

## ANNEX III

### EC DECLARATION OF CONFORMITY

6. For devices for self-testing the manufacturer shall lodge an application for examination of the design with a notified body.

6.1. The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of the directive to be assessed.

It shall include:

- test reports including, where appropriate, results of studies carried out with lay persons,
- data showing the handling suitability of the device in view of its intended purpose for self-testing,
- the information to be provided with the device on its label and its instructions for use.

6.2. The notified body shall examine the application and, if the design conforms to the relevant provisions of this Directive shall issue the applicant with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the design-related requirements of the Directive. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.

6.3. The applicant shall inform the notified body which issued the EC design-examination certificate of any significant change made to the approved design. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. This additional approval shall take the form of a supplement to the EC design-examination certificate.