STRMTG

NB ◆ 1267

General terms and conditions of sale of the activity of evaluating the conformity of a safety component or subsystem with respect to Regulation (EU) 2016/424 of 9 March 2016 on cableway installations

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Purpose - Field of application - Intended recipients

The purpose of this document is to define the general terms of intervention of the STRMTG- NB1267 for evaluating the conformity of the safety components or subsystems requested by a manufacturer.

The conformity is evaluated according to the modules defined in article 18 of Regulation (EU) 2016/424 of 9 March 2016 relating to cableway installations and repealing Directive 2000/9/EC.

This document is addressed to the manufacturer who sends a request for evaluating the conformity of a safety component or subsystem to the STRMTG-NB1267.

It constitutes, along with the financial offer, the contract that governs the relationship between the STRMTG-NB1267 and the manufacturer, with effect from the starting date of the service and extending throughout the duration of validity of the certificates issued in this respect. This contract prevails over all other documents as soon as the manufacturer accepts the financial offer.

History of updates:

Version n°	Date	Version type
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See the French version			

Mailing list:
The document is attached to every new financial offer. It is also available on the website of STRMTG.
The associated documents (intervention request, declarative form) are available on the website of STRMTG.

Summary

1 - General

1.1 - Reference documents

– Regulation (EU) 2016/424 of the European Parliament and of the Council dated 9 March 2016 relating to cableway installations and repealing Directive 2000/9/EC
– (to be prepared) Implementing guide for Regulation (EU) 2016/424
– Recommendations for Use (RfU) of the coordination group of notified bodies
– 'Blue Guide' on the implementation of European Union product rules
– Conditions of notification of the STRMTG (see § 8.1)

Website of the European Commission on cableway installations:
http://ec.europa.eu/growth/sectors/mechanical-engineering/cableways_en

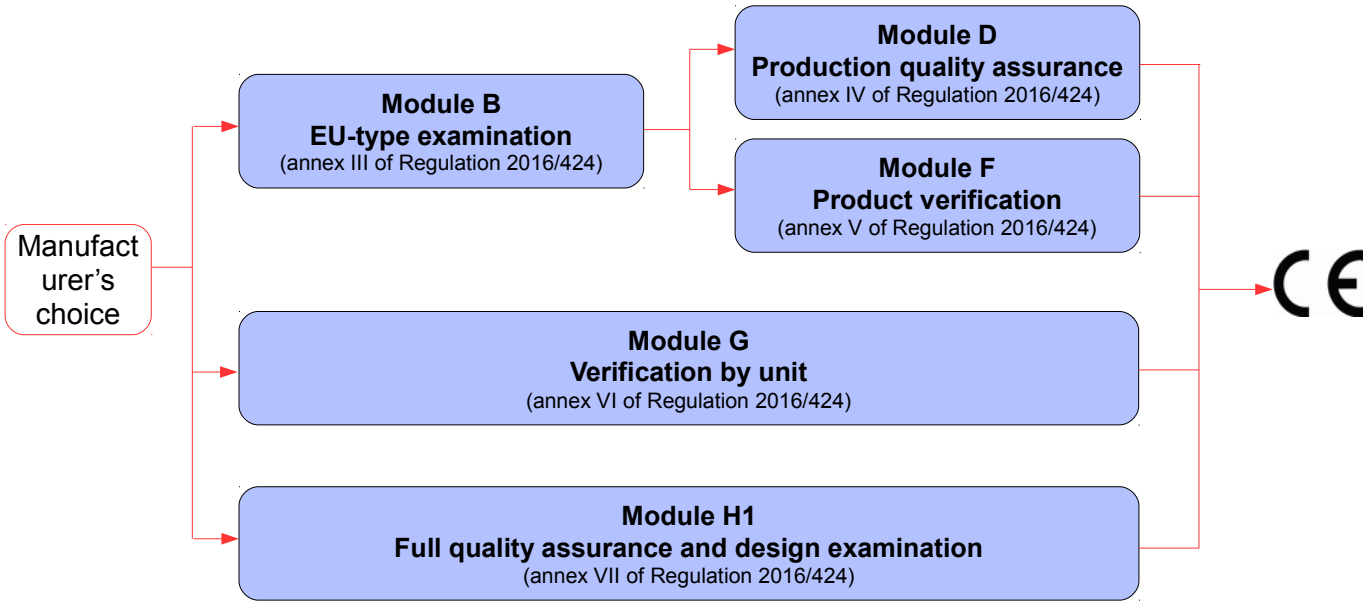
1.2 - Definitions

The definitions are those given in article 3 of the Regulation (EU) 2016/424.

