances.
  - 5.4.3. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.
- 5.5. Statistical verification
  - 5.5.1. Manufacturers must present the appliances manufactured in the form of uniform batches and must take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.
  - 5.5.2. Statistical control is as follows:

Appliances are subject to statistical control by attributes. They should be grouped into identifiable batches consisting of units of a single model manufactured under the same conditions. A batch is examined at random intervals. The appliances constituting a sample are examined individually and appropriate tests, as laid down in the respective standard(s) referred to in Article 5, or equivalent tests are carried out to determine whether the batch is to be accepted or rejected.

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A sampling system with the following characteristics is applied:

- a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity percentage of between 0,5 and 1,5 %,
- a limit quality corresponding to a probability of acceptance of 5 %, with a percentage of non-conformity of between 5 and 10 %.

5.5.3. Where batches are accepted, the notified body must affix, or cause to be affixed, its identification number to each appliance and draw up a written certificate of conformity relating to the tests carried out. All appliances in the batch may be placed on the market except for those products from the sample which were found not to be in conformity.

Where a batch is rejected, the notified body must take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the notified body may suspend the statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

5.5.4. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.