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ANNEXES 1 to 11

ANNEXES

to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on cableway installations

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ANNEX I

SUBSYSTEMS

A cableway installation is divided up into infrastructure and the subsystems listed below, with exploitability and maintainability having to be taken into account in each case:

1. Cables and cable connections.
2. Drives and brakes.
3. Mechanical equipment:
3.1. Cable winding gear.
3.2. Station machinery.
3.3. Line engineering.
4. Vehicles:
4.1. Cabins, seats or drag devices.
4.2. Suspension gear.
4.3. Driving gear.
4.4. Connections to the cable.
5. Electrotechnical devices:
5.1. Monitoring, control and safety devices.
5.2. Communication and information equipment.
5.3. Lightning protection equipment.
6. Rescue equipment:
6.1. Fixed rescue equipment.
6.2. Mobile rescue equipment.

ANNEX II

ESSENTIAL REQUIREMENTS

1. Purpose

This Annex sets out the essential requirements, including maintainability and operability, applicable to the design, construction and entry into service of cableway installations.

2. General requirements

2.1. Safety of persons

The safety of users, workers and third parties is a fundamental requirement for the design, construction and operation of cableway installations.

2.2. Principles of safety

All cableway installations shall be designed, operated and serviced in accordance with the following principles, which are to be applied in the order given:

– eliminate or, if that is not possible, reduce risks by means of design and construction features,

– define and implement all necessary measures to protect against risks which cannot be eliminated by the design and construction features,

– define and state the precautions which should be taken to avoid the risks which it has not been possible to eliminate completely by means of the provisions and measures referred to in the first and second indents.

2.3. Consideration of external factors

Cableway installations must be so designed and constructed as to make it possible to operate them safely, taking into account the type of cableway installation, the nature and physical features of the terrain on which it is installed, its surroundings and atmospheric and meteorological factors, as well as possible structures and obstacles located in the vicinity either on the ground or in the air.

2.4. Dimensions

The cableway installation, the subsystems and all its safety components shall be dimensioned, designed and constructed to withstand, with a sufficient degree of safety, all stresses encountered under all foreseeable conditions, including those which occur when not in operation, and taking account in particular of outside influences, dynamic effects and fatigue phenomena, while complying with the acknowledged rules of the art, in particular with regard to the choice of materials.

2.5. Assembly

2.5.1. The cableway installation, the subsystems and all the safety components shall be designed and constructed in such a way as to ensure that they can be safely assembled and put into place.

2.5.2. The safety components shall be so designed as to make assembly mistakes impossible, either as a result of construction or by means of appropriate markings on the components themselves.

2.6. Integrity of the cableway installation

2.6.1. The safety components shall be designed and constructed and be usable in such a way as to ensure that, in every case, their own operational integrity and/or the safety of the cableway installation is ensured, as defined in the safety analysis in Annex III, so that their failure is highly improbable and with an adequate safety margin.

2.6.2. The cableway installation shall be designed and constructed in such a way as to ensure that, during its operation, any failure of a component which might affect safety, even indirectly, is met by an appropriate measure being taken in good time.

2.6.3. The safeguards referred to in points 2.6.1 and 2.6.2 shall apply throughout the period between two scheduled inspections of the component concerned. The time period for the scheduled inspection of the safety components shall be clearly indicated in the instruction manual.

2.6.4. Safety components which are incorporated into cableway installations as spare parts shall satisfy the essential requirements of this Regulation and the conditions relating to the smooth interaction with the other parts of the cableway installations.

2.6.5. Measures shall be taken to ensure that the effects of a fire in the cableway installation do not endanger the safety of persons being transported and workers.

2.6.6. Special measures shall be taken to protect cableway installations and persons from the effects of lightning.

2.7. Safety devices

2.7.1. Any defect in the cableway installation which could result in a failure endangering safety shall, where practicable, be detected, reported and processed by a safety device. The same applies to any normally foreseeable external event which may endanger safety.

2.7.2. It shall be possible at all times to shut down the cableway installation manually.

2.7.3. After the cableway installation has been shut down by a safety device, it shall not be possible to restart it unless appropriate action has been taken.

