5.6. EXHAUST EMISSIONS

Exhaust emissions from internal combustion engines must not be discharged upwards.

6. *SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS*

Machinery presenting hazards due to the lifting of persons must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

6.1. GENERAL

6.1.1. ***Mechanical strength***

The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.

6.1.2. ***Loading control for machinery moved by power other than human strength***

The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2. CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices.

The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.

6.3. RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1. ***Risks due to movements of the carrier***

Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.

6.3.2. ***Risk of persons falling from the carrier***

The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving.

Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.

If the measures referred to in section 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment against falls from a height.

Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.

6.3.3. ***Risk due to objects falling on the carrier***

Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.

6.4. MACHINERY SERVING FIXED LANDINGS

6.4.1. ***Risks to persons in or on the carrier***

The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.

The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.

6.4.2. ***Controls at landings***

Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:

— the control devices in the carrier are being operated,

— the carrier is not at a landing.

6.4.3. ***Access to the carrier***

The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

6.5. MARKINGS

The carrier must bear the information necessary to ensure safety including:

— the number of persons permitted on the carrier,

— the maximum working load.

ANNEX II

Declarations

1. **CONTENT**

A. EC DECLARATION OF CONFORMITY OF THE MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:

1. business name and full address of the manufacturer and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the technical file, who must be established in the Community;
3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the *Official Journal of the European Union;*
5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate;
6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X;
7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);
8. where appropriate, the reference to other technical standards and specifications used;
9. the place and date of the declaration;
10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;
3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;
4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the *Official Journal of the European Union;*
5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;
6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;
7. the place and date of the declaration;
8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

2. **CUSTODY**

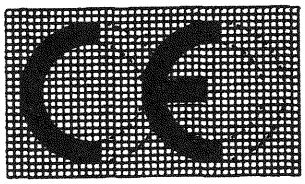
The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.

The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.

ANNEX III

CE marking

The CE conformity marking shall consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.

Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.

ANNEX IV

Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:

1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;

1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;

1.3 sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;

1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.

2. Hand-fed surface planing machinery for woodworking.

3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.

4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:

4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;

4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.

5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.

6. Hand-fed tenoning machinery with several tool holders for woodworking.

7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.

8. Portable chainsaws for woodworking.

9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

10. Injection or compression plastics-moulding machinery with manual loading or unloading.

11. Injection or compression rubber-moulding machinery with manual loading or unloading.

12. Machinery for underground working of the following types:

12.1. locomotives and brake-vans;

12.2. hydraulic-powered roof supports.

13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Removable mechanical transmission devices including their guards.

15. Guards for removable mechanical transmission devices.

16. Vehicle servicing lifts.

17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.

18. Portable cartridge-operated fixing and other impact machinery.

19. Protective devices designed to detect the presence of persons.

20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.

21. Logic units to ensure safety functions.

22. Roll-over protective structures (ROPS).

23. Falling-object protective structures (FOPS).

ANNEX V

Indicative list of the safety components referred to in Article 2(c)

1. Guards for removable mechanical transmission devices.
2. Protective devices designed to detect the presence of persons.
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.
6. Extraction systems for machinery emissions.
7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.
8. Monitoring devices for loading and movement control in lifting machinery.
9. Restraint systems to keep persons on their seats.
10. Emergency stop devices.
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.
13. Systems and devices to reduce the emission of noise and vibrations.
14. Roll-over protective structures (ROPS).
15. Falling-object protective structures (FOPS).
16. Two-hand control devices.
17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:
    (a) devices for locking landing doors;
    (b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
    (c) overspeed limitation devices;
    (d) energy-accumulating shock absorbers,
        — non-linear, or
        — with damping of the return movement;
    (e) energy-dissipating shock absorbers;
    (f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
    (g) electric safety devices in the form of safety switches containing electronic components.

ANNEX VI

Assembly instructions for partly completed machinery

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

ANNEX VII

A. **Technical file for machinery**

This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.

1. The technical file shall comprise the following:

   (a) a construction file including:

   — a general description of the machinery,

   — the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,

   — full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,

   — the documentation on risk assessment demonstrating the procedure followed, including:

   (i) a list of the essential health and safety requirements which apply to the machinery,

   (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,

   — the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

   — 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,

   — a copy of the instructions for the machinery,

   — where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,

   — where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,

   — a copy of the EC declaration of conformity;

   (b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.

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

2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

   The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.

   The technical file does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.

3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.

B. **Relevant technical documentation for partly completed machinery**

This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

It shall comprise the following:

(a) a construction file including:

— the overall drawing of the partly completed machinery and drawings of the control circuits,

— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,

— 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.

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.

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.

It must contain, in particular, an adequate description of:

— the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,

— the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are fulfilled,

— the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by this Directive,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,

— the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2.

The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.

The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3. Surveillance under the responsibility of the notified body

3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:

— the documentation concerning the quality system,

— the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,

— the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.

