

## ANNEX III

### EC DECLARATION OF CONFORMITY

1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by section 2 to 5 and additionally, in the case of devices for self-testing, the obligations imposed by section 6, ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 16.