2.8. Maintainability

The cableway installation shall be designed and constructed so as to enable routine or special maintenance and repair operations and procedures to be carried out safely.

2.9. Nuisance

The cableway installation shall be designed and constructed in such a way as to ensure that any internal or external nuisance resulting from noxious gases, noise emissions or vibrations falls within the prescribed limits.

3. Infrastructure requirements

3.1. Layout, speed, distance between vehicles

3.1.1. The cableway installation shall be designed to operate safely taking into account the characteristics of the terrain and its surroundings, atmospheric and meteorological conditions, any possible structures and obstacles located in the vicinity either on the ground or in the air in such a way as to cause no nuisance or pose no danger under any operational or servicing conditions or in the event of an operation to rescue persons.

3.1.2. Sufficient distance shall be maintained laterally and vertically between vehicles, towing devices, tracks, cables, etc., and possible structures and obstacles located in the vicinity either on the ground or in the air, taking account of the vertical, longitudinal and lateral movement of the cables and vehicles or of the towing devices under the most adverse foreseeable operating conditions.

3.1.3. The maximum distance between vehicles and ground shall, take account of the nature of the cableway installation, the type of vehicles and the rescue procedures. In the case of open cars it shall also take account of the risk of fall as well as the psychological aspects associated with the distance between vehicles and ground.

3.1.4. The maximum speed of the vehicles or towing devices, the minimum distance between them and their acceleration and braking performance shall be chosen to ensure the safety of persons and the safe operation of the cableway installation.

3.2. Stations and structures along the line

3.2.1. Stations and structures along the line shall be designed, installed and equipped so as to ensure stability. They shall permit safe guidance of the cables, vehicles and the towing devices, and enable maintenance to be safely carried out, under all operating conditions.

3.2.2. The entry and exit areas of the cableway installation shall be designed so as to guarantee the safety of the traffic of vehicles, towing devices and persons. The movement of vehicles and towing devices in the stations shall be capable of taking place without risk to persons, taking into account their possible active collaboration to their movement.

4. Requirements relating to cables, drives and brakes and to mechanical and electrical installations

4.1. Cables and their supports

4.1.1. All measures shall be taken in line with the latest technological developments:

– to avoid cables or their attachments breaking,

– to cover their minimum and maximum stress values,

– to ensure that they are safely mounted on their supports and prevent derailment,

– to enable them to be monitored.

4.1.2. It is not possible to prevent all risk of cable derailment, measures shall be taken to ensure that cables can be retrieved and the cableway installations shut down without risk to persons in the event of derailment.

4.2. Mechanical installations

4.2.1. Drives

The drive system of a cableway installation shall be of a suitable performance and capability, adapted to the various operating systems and modes.

4.2.2. Standby drive

The cableway installation shall have a standby drive with an energy supply which is independent of that of the main drive system. A standby drive is not, however, necessary if the safety analysis shows that people can leave the vehicles and, in particular, towing devices easily, quickly and safely even if a standby drive is not available.

4.2.3. Braking

4.2.3.1. In an emergency, it shall be possible to shut down the cableway installation and/or the vehicles at any moment, under the most unfavourable conditions in terms of authorised load and pulley adhesion during operation. The stopping distance shall be as short as the security of the cableway installation dictates.

4.2.3.2. Deceleration values shall be within adequate limits fixed in such a way to ensure both the safety of the persons and the satisfactory behaviour of the vehicles, cables and other parts of the cableway installation.

4.2.3.3. In all cableway installations there shall be two or more braking systems, each capable of bringing the cableway installation to a halt, and coordinated in such a way that they automatically replace the active system when its efficiency becomes inadequate. The traction cable's last braking system shall act directly on the driving pulley. These provisions do not apply to drag lifts.

4.2.3.4. The cableway installation shall be fitted with an effective clamp and locking mechanism to guard against premature restarts.

4.3. Control devices

The control devices shall be designed and constructed so as to be safe and reliable, to withstand normal operating stresses and external factors such as humidity, extreme temperatures or electromagnetic interference and so as not to cause dangerous situations, even in the event of operational error.

4.4. Communication devices

Suitable facilities shall be provided to enable operational staff to communicate with one another at all times and to inform users in case of emergency.