3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:

— the results of previous surveillance visits,

— the need to monitor remedial measures,

— where appropriate, special conditions attaching to approval of the system,

— significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.

4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:

— the documentation referred to in point 2.1,

— the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4.

ANNEX XI

Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.
4. The staff responsible for inspection shall have:
   — sound technical and vocational training,
   — satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
   — the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.
8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.
9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.

ANNEX XII

Correlation table [1]

Directive 98/37/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)(a)	Article 2(a) and (b)
Article 1(2)(b)	Article 2(c)
Article 1(3)	Article 1(2)
Article 1(4)	Article 3
Article 1(5)	—
Article 2(1)	Article 4(1)
Article 2(2)	Article 15
Article 2(3)	Article 6(3)
Article 3	Article 5(1)(a)
Article 4(1)	Article 6(1)
Article 4(2), first subparagraph	Article 6(2)
Article 4(2), second subparagraph	—
Article 4(3)	—
Article 5(1), first subparagraph	Article 7(1)
Article 5(1), second subparagraph	—
Article 5(2), first subparagraph	Article 7(2) and (3)
Article 5(2), last subparagraph	—
Article 5(3)	Article 7(4)
Article 6(1)	Article 10
Article 6(2)	Article 22
Article 7(1)	Article 11(1) and (2)
Article 7(2)	Article 11(3) and (4)
Article 7(3)	Article 11(4)
Article 7(4)	Article 11(5)
Article 8(1), first subparagraph	Article 5(1)(e) and Article 12(1)
Article 8(1), second subparagraph	Article 5(1)(f)
Article 8(2)(a)	Article 12(2)
Article 8(2)(b)	Article 12(4)
Article 8(2)(c)	Article 12(3)
Article 8(3)	—
Article 8(4)	—
Article 8(5)	—

[1] This table indicates the relation between parts of Directive 98/37/EC and the parts of this Directive that deal with the same subject. However, the content of the correlated parts is not necessarily identical.

Directive 98/37/EC	This Directive
Article 8(6)	Article 5(4)
Article 8(7)	—
Article 8(8)	—
Article 9(1), first subparagraph	Article 14(1)
Article 9(1), second subparagraph	Article 14(4)
Article 9(2)	Article 14(3) and (5)
Article 9(3)	Article 14(8)
Article 10(1 to 3)	Article 16(1) to (3)
Article 10(4)	Article 17
Article 11	Article 20
Article 12	Article 21
Article 13(1)	Article 26(2)
Article 13(2)	—
Article 14	—
Article 15	Article 28
Article 16	Article 29
Annex I — Preliminary observation 1	Annex I — General Principles point 2
Annex I — Preliminary observation 2	Annex I — General Principles point 3
Annex I — Preliminary observation 3	Annex I — General Principles point 4
Annex I, Part 1	Annex I, Part 1
Annex I, Section 1.1.	Annex I, Section 1.1.
Annex I, Section 1.1.1.	Annex I, Section 1.1.1.
Annex I, Section 1.1.2.	Annex I, Section 1.1.2.
Annex I, Section 1.1.2(d)	Annex I, Section 1.1.6.
Annex I, Section 1.1.3.	Annex I, Section 1.1.3.
Annex I, Section 1.1.4.	Annex I, Section 1.1.4.
Annex I, Section 1.1.5.	Annex I, Section 1.1.5.
Annex I, Section 1.2.	Annex I, Section 1.2.
Annex I, Section 1.2.1.	Annex I, Section 1.2.1.
Annex I, Section 1.2.2.	Annex I, Section 1.2.2.
Annex I, Section 1.2.3.	Annex I, Section 1.2.3.
Annex I, Section 1.2.4.	Annex I, Section 1.2.4.
Annex I, Section 1.2.4., paragraphs 1 to 3	Annex I, Section 1.2.4.1.
Annex I, Section 1.2.4., paragraphs 4 to 6	Annex I, Section 1.2.4.3.
Annex I, Section 1.2.4., paragraph 7	Annex I, Section 1.2.4.4.
Annex I, Section 1.2.5.	Annex I, Section 1.2.5.

