SCHEDULE 11

Regulation 2(1)

(Annex XII to the Lifts Directive) PRODUCT QUALITY ASSURANCE FOR LIFTS (module E)

1. Product quality assurance is the procedure whereby the installer of a lift who satisfies Section 2 ensures and declares that the lifts installed are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that apply to them.

The installer of a lift must affix the CE marking to each lift and draw up an EC declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.

2. The installer of a lift must apply an approved quality assurance system for final inspection of the lift and testing as specified in Section 3, and must be subject to surveillance as specified in Section 4

3 Quality assurance system

(3.1) The installer of a lift must lodge an application for assessment of his quality assurance system for the lifts concerned with a notified body of his choice.

The application must include:

- all relevant information for the lifts envisaged,
- the documentation on the quality assurance system,
- the technical documentation on the approved lifts and a copy of the EC type-examination certificates.
- (3.2) Under the quality assurance system, each lift must be examined and appropriate tests as set out in the relevant standards referred to in Article 5 or equivalent tests must be carried out in order to ensure its conformity to the relevant requirements of the Directive.

All the elements, requirements and provisions adopted by the installer of a lift must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality assurance system documentation must ensure a common understanding of the quality programmes, plans, manuals and quality records.

It must contain in particular an adequate description of:

- (a) the quality objectives,
- (b) the organisational structure, responsibilities and powers of the management with regard to lift quality,
- (c) the examinations and tests that will be carried out before placing on the market, including at the very least the tests laid down in Annex VI, 4(b),
- (d) the means to verify the effective operation of the quality assurance system,
- (e) quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.
- (3.3) The notified body must assess the quality assurance system to determine whether it satisfies the requirements referred to in Section 3.2. It must presume conformity with these requirements in respect of quality assurance systems that implement the relevant harmonized standard(1).

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⁽¹⁾ This harmonised standard will be EN 29003, supplemented where necessary to take account of the specific features of the lifts.

The auditing team must have at least one member with experience of assessment in the lift technology concerned. The assessment procedure must include a visit to the premises of the lift installer and a visit to the installation site.

The decision must be notified to the lift installer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

(3.4) The installer of a lift must undertake to discharge the obligations arising from the quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

The installer of a lift must keep the notified body which has approved the quality assurance system informed of any intended updating of the quality assurance system.

The notified body must assess the modifications proposed and decide whether the modified quality assurance system still satisfies the requirements referred to in Section 3.2 or whether a reassessment is required.

It must notify its decision to the lift installer. The notification must contain the conclusions of the examination 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 installer of a lift duly fulfils the obligations arising out of the approved quality assurance system.
- (4.2) The installer of a lift must allow the notified body access for inspection purposes to the inspection and testing locations and provide it with all necessary information, in particular:
 - the quality assurance system documentation,
 - the technical documentation,
 - the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.
- (4.3) The notified body must periodically carry out audits to ensure that the installer of a lift maintains and applies the quality assurance system and must provide an audit report to the lift installer.
 - (4.4) Additionally, the notified body may pay unexpected visits to the lift installation sites.

At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality assurance system where necessary and of the lift; it must provide the lift installer with a visit report and, if a test has been carried out, with a test report.

- **5.** The installer of a lift must, for a period of 10 years after the last lift has been manufactured, keep at the disposal of the national authorities:
 - the documentation referred to in the third indent of the second paragraph of Section 3.1,
 - the updating referred to in the second paragraph of Section 3.4,
 - the decisions and reports from the notified body which are referred to in the final paragraph of Section 3.4 and in Sections 4.3 and 4.4.
- **6.** Each notified body must forward to the other notified bodies the relevant information concerning the quality assurance system approvals issued and withdrawn.