5. Vehicles and towing devices

5.1. Vehicles and/or towing devices shall be designed and fitted out in such a way that under foreseeable operating conditions no person can fall out or encounter any other risks.

5.2. The fittings of vehicles and towing devices shall be dimensioned and constructed so as not to:

– damage the cable, or

– slip, except where slippage does not significantly affect the safety of the vehicle, the towing device or the installation

under the most unfavourable conditions.

5.3. Vehicle doors (on cars, cabins) shall be designed and constructed in such a way as to make it possible to close and lock them. The vehicle floor and walls shall be designed and constructed so as to withstand pressure and loads exerted by users under any circumstances.

5.4. If for reasons of operational safety an operator is required on board the vehicle, the vehicle shall be fitted with the equipment required for him to carry out his tasks.

5.5. Vehicles and/or towing devices and, in particular, their suspension mechanisms shall be designed and fitted so as to ensure the safety of workers servicing them in accordance with appropriate rules and instructions.

5.6. In the case of vehicles equipped with disconnectable fittings, all measures shall be taken to bring to a halt, without risk to users, at the moment of departure, any vehicle whose fitting has been incorrectly connected to the cable and, at the moment of arrival, any vehicle whose fitting has not been disconnected, and to prevent the vehicle from falling.

5.7. Funicular vehicles and, in so far as the configuration of the cableway installation so permits, bi-cable cable cars shall be equipped with an automatic braking device on the track, when the possibility of carrier cable breaking cannot reasonably be excluded.

5.8. Where all risk of derailment of the vehicle cannot be eliminated by other measures, the vehicle shall be fitted with an anti-derailment device which enables the vehicle to be brought to a halt without risk to persons.

6. Equipment for users

The access to embarkation areas and exit from disembarkation areas and the embarkation and disembarkation of users shall be organised with regard to the movement and stopping of vehicles in such a way as to ensure the safety of persons, in particular in areas where there is a risk of falling.

It must be possible for children and persons with reduced mobility to use the cableway installation safely if the cableway installation is designed for the transport of such persons.

7. Operability

7.1. Safety

7.1.1. All technical provisions and measures shall be taken to ensure that the cableway installation is used for its intended purpose according to its technical specification and to the specified operating conditions and that the instructions on safe operation and maintenance can be complied with. The instruction manual and the corresponding notes shall be drawn up in a language which can be easily understood by users, as determined by the Member State in the territory of which the cableway installation is constructed.

7.1.2. The persons responsible for operating the cableway installation shall be provided with the appropriate material resources and shall be qualified to carry out the task in hand.

7.2. Safety in the event of immobilisation of the cableway installation

All technical provisions and measures shall be adopted to ensure that users can be brought to safety within a set time appropriate to the type of cableway installation and its surroundings when the cableway installation is immobilised and cannot be restarted quickly.

7.3. Other special provisions concerning safety

7.3.1. Operators' stands and workplaces

Movable parts which are normally accessible in the stations shall be designed, constructed and installed in such a way as to preclude any risks or, where such risks exist, be fitted with protective devices so as to prevent any contact with parts of the cableway installation which may cause accidents. These devices shall be of a type that cannot easily be removed or rendered inoperative.

7.3.2. Risk of falling

Workplaces and working areas, including those used only occasionally, and the access to them, shall be designed and constructed in such a way as to prevent persons required to work or move in them from falling. Should the construction not be adequate, they shall also be provided with anchorage points for personal protective equipment to prevent falls.

ANNEX III

SAFETY ANALYSIS

The safety analysis required according to Article 8 for every cableway installation shall take into account every mode of operation envisaged. The analysis shall follow a recognised or established method and take into account the current state of the art and the complexity of the cableway installation in question. The aim is also to ensure that the design and configuration of the cableway installation should take account of the local surroundings and the most adverse situations in order to ensure satisfactory safety conditions.

The safety analysis shall also cover the safety devices and their effect on the cableway installation and related subsystems that they bring into action so that either:

– they are capable of reacting to an initial breakdown or failure detected so as to remain either in a state that guarantees safety, in a lower operating mode or in a fail-safe state,

– they are redundant and are monitored, or

– they are such that the probability of their failure can be evaluated and they are of a standard equivalent to that achieved by safety devices that meet the criteria in the first and second indents.

