ANNEX VII

CONFORMITY BASED ON FULL QUALITY ASSURANCE FOR SAFETY COMPONENTS FOR LIFTS(module H)

1. Conformity based on full quality assurance for safety components for lifts is the conformity assessment procedure whereby a notified body assesses the quality system of a manufacturer to ensure that the safety components for lifts are designed, manufactured, inspected and tested in order to satisfy the applicable requirements of Annex I and to enable a lift to which they are correctly incorporated to satisfy those requirements.

2. **Obligations of the manufacturer**

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

3. **Quality system**

3.1. The manufacturer 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 manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) the address of the premises where the safety components for lifts are designed, manufactured, inspected and tested;

(c) all relevant information on safety components for lifts to be manufactured;

(d) the technical documentation described in point 3 of Annex IV, Part A for one model of each category of safety component for lifts to be manufactured;

(e) the documentation on the quality system;

(f) 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 safety components for lifts with the conditions referred to in point 1. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This 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 design and product quality;

(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied or not applied in full, the means, including other relevant technical specifications, that will be used to ensure that the conditions referred to in point 1 will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the safety components for lifts;

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

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

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

(g) the means of monitoring the achievement of the required design and 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 systems that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, 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 manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1(d) to verify the manufacturer's ability to identify the applicable essential health and safety requirements set out in Annex I and to carry out the necessary examinations with a view to ensuring compliance of the safety components for lifts with those requirements.

The decision shall be notified to the manufacturer and, where appropriate, to his authorised representative. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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

3.5. The manufacturer shall keep the notified body which has approved the quality system informed of any intended change to the quality system.

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

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

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

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

(a) the quality system documentation;

(b) the quality records provided for in the design part of the quality system such as results of analyses, calculations, tests;

(c) the technical documentation for the safety components for lifts manufactured;

(d) the quality records provided for in the manufacturing part of the full quality system, 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 manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may, where 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 tests have been carried out, with a test report.

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

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual safety component for lifts that meets the conditions referred to in point 1.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each safety component for lifts and keep a copy of it at the disposal of the national authorities for 10 years after the safety component for lifts has been placed on the market. The EU declaration of conformity shall identify the safety component for lifts for which it has been drawn up.

6. The manufacturer shall, for a period ending 10 years after the safety component for lifts has been placed on the market, keep at the disposal of the national authorities:

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

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

(c) the information relating to the change referred to in the first paragraph of point 3.5;

(d) the decisions and reports from the notified body referred to in the third paragraph of point 3.5. and in points 4.3 and 4.4.

7. 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 decisions which it has refused, suspended or withdrawn and, upon request, of approval decisions 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.

The notified body shall keep a copy of the approval decision issued, its annexes and additions, as well as the technical documentation for 15 years from the date of their issue.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.