ANNEX XII

CONFORMITY TO TYPE BASED ON PRODUCTION QUALITY ASSURANCE FOR LIFTS(module D)

1. Conformity to type based on production quality assurance for lifts is the part of the conformity assessment procedure whereby a notified body assesses the production quality system of an installer to ensure that the lifts installed are in conformity with the approved type as described in the EU-type examination certificate or with a lift designed and manufactured under a quality system approved in accordance with Annex XI, and satisfy the applicable essential health and safety requirements set out in Annex I.

2. **Obligations of the installer**

The installer shall operate an approved quality system for manufacture, assembly, installation, final inspection and testing of the lifts as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The installer shall lodge an application for assessment of his quality system with a single notified body of his choice.

The application shall include:

(a) the name and address of the installer, and, if the application is lodged by the authorised representative, his name and address as well;

(b) all relevant information for the lifts to be installed;

(c) the documentation on the quality system;

(d) the technical documentation of the lifts to be installed;

(e) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the lifts with the applicable essential health and safety requirements set out in Annex I.

All the elements, requirements and provisions adopted by the installer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

(a) the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the product quality;

(b) the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after installation;

(d) the quality records, such as inspection reports and test data, calibration data, reports on the qualification of the personnel concerned;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

The auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Annex I.

The audit shall include an assessment visit to the installer's premises and a visit to an installation site.

The decision shall be notified to the installer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The installer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

3.4.1. The installer shall keep the notified body that has approved the quality system informed of any intended change to the system.

3.4.2. The notified body shall assess the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify its decision to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Articles 18 and 19.

4. **Surveillance under the responsibility of the notified body**

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

4.2. The installer shall, for assessment purposes, allow the notified body access to the manufacture, assembly, installation, inspection, testing and storage locations, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation;

(c) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned.

4.3. The notified body shall carry out periodic audits to make sure that the installer maintains and applies the quality system and shall provide the installer with an audit report.

4.4. Additionally, the notified body may pay unexpected visits to the installer. During such visits the notified body may, where necessary carry out tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body

shall provide the installer with a visit report and, if tests have been carried out, with a test report.

5. The installer shall, keep at the disposal of the national authorities for a period ending 10 years after the lift has been placed on the market:

(a) the documentation referred to in point 3.1(c);

(b) the technical documentation referred to in point 3.1(d);

(c) the information relating to the changes referred to in point 3.4.1;

(d) the decisions and reports from the notified body which are referred to in the second paragraph of point 3.4.2, and in points 4.3 and 4.4.

6. Each notified body shall inform its notifying authority of quality system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of approval decisions refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approval decision(s) which it has refused, suspended or withdrawn, and, upon request, of approval decision(s) which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of quality system approval decision(s) issued.

7. **CE marking and EU declaration of conformity**

7.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.

7.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. **Authorised representative**

The installer's obligations set out in points 3.1, 3.4.1, 5 and 7 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.