

SCHEDULE 2

Regulations 2(3), 5(2)(e) and 9(1)

(Annex II of Directive 99/5/EC)

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(3)

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy 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 product and draw up a written declaration of conformity.

2. The manufacturer must establish the technical documentation described in point 4 and he or his authorised representative established within the Community must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes.

3. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

4. The technical documentation must enable the conformity of the product with the essential requirements to be assessed. It must cover the design, manufacture and operation of the product, in particular:

- a general description of the product;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 5 have not been applied or do not exist;
- results of design calculations made, examinations carried out, etc.;
- test reports.

5. The manufacturer or his authorised representative must keep a copy of the declaration of conformity with the technical documentation.

6. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.