Safety analysis must be used to draw up the inventory of risks and dangerous situations in accordance with Article 8(1) and to determine the list of safety components referred to in Article 8(2) thereof. The result of the safety analysis shall be summarised in a safety report.

ANNEX IV

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE B: EU-TYPE EXAMINATION – PRODUCTION TYPE

1. EU type-examination is the part of a conformity assessment procedure in which a notifiedbody examines the technical design of a subsystem or a safety component and verifies and attests that it meets the requirements of this Regulation.

2. EU-type examination is carried out by assessment of the adequacy of the technical design of the subsystem or the safety component through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete subsystem or safety component (production type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include all the following:

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

(c) the technical documentation for the subsystem and/or the safety component according to Annex IX.

(d) a representative specimen of the subsystem or the safety component envisaged or details of the premises where it can be examined. The notified body may request further specimens if needed for carrying out the test program;

4. The notified body shall:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the subsystem or the safety component;

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards and technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. where the manufacturer has applied the specifications of the relevant harmonised standards, carry out the appropriate examinations and tests, or have them carried out, to check whether these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

4.5. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of this Regulation;

4.6. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Regulation, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, any conditions for its validity, the necessary data for identification of the approved type (subsystem or safety component) and if relevant, descriptions of its functioning. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems and safety components with the examined type to be evaluated and to allow for in-service control.

The certificate shall have a maximum validity period of thirty years from the date of its issue. Where the type does not satisfy the applicable requirements of this Regulation, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Regulation and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of any modifications to the approved type that may affect the conformity of the subsystem or the safety component with the essential requirements of this Regulation or the conditions for validity of the certificate.

The notified body shall examine the modification and inform the manufacturer whether the EU type-examination certificate remains valid or whether further examinations, verifications or tests are needed. As appropriate, the notified body shall issue an addition to the original EU type-examination certificate or ask for a new application for an EU type-examination to be submitted.

8. Each notified body shall inform its notifying authorities and the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has issued.

The notified body which refuses to issue or withdraws, suspends or otherwise restricts an EU-type examination certificate must inform its notifying authorities and the other notified bodies accordingly, giving the reasons for its decision.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market.

10. The manufacturer's obligations set out in points 7 and 9, may be fulfilled by his authorised representative, provided that they are specified in the mandate.

ANNEX V

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby ~~a~~ the manufacturer fulfils the obligations laid down in points 2.2 and 2.5, and ensures and declares on his sole responsibility that the subsystems or safety components concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the subsystems or safety components concerned as specified in point 2.3, and shall be subject to surveillance as specified in point 2.4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the 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) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the subsystems or safety components approved under module B;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate(s);

(f) details of the premises where the subsystem or the safety component is manufactured.

3.2. The quality system shall ensure that the subsystems or safety components are in conformity with the type(s) described in the EU-type examination certificate(s) and comply with the requirements of this Regulation that apply to them.

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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

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

(b) the corresponding 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 manufacture, and the frequency with which they will be carried out,

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

(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 national standard that implements the relevant harmonised standard and/or technical specifications.

The audit shall include an assessment visit to the premises where the subsystems or the safety components are manufactured, inspected and tested.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the field of cableway installations and in the technology of the subsystems or safety components concerned, and knowledge of the applicable requirements of this Regulation. 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(e), to verify the manufacturer's ability to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the subsystems or safety components with those requirements.

The decision shall be notified to the manufacturer. 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 out of the quality system as approved and to maintain it so that it remains adequate and efficient.

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

The notified body shall evaluate any proposed changes 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 the outcome of the evaluation. In case of a reassessment, it shall notify the manufacturer of its decision. The notification shall 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 manufacturer duly fulfils the obligations arising out of the approved production quality system.

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

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits of at least once every two years to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body 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 subsystem or safety component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the subsystems or safety components during the manufacturing process.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each subsystem or safety component and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or safety component model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period of 30 years after the last subsystem or safety component has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals withdrawn, and shall, periodically or upon request, make available to its notifying authorities information related to quality system assessments.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, giving the reasons for its decision.

