

ANNEX VI

INTERNAL CONTROL OF PRODUCTION WITH ASSESSMENT OF
TECHNICAL DOCUMENTATION AND PERIODICAL CHECKING

1. This Annex describes the procedure whereby the manufacturer, or his authorised representative established in the Community, who carries out the obligations laid down in points 2, 5 and 6 ensures and declares that the equipment concerned satisfies the requirements of this Directive. The manufacturer, or his authorised representative established in the Community, must affix the CE marking of conformity and the indication of the guaranteed sound power level as required in Article 11 to each piece of equipment and draw up a written EC declaration of conformity as required in Article 8.
2. The manufacturer, or his authorised representative established in the Community, must draw up the technical documentation described in point 3 and he 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 for inspection purposes. The manufacturer, or his authorised representative established in the Community, may entrust another person to keep the technical documentation. In this case he has to include the name and address of this person in the EC declaration of conformity.
3. The technical documentation must enable the conformity of the equipment with the requirements of this Directive to be assessed. It must contain at least the following information:
 - name and address of the manufacturer or his authorised representative established in the Community
 - a description of the equipment
 - make
 - trade name
 - type, series and numbers
 - the technical data relevant for the identification of the equipment and the assessment of its noise emission, including, if appropriate, schematic drawings and any description and explanation necessary for their understanding
 - the reference to this Directive
 - the technical report of noise measurements carried out in accordance with the provisions of this Directive
 - the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level.
4. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured equipment with the technical documentation referred to in points 2 and 3 and with the requirements of this Directive.
5. Evaluation by the notified body prior to placing on the market

The manufacturer, or his authorised representative established in the Community, shall present a copy of his technical documentation to a notified body of his choice before the first item of equipment is placed on the market or put into service.

If there are doubts about the plausibility of the technical documentation, the notified body shall inform accordingly the manufacturer or his authorised representative established in the Community, and, if need be, carry out, or have carried out modifications to the technical documentation, or possibly, tests deemed necessary.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

After the notified body has issued a report confirming that the technical documentation satisfies the provisions of this Directive, the manufacturer or his authorised representative established within the Community may affix the CE marking to the equipment and issue an EC declaration of conformity in accordance with Articles 11 and 8, for which he will bear complete responsibility.

6. Evaluation by the notified body during production

The manufacturer, or his authorised representative established in the Community, shall further involve the notified body in the production phase according to one of the following procedures to be chosen by the manufacturer or his authorised representative established within the Community:

- the notified body shall carry out periodical checks in order to verify continuing compliance of the manufactured equipment with the technical documentation and with the requirements of this Directive; in particular the notified body shall concentrate on:
 - the correct and complete marking of the equipment according to Article 11,
 - issuing of the EC declaration of conformity according to Article 8,
 - the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level,

The manufacturer, or his authorised representative established in the Community, shall give the notified body free access to all the internal documentation supporting these procedures, the actual results of the internal audits and the corrective actions which have been taken, if any.

Only if the above checks give unsatisfactory results shall the notified body carry out noise tests, which, on its own judgement and experience, may be simplified or completely carried out according to the provisions laid down in Annex III for the relevant type of equipment,

- the notified body shall carry out or have carried out product checks at random intervals. An adequate sample of the final equipment, chosen by the notified body, must be examined and appropriate noise tests as set out in Annex III, or equivalent tests, must be carried out to check the conformity of the product with the relevant requirements of the Directive. The product checking must include the following aspects:
 - the correct and complete marking of the equipment according to Article 11,
 - issuing of the EC declaration of conformity according to Article 8.

In both procedures, the frequency of the checks shall be defined by the notified body according to the results of previous evaluations, the need to monitor corrective actions and further guidance for the frequency of the checks that may be given by the yearly production and the general reliability of the manufacturer to maintain the guaranteed values; however a check shall be carried out at least once every three years.

If there are doubts about the plausibility of the technical documentation or the adherence during production, the notified body shall inform accordingly the manufacturer, or his authorised representative established in the Community.

In those cases where equipment checked does not conform to the provisions of this Directive, the notified body must inform the notifying Member State.