2 - Principles of intervention

2.1 - General principle

The interventions of STRMTG-NB1267 are carried out pursuant to the module(s) requested by the manufacturer.



2.2 - Intervention request

The manufacturer can request the STRMTG-NB1267's intervention:
– for a new product, via the intervention request;
– for a change in the design of an already evaluated product (module B, module G and module H1 § 3.6), via the declarative form (DOC OP 58).

2.3 - Documents to be provided by the manufacturer

To allow the STRMTG-NB1267 to carry out its evaluation work, two types of documentation must be provided.

2.3.1 - The technical documentation

The technical documentation for the safety component or subsystem is described in annex VIII of Regulation (EU) 2016/424.

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 referred to in Article 17, applied in full or in part, the references of which have been published in the Official Journal of the European Union, and where those harmonised standards have not been applied descriptions of the solutions adopted to meet the essential requirements of this Regulation including a list of other relevant technical specifications 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;
This includes documents concerning the installation, use and maintenance of the product.

f) for subsystems, copies of the EU declarations of conformity for the safety components incorporated into the subsystem.

The type of documents for points b) and d) must be adjusted based on the safety component or subsystem in question: mechanical, hydraulic, electric, cable, etc.

The manufacturer must also provide a document called the “conditions of use” that will accompany the issued certificate (see § 4.3.1) in order to describe the product. Its contents include:
– a description and the identification of the product;
– the field / the conditions of use, its characteristics;
– the CE marking;
– the interfaces;
– for a safety component: the list of “basic safety components/constituents” / “safety parts” / “components contributing to safety” / “sub-components”;
– for a subsystem: the list of safety components with a reference of the “conditions of use”;
– the references of the documents required for the identification, commissioning, use and maintenance, etc.

2.3.2 - The documentation related to the quality system

The documentation related to the quality system is that described in module D or module H1 of Regulation (EU) 2016/424.

Module H1 for the design, manufacturing, final inspection and testing	**Module D for the production, final inspection of products and testing**
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 product quality;	*a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the product quality;*
(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, including other relevant technical specifications, 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;	*b) 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;	*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;*
f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;	*d) 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.	*e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.*

This quality documentation is not expected to be provided in its entirety during the intervention request.The manufacturer can provide it to STRMTG-NB1267 as part of the preparation and execution of the audit (see § 5).

In addition to this documentation listed in Regulation (EU) 2016/424, the following documents must also be provided to STRMTG-NB1267:

– (if it exists) copy of ISO 9001 quality management certificate;
– (if applicable) provisions for monitoring subcontractors;
– quality system surveillance (deviation and non-conformity management, audit report, management review, etc.).

3 - The evaluation work conducted by STRMTG-NB1267

The work conducted by the STRMTG-NB1267 is, for each of the modules, indicated in the following table, and detailed in paragraphs 4 and 5 hereinafter:

		B	D	F	G	H1
DESIGN EXAMINATION						
Technical specifications	See § 4.1.2	X			X	X
Examination of the technical documentation	See § 4.1.1	X			X	X
Tests	See § 4.1.3	X			X	X
Examination of the representative specimen	See § 4.2	X				
MANUFACTURING EXAMINATION - control						
Intervention during manufacturing	See § 4.2				X	
Final verification	See § 4.2			X	X	
ISSUANCE OF CERTIFICATES						
EU-type examination certificate	See § 4.3.1	X				
EU design examination certificate	See § 4.3.1					X § 3.6
Certificate of conformity	See § 4.3.2			X	X	
EVALUATION OF THE QUALITY SYSTEM						
Examination of the documentation related to the quality system	See § 5		X			X
Initial evaluation			X			X
Surveillance / Re-evaluation			X			X
Notification of decisions (quality system approval)			X			X
CE MARKING						
Affixing of the STRMTG identification No.: 1267	See § 7.3		X	X	X	X

4 - Evaluation work carried out for the non-quality system modules

4.1 - Design examination (modules B, G, H1 §3.6)

4.1.1 - Examination of the technical documentation

This examination pertains to the technical documentation defined in § 2.3.1, which allows the STRMTG-NB1267 to analyse its relevance and to verify that the subsystem or safety component complies with the essential requirements of Regulation (EU) 2016/424, as regards:
– its characteristics,
– its functionality and interfaces,
– its dimensioning (for mechanical products),
– its safety, command and programmed logic functions (for electric products),
– its conditions of use,
– its maintainability and operability,

with respect to the applied technical specifications (see the § below).

