SCHEDULES

SCHEDULE 2

Regulation 9(b)(i)

Module A: internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 to 5 of this Schedule, and ensures and declares on the manufacturer's sole responsibility that the apparatus concerned satisfies the requirements of these Regulations that apply to it.

Electromagnetic compatibility assessment

2. The manufacturer must perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in paragraph 1 of Schedule 1.

3. The electromagnetic compatibility assessment must take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment must confirm whether the apparatus meets the essential requirements set out in paragraph 1 of Schedule 1 in all the possible configurations identified by the manufacturer as representative of its intended use.

Technical documentation

4. The manufacturer must establish the technical documentation. The documentation must make it possible to assess the conformity of the apparatus to the relevant requirements, and must include an adequate analysis and assessment of the risks.

5. The technical documentation must specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation must, wherever applicable, contain at least the following elements—

(a) a general description of the apparatus;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of a partly applied harmonised standard, the technical documentation must specify the parts of the standard that have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

Manufacturing

6. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure the compliance of the manufactured apparatus with the technical documentation referred to in paragraphs 4 and 5 of this Schedule and the essential requirements set out in paragraph 1 of Schedule 1.

CE marking and EU declaration of conformity

7. The manufacturer must affix the CE marking to each individual apparatus that satisfies the applicable requirements of these Regulations,

8. The manufacturer must draw up a written EU declaration of conformity for an apparatus model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity must identify the apparatus model for which it has been drawn up.

Authorised Representative

9. The manufacturer's obligations set out in paragraphs 7 and 8 may be fulfilled by the authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.