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.

ANNEX VI

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE F: CONFORMITY TO TYPE BASED ON SUBSYSTEM OR SAFETY COMPONENT VERIFICATION

1. Conformity to type based on subsystem or safety component verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.5.1 and 3.6, and ensures and declares on his sole responsibility that the subsystems or safety components concerned, which have been subject to the provisions of point 3.3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Regulation.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured subsystems or safety components with the approved type described in the EU-type examination certificate and with the requirements of this Regulation.

3. Verification

3.1. The manufacturer shall lodge an application for subsystem or safety component verification with the 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) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the subsystems or safety components approved under module B;

(d) the technical documentation of the approved type and a copy of the EU-type examination certificate(s);

(e) details of the premises where the subsystem or the safety component (is manufactured) can be examined.

3.2 The notified body shall carry out appropriate examinations and tests, or have them carried out, in order to check the conformity of the subsystems or safety components with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.

The examinations and tests to check the conformity of the subsystems or safety components with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every subsystem or safety component as specified in point 4 or by examination and testing of the subsystems or safety components on a statistical basis as specified in point 5.

4. Verification of conformity by examination and testing of every subsystem or safety component

4.1. All subsystems or safety components shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved subsystem or safety component or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 30 years after the subsystem or safety component has been placed on the market.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his subsystem or safety component for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of this Regulation. All the subsystems or safety components in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to ensure their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Regulation in order to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. If a lot is accepted, all the subsystems or safety components of the lot shall be considered approved, except for those subsystems or safety components from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved subsystem or safety component or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market.

5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots, the notified body may suspend the statistical verification and take appropriate measures.

6. CE marking and EU declaration of conformity

6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual subsystem or safety component that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each subsystem or safety component and keep it at the disposal of the national authorities, for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or safety component for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be made available upon request.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the subsystems or safety components.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the subsystems or safety components during the manufacturing process.

8. Authorised representative

The manufacturer's obligations set out in points 2 and 5.1 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX VII

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby ~~a~~ the manufacturer fulfils the obligations laid down in points 4.2, 4.3 and 4.5, and ensures and declares on his sole responsibility that the subsystem or safety component concerned, which has been subject to the provisions of point 4.4, is in conformity with the requirements of this Regulation.

2. Manufacturing

The manufacturer shall take all measures necessary so that the design and manufacturing process and its monitoring ensure conformity of the manufactured subsystem or safety component with the applicable requirements of this Regulation.

3. Verification

3.1. The manufacturer shall lodge an application for unit verification of a subsystem or a safety component with the 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) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation for the subsystem or the safety component according to Annex IX;

(d) details of the premises where the subsystem or the safety component (is manufactured) can be examined.

3.2 The notified body shall examine the technical documentation for the subsystem or the safety component and shall carry out the appropriate examinations and tests, as set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to ensure its conformity with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved subsystem or the safety component, or have it affixed under its responsibility.

If the notified body refuses to issue a certificate of conformity, it shall state in detail the reasons for the refusal and indicate the necessary corrective measures to be taken.

When the manufacturer reapplies for unit verification of the subsystem or the safety component concerned, he shall apply to the same notified body.

On request, the notified body shall provide the Commission and the member States with a copy of the certificate of conformity.

The manufacturer shall keep the technical documentation and a copy of the certificate of conformity at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each subsystem or safety component that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or the safety component for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in points 3.1 and 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX VIII

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the subsystems or safety components concerned satisfy the requirements of this Regulation.

2. Manufacturing

The manufacturer shall operate an approved quality system for the design, manufacture and final inspection and testing of subsystems or safety components 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 the notified body of his choice, for the subsystems or safety components concerned.

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) all necessary information on the subsystems or safety components to be manufactured;

(c) the technical documentation in accordance to Annex IX for one representative type of each category of subsystem or safety component to be manufactured.

(d) the documentation concerning the quality system;

(e) details of the premises where the subsystems or safety components are designed, manufactured, inspected and tested;

(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 subsystem or the safety component with the requirements of this Regulation that apply to it.