Subcontracting
The STRMTG-NB1267 uses subcontracting for a limited part of the evaluation of electric components (design analysis and testing of the control-command software).
The STRMTG-NB1267 must be a recipient of all exchanges between the manufacturer and the subcontractor. The subcontractor's services are monitored and validated by the STRMTG-NB1267's inspector who is in charge of the project. The STRMTG-NB1267 retains responsibility for the evaluation decision.
For the contractual provisions with the subcontractor, refer to § 7.1.3 and for the payment conditions regarding its services, refer to § 8.4.2.

4.1.2 - The technical specifications

On the basis of the technical solutions adopted by the manufacturer, (refer to point c) of the technical documentation *"a list of the harmonised standards referred to in Article 17, applied in full or in part, the references of which have been published in the Official Journal of the European Union, and where those harmonised standards have not been applied, the description of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied.",* the STRMTG-NB1267 verifies that the essential requirements of Regulation (EU) 2016/424 applicable to the product have been taken into account by the manufacturer and that they have been met.

The use of harmonised standards confers a presumption of conformity to the essential requirements that they cover. The STRMTG-NB1267 verifies the compliance with every relevant normative specification.

Note that a deviation from a specification of a harmonised standard does not systematically result in a non-conformity with the essential requirements of Regulation (EU) 2016/424. Furthermore, the STRMTG-NB1267 can accept such deviations provided that they were the subject of a supporting analysis provided by the manufacturer, which allows verifying that an equivalent level of safety has been achieved, if necessary after determining compensatory measures or verifications. Similarly, if the manufacturer uses other technical specifications instead of the harmonised standards, it must provide a specific analysis to prove the achieved safety level.

In the case of innovative safety components or subsystems, which are not covered by the harmonised standards and the acknowledged state of the art, the STRMTG-NB1267 and the manufacturer shall decide on a different set of guidelines, possibly one that has yet to be defined.

4.1.3 - The tests

Tests can either be prescribed by the standards, or requested by STRMTG-NB1267 as proof of a requirement deemed as non-demonstrable by other means.
The manufacturer must submit the definition of these tests (protocol, service provider, terms of execution, installation of gauges for strain measurements), the reports of which are provided for by the technical documentation, to the STRMTG-NB1267 for validation.

The STRMTG-NB1267 may request to be present for these tests.

4.1.4 - Change management

The manufacturer must inform STRMTG-NB1267 before making any change that it wishes to make to the certified subsystem or safety component, irrespective of whether it is meant to improve the existing design, or results from a change in the applied specifications.[1]

The STRMTG-NB1267 shall examine the changes, without necessarily redoing all the initial examinations.

Similarly, if the STRMTG-NB1267 detects a change in the generally acknowledged state of the art[2] that is likely to affect the conformity of the approved design, it shall request the manufacturer to provide additional proof or make changes to the subsystem or safety component.

4.2 - Additional or special examinations (modules B, G and F)

<table>
<tr><th colspan="2"></th><th>Examination of the STRMTG-NB1267</th></tr>
<tr><td rowspan="3">The manufacturer provides information on the place where the product can be examined, and provides the documents related to its manufacturing and control.</td><td>Module B =
a representative specimen</td><td rowspan="3">– verifies the provisions and results of the manufacturing and control operations,
– carries out a visual inspection of all accessible parts of the product and ensures its conformity to the drawings.
As this visual inspection is not relevant for all types of subsystems or safety components, the STRMTG-NB1267 only performs a verification of the manufacturing and control documents.
– has the tests and additional checks carried out, if necessary.</td></tr>
<tr><td>Module G = the unique safety component or subsystem</td></tr>
<tr><td>Module F =
– either every subsystem or safety component;
– or a random sample taken from each batch of subsystems or safety components.</td></tr>
</table>

1 Manufacturer’s obligations (art 11, § 4 of Regulation (EU) 2016/424)
Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the subsystem or the safety component is declared shall be adequately taken into account.

2 Obligations of the notified bodies (module B § 7, module H1 § 3.6.4 of Regulation (EU) 2016/424)
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.

4.3 - Documents issued by the STRMTG-NB1267

4.3.1 - EU-type examination or EU design examination certificate (module B and H1 §3.6)

If the design examinations of the subsystem or safety component allow concluding on its conformity to the essential requirements of Regulation (EU)2016/424, then the STRMTG-NB1267:

- issues the following to the manufacturer:
  – an EU-type examination certificate for module B,
  – an EU design examination certificate for module H1 §3.6,
- validates the conditions of use of the subsystem or safety component by signing it and affixing its seal.
  This conditions of use comes with the certificate to provide the information required for the proper use of the subsystem or safety component. Its reference is given in the certificate.

