ANNEX II

MODULE A:INTERNAL PRODUCTION CONTROL

1. ‘Internal production control’ is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument’s conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured instruments with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

4. **Conformity marking and EU declaration of conformity**

4.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive to each individual measuring instrument that satisfies the applicable requirements of this Directive.

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

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

5. **Authorised representative**

The manufacturer’s obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.