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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the design and quality of the subsystems and the safety components;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Regulation will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the subsystems or the safety components.

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

(e) the examinations and tests to 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, qualification reports on the personnel concerned, etc.;

(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 system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

The audit shall include an assessment visit to the premises where the subsystems or the safety components are designed, manufactured, inspected and tested.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as assessor in the field of cableway installations and in the technology of the subsystems or safety components concerned, and knowledge of the applicable requirements of this Regulation.

The auditing team shall review the technical documentation referred to in point 3.1 to verify the manufacturer's ability to identify the applicable requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the subsystems or the safety components with those requirements.

The notified body shall notify its decision to the manufacturer or 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 out of the quality system as approved and to maintain it so that it remains adequate and efficient.

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

The notified body shall evaluate any proposed changes 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 the outcome of the evaluation. In case of a reassessment, 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, testing, and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

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

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

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. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer.

During such visits, the notified body may, if necessary, carry out product 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 subsystem or safety component that is in conformity with the type as described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the subsystems or safety components during the manufacturing process.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each subsystem or safety component and keep a copy of it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or the safety component for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period of 30 years after the last subsystem or safety component has been placed on the market, keep at the disposal of the national authorities:

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

(b) the documentation concerning the quality system referred to in point 3.1;

(c) the documentation relating to the change referred to in point 3.5 as approved;

(d) the decisions and reports of the notified body referred to in points 3.3, 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

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

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.

ANNEX IX

TECHNICAL DOCUMENTATION FOR SUBSYSTEMS AND SAFETY COMPONENTS:

(1) The technical documentation shall make it possible to assess the conformity of the subsystem or the safety component with the applicable requirements of this Regulation and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the conformity assessment, the design, manufacture and operation of the subsystem or safety component.

(2) The technical documentation shall contain, at least the following elements:

(a) a general description of the subsystem or the safety component,

(b) design and manufacturing drawings and diagrams of components, subassemblies, circuits etc. and the descriptions and explanations necessary for the understanding of those drawings and diagrams and of the operation of the subsystem or safety component,

(c) a list of the harmonised standards and/or other technical specifications, the references of which have been published in the *Official Journal of the European Union*, applied in full or in part and descriptions of the solutions adopted to meet the essential requirements of this Regulation where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(d) the supporting evidence for the adequacy of the design, including the results of any design calculations, examinations or tests carried out by or for the manufacturer and the related reports;

(e) a copy of the instructions for the subsystem or the safety component;

(f) for subsystems, a copy of the EU Declarations of conformity for the safety components incorporated into the subsystem.

ANNEX X

EU DECLARATION OF CONFORMITY FOR SUBSYSTEMS AND SAFETY COMPONENTS

(1) The EU declaration of conformity shall accompany the subsystem or the safety component. It shall be drawn up in the same language or languages as the manual referred to in point 7.1.1 of Annex II.

(2) The EU declaration of conformity shall contain the following elements:

(a) Subsystem/safety component model (product, batch, type or serial number).

(b) Name and address of the manufacturer and, where applicable, his authorised representative.

(c) This declaration of conformity is issued under the sole responsibility of the manufacturer.

(d) Object of the declaration (identification of the subsystem or safety component allowing traceability. It may, where necessary for the identification of the subsystem or safety component, include an image):

– description of the subsystem or safety component (type, etc.);

– conformity assessment procedure followed;

– name and address of the notified body which carried out the conformity assessment;

– reference to the EU-type examination certificate with details, including its date, and where appropriate, information on the duration and conditions of its validity;

– all relevant provisions with which the component must comply and, in particular, the conditions of use.

(e) The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: ……. (reference to the other Union Acts applied):

(f) References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

(g) The notified body or bodies … (name, address, number) … performed … (description of intervention) … and issued the certificate(s): …

(h) - identification of the person empowered to sign on behalf of the manufacturer or his authorised representative;.

(i) Additional information:

Signed for and on behalf of: …….

(place and date of issue):

(name, function) (signature):

ANNEX XI

CORRELATION TABLE	
Directive 2000/9/EC	This Regulation
___	Article 1
Article 1(1)	Article 2(1)
Article 1(2)	Article 3(1)
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