The EU design examination certificate for module H1 §3.6 has no duration of validity whereas the EU-type examination certificate for module B is valid for 30 years from the date of issue.

When changes are made to the design, the STRMTG-NB1267 stamps the declarative form (DOP OP 58). It may also be required to issue a revision of the original certificate.

4.3.2 - Certificate of conformity (Modules F and G)

After an evaluation is deemed satisfactory, the STRMTG-NB1267 issues a certificate of conformity and authorises the manufacturer to affix its identification number.

Note: The design examination in the context of module G does not result in the issue of an EU design examination certificate.

5 - Evaluation work carried out for the quality system modules (D and H1)

The services of the STRMTG-NB1267 (audits and surveillance) are offered for one approval cycle of the quality system, taking into account the categories of manufactured products, the production volumes and the organisation of the production on one or more sites.

5.1 - The audits

For evaluating the manufacturer's quality system, the STRMTG-NB1267 carries out audits in the manufacturer's facilities[3] with the following objectives:

– examining the structure, policies, processes, procedures, records and associated documents of the manufacturer that are applicable to the quality system to be evaluated;
– confirming their compliance with all the requirements applicable to the scope of the quality system applicable for the module concerned;
– confirming that the processes and procedures have been defined, implemented and maintained effectively for enhancing confidence in the manufacturer's quality system;
– offering the manufacturer areas for improvement regarding its policy, objectives, methods or results.

The audits are carried out by a team of auditors comprising:

– a lead auditor, having experience in quality management systems;
– one or more technical auditors having experience in evaluating cableway installations and the technology of the subsystems or safety components concerned, as well as having knowledge of the requirements applicable to Regulation (EU) 2016/424.

The audit team is suggested to the manufacturer, who may reject one or more members of the team. In this case, the manufacturer must send its duly justified request, rejecting the auditor(s), to STRMTG-NB1267.

The STRMTG-NB1267 evaluates the quality system on the basis of the requirements of standard EN ISO 9001:2015 and the essential requirements of Regulation (EU) 2016/424; it examines the documentation related to the manufacturer's quality system (see § 2.3.2) during the preparation and execution of the audit.

If the manufacturer already has a certification pursuant to standard EN ISO 9001:2015, the STRMTG-NB1267 deems that it confers the presumption of conformity to the chosen module as regards the provisions of this module covered by standard ISO 9001:2015. The STRMTG-NB1267 then limits its evaluation to examining the proper application of the requirements specific to the safety component or subsystem in the certified quality system, and verifies the specific organisation of the manufacturing of the said category of subsystem and safety component, as well as the specific organisation of the design in the context of module H1.

3 If the manufacturer subcontracts all or a part of the product creation steps, the STRMTG-NB1267 may also carry out audits in the facilities of the subcontractor.

The evaluation shall particularly pertain to the following topics:

Topics of the audit	D	H1	Correspondence EN ISO 9001:2015
Quality objectives, organisational structure as well as responsibilities and powers of the management with regard to the product quality	X	X	§ 5.1.1, § 5.2, § 5.3, § 6, § 9.3 (excluding c-1) of § 9.3.2) § 4.3, § 4.4
The technical design specifications, including the set of technical guidelines used to ensure that the essential safety requirements of the regulation will be met		X	§ 8.3.1, § 8.3.2, § 8.3.3, § 8.3.5,
The design control and design verification techniques, processes and systematic actions that will be used when designing the subsystems or the safety components;		X	§ 8.3.4, § 8.3.6,
The manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used	X	X	§ 8.5.1, § 8.5.2,
The examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out	X	X	§ 7.1.5.1, § 7.1.5.2,
The means of monitoring the achievement of the required product quality			§ 8.6, § 8.7
The quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;	X	X	§ 7.5
The control of suppliers and subcontractors	X	X	§ 8.4
The means used to monitor the proper functioning of the quality system.	X	X	§ 9.1.1, § 9.1.3 (excluding b), § 9.2, § 9.3 (excluding c-1) of § 9.3.2), § 10
The retention period (thirty years from when the subsystem or safety component was first marketed)	X	X	§ 7.5
The CE marking	X	X	Not applicable

5.2 - Notification of decisions

5.2.1 - The audit findings

The findings of the audits are categorised according to the following classification:

- **Strength**

Provision of the quality system in which the manufacturer:

- ✗ either exceeds the requirements of the audit guidelines;
- ✗ or distinguishes itself via an effective practice, method or technique.

- **Major Nonconformity (maj NC)**

Deviation from the Regulation or the guidelines (internal and external), directly calling into question the safety of the safety components or subsystems, or the reliability of the quality system.

