SCHEDULE 8

ARTICLE 11 OF THE PPE DIRECTIVE

CHECKING OF PPE MANUFACTURED

System for ensuring EC quality of production by means of monitoring

1. The system

(a) Under this procedure the manufacturer submits an application for the approval of his quality-control system to a body of which notification has been given, of his choice.

That application shall include:

— all the information relating to the category of PPE concerned, including, where appropriate, documentation relating to the model approved,

— documentation on the quality-control system,

— the undertaking to maintain the obligations arising from the quality-control system and to maintain its adequacy and efficiency.

(b) Under the quality-control system, each PPE shall be examined and the appropriate tests referred to in Section A paragraph 3 shall be carried out to check their conformity to the relevant basic requirements of this Directive.

The documentation on the quality-control system shall in particular include an adequate description of:

— the quality objectives, the organisation chart, the responsibilities of executives and their powers in respect of product quality,

— the checks and tests which must be carried out after manufacture,

— the means to be employed to check the efficient operation of the quality-control system.

(c) The body shall assess the quality-control system to determine whether it satisfies the provisions referred to in paragraph 1(b). It shall assume that quality-control systems applying the relevant harmonised standard satisfy those provisions.

The body carrying out audits shall make all necessary objective evaluations of the components of the quality-control system and shall check in particular whether the system ensures conformity of PPE manufactured with the approved model.

The decision shall be communicated to the manufacturer. It shall include the conclusions of the check and the reasoned assessment decision.

(d) The manufacturer shall inform the body which approved the quality-control system of any plan to alter the quality-control system.

The body shall examine the proposed changes and decide whether the altered quality-control system satisfies the relevant provisions. It shall communicate its decision to the manufacturer. The communication shall include the conclusions of the check and the reasoned assessment decision.