Directive 98/37/EC	This Directive
Annex I, Section 1.2.6.	Annex I, Section 1.2.6.
Annex I, Section 1.2.7.	Annex I, Section 1.2.1.
Annex I, Section 1.2.8.	Annex I, Section 1.1.6.
Annex I, Section 1.3	Annex I, Section 1.3
Annex I, Section 1.3.1.	Annex I, Section 1.3.1.
Annex I, Section 1.3.2.	Annex I, Section 1.3.2.
Annex I, Section 1.3.3.	Annex I, Section 1.3.3.
Annex I, Section 1.3.4.	Annex I, Section 1.3.4.
Annex I, Section 1.3.5.	Annex I, Section 1.3.5.
Annex I, Section 1.3.6.	Annex I, Section 1.3.6.
Annex I, Section 1.3.7.	Annex I, Section 1.3.7.
Annex I, Section 1.3.8	Annex I, Section 1.3.8.
Annex I, Section 1.3.8 A	Annex I, Section 1.3.8.1.
Annex I, Section 1.3.8 B	Annex I, Section 1.3.8.2.
Annex I, Section 1.4.	Annex I, Section 1.4.
Annex I, Section 1.4.1.	Annex I, Section 1.4.1.
Annex I, Section 1.4.2.	Annex I, Section 1.4.2.
Annex I, Section 1.4.2.1.	Annex I, Section 1.4.2.1.
Annex I, Section 1.4.2.2.	Annex I, Section 1.4.2.2.
Annex I, Section 1.4.2.3.	Annex I, Section 1.4.2.3.
Annex I, Section 1.4.3.	Annex I, Section 1.4.3.
Annex I, Section 1.5.	Annex I, Section 1.5.
Annex I, Section 1.5.1.	Annex I, Section 1.5.1.
Annex I, Section 1.5.2.	Annex I, Section 1.5.2.
Annex I, Section 1.5.3.	Annex I, Section 1.5.3.
Annex I, Section 1.5.4.	Annex I, Section 1.5.4.
Annex I, Section 1.5.5.	Annex I, Section 1.5.5.
Annex I, Section 1.5.6.	Annex I, Section 1.5.6.
Annex I, Section 1.5.7.	Annex I, Section 1.5.7.
Annex I, Section 1.5.8.	Annex I, Section 1.5.8.
Annex I, Section 1.5.9.	Annex I, Section 1.5.9.
Annex I, Section 1.5.10.	Annex I, Section 1.5.10.
Annex I, Section 1.5.11.	Annex I, Section 1.5.11.
Annex I, Section 1.5.12.	Annex I, Section 1.5.12.
Annex I, Section 1.5.13.	Annex I, Section 1.5.13.
Annex I, Section 1.5.14.	Annex I, Section 1.5.14.

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Annex I, Section 1.5.15.	Annex I, Section 1.5.15.
Annex I, Section 1.6.	Annex I, Section 1.6.
Annex I, Section 1.6.1.	Annex I, Section 1.6.1.
Annex I, Section 1.6.2.	Annex I, Section 1.6.2.
Annex I, Section 1.6.3.	Annex I, Section 1.6.3.
Annex I, Section 1.6.4.	Annex I, Section 1.6.4.
Annex I, Section 1.6.5.	Annex I, Section 1.6.5.
Annex I, Section 1.7.	Annex I, Section 1.7.
Annex I, Section 1.7.0.	Annex I, Section 1.7.1.1.
Annex I, Section 1.7.1.	Annex I, Section 1.7.1.2.
Annex I, Section 1.7.2.	Annex I, Section 1.7.2.
Annex I, Section 1.7.3.	Annex I, Section 1.7.3.
Annex I, Section 1.7.4.	Annex I, Section 1.7.4.
Annex I, Section 1.7.4.(b) and (h)	Annex I, Section 1.7.4.1.
Annex I, Section 1.7.4.(a) and (c) and (e) to (g)	Annex I, Section 1.7.4.2.
Annex I, Section 1.7.4.(d)	Annex I, Section 1.7.4.3.
Annex I, Part 2	Annex I, Part 2
Annex I, Section 2.1.	Annex I, Section 2.1.
Annex I, Section 2.1., paragraph 1	Annex I, Section 2.1.1.
Annex I, Section 2.1., paragraph 2	Annex I, Section 2.1.2.
Annex I, Section 2.2.	Annex I, Section 2.2.
Annex I, Section 2.2., paragraph 1	Annex I, Section 2.2.1.
Annex I, Section 2.2., paragraph 2	Annex I, Section 2.2.1.1.
Annex I, Section 2.3.	Annex I, Section 2.3.
Annex I, Part 3	Annex I, Part 3
Annex I, Section 3.1.	Annex I, Section 3.1.
Annex I, Section 3.1.1.	Annex I, Section 3.1.1.
Annex I, Section 3.1.2.	Annex I, Section 1.1.4.
Annex I, Section 3.1.3.	Annex I, Section 1.1.5.
Annex I, Section 3.2.	Annex I, Section 3.2.
Annex I, Section 3.2.1.	Annex I, Section 1.1.7. and 3.2.1.
Annex I, Section 3.2.2.	Annex I, Sections 1.1.8. and 3.2.2.
Annex I, Section 3.2.3.	Annex I, Section 3.2.3.
Annex I, Section 3.3.	Annex I, Section 3.3.
Annex I, Section 3.3.1.	Annex I, Section 3.3.1.
Annex I, Section 3.3.2.	Annex I, Section 3.3.2.