- **Minor Nonconformity (min NC)**

Deviation from the Regulation or the guidelines (internal and external), that might generate a risk regarding the conformity of the safety components or subsystems, or the reliability of the quality system.

- **Weak point**

A compliant provision, but one that could lead to a nonconformity in the short or medium term.

- **Avenue for improvement**

Suggestion to help the manufacturer improve the quality system.

5.2.2 - The processing of the findings and especially nonconformities

The consideration of the findings by the manufacturer, their processing as well as the verification of the STRMTG-NB1267 are carried out in the following manner:

- **Major Nonconformity (maj NC) and Minor Nonconformity (min NC)**

Every nonconformity (major and minor) is entered into a sheet that is submitted to the manufacturer and signed by it during the exit meeting. The manufacturer then has a period of 15 days to analyse the causes and impacts and to define the actions that it intends to adopt for resolving the nonconformity, as well as the implementation timeframes.

The STRMTG-NB1267 then analyses the proposed actions and updates the nonconformity sheet, which is part of the report.

The proper implementation of the actions and the resolution of the non-conformities are monitored through documentation, or during the follow-up audit or any other surveillance action. An additional audit may possibly be required to verify that the manufacturer has applied the actions.

- **Weak point**

The treatment of the weak point is examined during the next audit.

- **Avenue for improvement**

The manufacturer does not have to justify whether or not it has taken an avenue for improvement into consideration.

5.2.3 - The audit report

The audit results in the preparation of a report summarising the findings according to the aforementioned classification, which is sent to the manufacturer within a maximum period of 2 months.

5.2.4 - The quality system approval decision

All decisions concerning the approval of the quality system are taken by a person belonging to the STRMTG-NB1267 (the manager or acting manager), who must be different from the persons of the audit team.

5.2.4.a - Initial audit / renewal audit

On the basis of the contents and conclusions of the audit report, the STRMTG-NB1267 decides on whether or not to approve the manufacturer’s quality system.

In case of a positive decision, the STRMTG-NB1267 issues a quality system approval to the manufacturer, with a maximum validity period of 4 years for module D and 3 years for module H1. It authorises the manufacturer to affix its identification number on the manufactured products.

5.2.4.b - Other audits

On the basis of the contents and conclusions of the audit report, the STRMTG-NB1267 decides on whether or not to maintain the approval of the manufacturer’s quality system. The decision is notified by mail.

5.3 - Summary of the steps of a scheduled audit

The main steps of performance of an audit are summarised in the following table, which also provides a timetable for information purposes.

Target date	Actions
D – 2 months	The STRMTG-NB1267 schedules the D day of performance of the audit with the manufacturer.
D – 6 weeks	The STRMTG-NB1267 forwards the audit framework letter, including the notification of the composition of the audit team.
D – 1 month	The manufacturer sends the requested documents. The manufacturer may reject one or more members of the team.
D – 15 days	The STRMTG-NB1267 sends the audit plan to the manufacturer.
D	Onsite audit. Possible submission of non-conformity sheets.
D + 15 days	The manufacturer must return the non-conformity sheets, updated with its analyses.
D + 2 months	The STRMTG-NB1267 sends its approval decision and the report to the manufacturer.

5.4 - The audits and surveillance conducted during the quality system approval cycle

	Initial audit	Surveillance audits
Module D	*§ 3.3 The audit shall include an assessment visit to the premises where the subsystems or the safety components are manufactured, inspected and tested.* => 1 audit	*§ 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.* => 1 audit every 2 years, including one at n + 4 years for renewing the quality system approval
Module H1	*§ 3.3 The audit shall include an assessment visit to the premises where the subsystems or the safety components are designed, manufactured, inspected and tested.* => 1 audit	*§ 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.* => 1 audit every 3 years, which can be performed: – either in one full audit, which then becomes a renewal audit; – or in multiple partial audits, including at least one audit every 3 years for the renewal of the approval.

The STRMTG-NB1267 may add other means of surveillance to the monitoring audits, such as :
– follow-up meetings with the manufacturer, either in person or over the phone;
– exchanges with the manufacturer regarding the changes and progress in the actions undertaken to resolve the non-conformities revealed during the audits;
– onsite visits/inspections of the installations bearing the subsystems or components manufactured by the manufacturer, in the construction or testing phase or after commissioning.

