

SCHEDULE 11

Regulation 10

(Annex VIII of the ATEX Directive)

MODULE: INTERNAL CONTROL OF PRODUCTION

1. This module describes the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in Section 2, ensures and declares that the equipment satisfy the requirements of the Directive applicable to it. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

(2) The manufacturer shall establish the technical documentation described in Section 3 and he or his authorized representative established within the Community shall keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last piece of equipment was manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment on the Community market.

3. Technical documentation shall enable the conformity of the equipment with the relevant requirements of the Directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product. It shall contain:

- a general description of the equipment,
- 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 equipment,
- a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the safety aspects of the Directive where the standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

4. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity with the technical documentation.

5. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees compliance of the manufactured equipment with the technical documentation referred to in Section 2 and with the requirements of the Directive applicable to such equipment.