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- the risk assessment documentation showing the procedure followed, including:
 - (i) a list of the essential health and safety requirements applied and fulfilled,
 - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,
 - (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
 - (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
 - (v) a copy of the assembly instructions for the partly completed machinery;
- (b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.

ANNEX VIII**ASSESSMENT OF CONFORMITY WITH INTERNAL CHECKS
ON THE MANUFACTURE OF MACHINERY**

1. This Annex describes the procedure by which the manufacturer or his authorised representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.
2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.
3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.

ANNEX IX**EC TYPE-EXAMINATION**

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the "type") satisfies the provisions of this Directive.

1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.

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2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, where appropriate, his authorised representative,
- a written declaration that the application has not been submitted to another notified body,
- the technical file.

Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.

3. The notified body shall:

- 3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those elements whose design is not based on the relevant provisions of those standards;
- 3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied;
- 3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;
- 3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.

4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.

The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.

5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.

6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.

7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.

8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.

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9. Validity of the EC type-examination certificate
- 9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.
- 9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.
- 9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.
- If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.
- The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.
- 9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.

ANNEX X

FULL QUALITY ASSURANCE

This Annex describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.

1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2, and shall be subject to the surveillance referred to in point 3.
2. Quality system
- 2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.
- The application shall contain:
- the name and address of the manufacturer and, where appropriate, his authorised representative;
 - the places of design, manufacture, inspection, testing and storage of the machinery;
 - the technical file described in Annex VII, *Part A*, for one model of each category of machinery referred to in Annex IV which he intends to manufacture;
 - the documentation on the quality system;
 - a written declaration that the application has not been submitted to another notified body.
- 2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.