Furthermore, the STRMTG-NB1267 can make unexpected visits to the manufacturer. The criteria that are most likely to trigger such a visit are:
– Depending on the results of previous audits and the manufacturer's responses to the findings, in case of any doubt, or if there is a desire to verify the corrective measures onsite;
– Knowledge of a failure in certified products that have already been marked;
– Significant organisational change in the manufacturer that was not voluntarily reported to the STRMTG-NB1267 (otherwise, this leads to a follow-up audit that is not performed unannounced).
– Major and justified complaint by a client of STRMTG-NB1267 or by any other stakeholder (notifying authority, authority of control, other cableways professionals).

The manufacturer is not informed about STRMTG-NB1267's arrival. This visit will be the subject of an audit report.

5.5 - Obligations of the manufacturer

The manufacturer must give STRMTG-NB1267 free access to all its facilities and to all requested documents (and to those of its subcontractors) and must pledge to guarantee the safety of the auditors by providing them, if necessary, with the required personal protective equipment.

In the context of the accreditation of the STRMTG-NB1267, the accreditation body or the internal auditors may audit STRMTG-NB1267 onsite. The manufacturer will be informed of the presence of an observer via the audit programme.

The manufacturer pledges to accomplish the obligations resulting from its approved quality system and to maintain it such that it remains adequate and effective.

5.5.1 - Change(s) made to the approved quality system

The manufacturer is required to inform the STRMTG-NB1267 of any significant organisational, administrative or legal change made to the design or production processes.

Examples of situations to be reported (non-exhaustive list):
– name of the legal entity benefiting from the approval;
– address for service of the legal entity benefiting from the approval;
– redistribution of the essential manufacturing activities between different sites/establishments;
– transfer of all or part of its activities to another legal entity;
– disappearance of the legal entity following a cessation of business, merger or absorption by another legal entity;
– initiation of receivership or compulsory liquidation;
– non-renewal of the ISO 9001 certification issued by an accredited certifying body;
– significant change in the manufacturing method or techniques used;
– etc.

The STRMTG-NB1267 evaluates the impact of these changes on the originally approved quality system. It takes a decision on whether these modifications can be accepted unconditionally or whether a re-evaluation or additional audit will be required.

5.5.2 - Regular information

The manufacturer communicates the following to the STRMTG-NB1267:
– periodically, its draft production programme,
– annually, the assessment of the manufactured products bearing the STRMTG-NB1267's number, sorted by CE-type and design examination certificates.

On the basis of this information and possibly that relating to the changes, the STRMTG-NB1267 may adjust the surveillance schedule.

6 - Fault detected in a product entered into service

In the event of a fault being detected or an accident or incident occurring, implicating a safety component or subsystem that has already entered into service, the manufacturer informs the STRMTG-NB1267 of this as soon as possible.

The manufacturer provides a technical analysis and a proposed action plan for:

- determining the causes of the problem;
- remedying this product and any similar products existing in the market, which are likely to be similarly affected;
- and predicting the occurrence of the same problem on future manufactured products.

The STRMTG-NB1267 sends a feedback to the manufacturer concerning its analysis and its action proposals. It also analyses their consequences on the validity of the quality system approval and/or certificate.

7 - The contractual provisions

7.1 - Contract

7.1.1 - First intervention or new product to be evaluated

In response to an intervention request from a new manufacturer or from a manufacturer already under a contract with STRMTG-NB1267 for evaluating a new subsystem or safety component, the STRMTG-NB1267 formalises a commercial offer that describes the specificities of the project, the timetable and the price offer.

The same contract may cover the evaluation of multiple products, especially when these products are intended to be used in the same installation.

The contract that governs the relationship between the STRMTG-NB1267 and the manufacturer requesting a conformity evaluation consists of these general terms and conditions and the commercial offer.

This contract prevails over all other documents.

It enters into force on the date of signing of the commercial offer, or on the date of issue of a “purchase order”, or by tacit acceptance when the manufacturer provides the complete file, and ends on the last date of validity of the certificate(s).

All “purchase orders” from the manufacturer must be made out in writing, and must bear the reference of the commercial offer. In return, the STRMTG-NB1267 shall accept the order by signing the “purchase order”. The STRMTG-NB1267 reserves the right to correct any error that might occur while registering the order and shall not incur any responsibility from this.

7.1.2 - Evaluation of modifications

Regulation (EU) 2016/424 states that the same product cannot be evaluated by two separate notified bodies. The STRMTG-NB1267 and the client are therefore bound by the contract for the entire duration of validity of the issued certificate(s) and the STRMTG-NB1267 is required to monitor the changes in the product or quality system over time. The manufacturer is required to inform it about any intention to change the design of its certified products or the provisions of its quality system, which are likely to call into question the conformity to the essential requirements of Regulation (EU) 2016/424 or the validity conditions of the certificate.

To inform the STRMTG-NB1267 about modifications made to the design, the manufacturer must use the declarative form (DOC OP 58) accompanied by the necessary technical documents, which is considered as an intervention request.

If it is a “major” modification and/or is made simultaneously with an evaluation request for a new product and/or is a modification requiring the intervention of a subcontractor, the STRMTG-NB1267 shall prepare a commercial offer.

If it is a “minor” modification, the price is communicated after the service is provided, on the basis of the time spent on processing the change.

To inform the STRMTG-NB1267 about changes made to the approved quality system, the manufacturer must write to the following email address: On.Strmtg@developpement-durable.gouv.fr

7.1.3 - Subcontracting

The STRMTG-NB1267 may subcontract a part of its evaluation.

The STRMTG-NB1267 has a control implemented on its subcontractors and only choses them among French « *Contrôleurs Techniques Indépendants* (CTI) » that are approved by the STRMTG in pursuance of the « *arrêté du 9 mai 2008 relatif à la procédure d'agrément des maîtres d'œuvre et des vérificateurs des remontées mécaniques et des tapis roulants mentionnés à l'article L. 342-17-1 du code du tourisme »*. These professionnals are known and recognised in the field of cableway installations.

In addition to this sovereign approval, the STRMTG-NB1267 audits its subcontractors to evaluate their skills and the other requirements applicable with respect to standard EN 17020.

When the commercial offer of the STRMTG-NB1267 provides for the intervention of a subcontractor, it separates the financial offer of the STRMTG-NB1267 from that of the subcontractor.The latter's offer is attached to the former's offer.

Thus, when a manufacturer accepts a commercial offer that includes the intervention of a subcontractor of STRMTG-NB1267, this implies acceptance of this subcontractor.

If the manufacturer accepts the commercial offer by drafting a "purchase order", it has two possibilities:

1) The manufacturer sends two purchase orders:

- one to the STRMTG-NB1267 for the financial sum of the STRMTG-NB1267 with reference to the commercial offer,
- one to the subcontractor for the financial sum of the subcontractor with reference to the subcontractor's offer and to the commercial offer of the STRMTG-NB1267.
  The STRMTG-NB1267 is sent a copy of this purchase order.

2) The manufacturer sends a single purchase order to the STRMTG-NB1267 for the total financial sum (STRMTG-NB1267 + subcontractor) with reference to the commercial offer.

For the payment of this subcontractor, refer to § 8.4.2

7.2 - The conditions of validity of the certificates

Some certificates have validity periods defined when they are issued:

- an « EU-type » examination certificate for module B is valid for 30 years,
- the quality system approval according to module D is valid for 4 years,
- the quality system approval according to module H1 is valid for 3 years.

The certificate of conformity (modules F and G) does not have a validity period
The same applies for the EU design examination certificate (module H1 §3.6), but this remains valid only for as long as the manufacturer has a valid quality system approval according to module H1.

Notwithstanding this concept of validity period, the STRMTG-NB1267 may suspend, restrict or withdraw a certificate under the following conditions:

- at the manufacturer's request;
- at its own initiative, when the manufacturer does not comply with the obligations of Regulation (EU) 2016/424 or the evaluation conditions, e.g.:
  – refusal to carry out audits within the required period or at the required frequency;
  – refusal of access to its premises;
  – refusal to communicate information and documents;
  – no response to deviations or non-compliance with the response deadlines;
  – no information communicated about changes made to the design of subsystems and safety

components or to the approved quality system;
– the manufactured subsystems and safety components do not correspond to the certified products;
– when the subsystem or safety component has a fault that was not detected during its certification;
– when the normative guidelines and the generally acknowledged state of the art change;
– fraudulent use of the certificates and the STRMTG identification number (1267);
– non-payment of invoices.

7.3 - CE Marking

The application of the CE marking is governed by articles 20 and 21 of Regulation (EU) 2016/424.

One of the rules and conditions for affixing the CE marking is that *« The CE marking shall be followed by the identification number of the notified body involved in the production control phase. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative. »*

The identification number of the STRMTG as a notified body is 1267, which is the property of the STRMTG.

The manufacturer may affix it on its subsystems and safety components when it has valid certificates (modules F and G) or approvals (modules D and H1) issued by the STRMTG-NB1267.

The manufacturer's use of the STRMTG's identification number (1267) is verified in the context of audits or product verifications.

Regardless of whether it pertains to the use of its certificate or any other information on the abusive use of the CE marking that it may be aware of, the STRMTG-NB1267 pledges to inform the market surveillance authorities and Member States, and to take the appropriate measures. « Abusive use » particularly includes the act of:
– mentioning a certificate that does not exist;
– mentioning a pending certificate that has not yet been issued;
– mentioning a certificate when it has been suspended or withdrawn;
– giving the same trade name to certified products and non-certified products.

7.4 - Use of the STRMTG-NB1267 logo and accreditation marking

The STRMTG-NB1267 logo cannot be used or reproduced in any manner without its prior authorisation, given in writing.
The use of the accreditation marking is strictly forbidden.

- **Case of reproducing documents issued and validated by STRMTG-NB1267**

Documents issued and validated by STRMTG-NB1267 (certificates, audit reports, conditions of use) can be reproduced. They must be reproduced in their entirety and must be true to the original (no modification or alteration of any kind).
The manufacturer may have them translated. In all cases, it incurs the manufacturer's responsibility to ensure that they are true to the original.

7.5 - Claims and appeals

All claims and appeals must be sent in writing (by post or email) to STRMTG-NB1267.
The procedure describing the processing of claims and appeals is provided to the manufacturer at its request.

7.6 - After-sales technical support

The STRMTG-NB1267 pledges to support the manufacturer in case of any question regarding the use of the certificates that it issues on a product. The STRMTG-NB1267 may especially explain the positions taken on the projects concerned, to the contact persons identified by the manufacturer in a Member State.

8 - The conditions of intervention of the STRMTG-NB1267

8.1 - The tasks and duties of the STRMTG-NB1267

The tasks of the STRMTG-NB1267 related to the evaluation of the CE conformity are as follows:

- to carry out the tasks of evaluating the conformity in accordance with the requirements of Regulation (EU) 2016/424 and to take appropriate corresponding decisions;
- to ensure that the other activities of the subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity evaluation activities;
- to monitor the generally acknowledged state of the art;
- to participate in standardisation activities;
- to participate in the activities of the European coordination group of notified bodies;
- to inform the notifying authority and other notified bodies of the certifications (and their revisions) that it has issued, rejected, withdrawn, suspended or subjected to other restrictions;
- to provide, at the request of the European Commission and the Member States, a copy of the certifications, technical documentation and results of the examinations carried out;
- to provide the notifying authority with the relevant documents concerning the evaluation of the subcontractor's qualifications and the work carried out by it.

To be accredited, the STRMTG-NB1267 must comply with the requirements defined in articles 26 and 34 of Regulation (EU) 2016/424. The ruling of 28 June 2004, amended by the ruling of 21 March 2017, requires accreditation according to standard NF EN ISO/ IEC 17 020 and an additional accreditation programme (INS REF 30) defined by the French accreditation committee (COFRAC) as a means to comply with the requirements.

The STRMTG-NB1267 is accredited by COFRAC under the number 3-140, the scope of which is available at www.cofrac.fr

The STRMTG-NB1267 carries out its services under the aegis of this accreditation.

8.2 - Impartiality and confidentiality

The STRMTG-NB1267 carries out its tasks with impartiality and neutrality, by processing projects in an objective and fair manner in order to always prioritise safety issues over individual interests.

The STRMTG-NB1267 pledges to maintain the confidentiality of any information communicated to it by the manufacturer and to refrain from disclosing or communicating it to third parties.

If the STRMTG-NB1267 is bound by law to disclose confidential information, the manufacturer concerned shall be informed about the disclosed information, unless forbidden by law.

Owing to its accreditation, the STRMTG-NB1267 mandates evaluators of the Cofrac as well as internal personnel or service providers to audit it. These persons may need to access the confidential information of the manufacturer. Owing to their code of ethics, the evaluators and auditors will also process this information confidentially, and furthermore, the STRMTG-NB1267 pledges not to provide any copy that could leave its premises.

8.3 - Language

The STRMTG-NB1267 is able to process files in at least the following languages:

- French
- English

for other languages, please contact us.

8.4 - Financial and payment conditions

8.4.1 - Financial conditions

The price owed to the STRMTG-NB1267 is defined and specified in the contract (see § 7.1).

Any changes in the documents submitted by the manufacturer during the execution of the service may result in additional time being required for examination, which shall be invoiced based on the time spent.

If, for any reason whatsoever, the procedure for the issuance of the certificate is interrupted, the sums corresponding to the work carried out or initiated by the STRMTG-NB1267 are owed or remain acquired by the STRMTG-NB1267.

If an audit is postponed or cancelled by the manufacturer who had accepted the dates of performance of the said audit, and it does so before the date scheduled for the start of the audit, the STRMTG-NB1267 reserves the right to ask the manufacturer to pay 30% of the price that would have been invoiced to it if the audit had been performed.

Delays or non-performance of orders resulting from events of force majeure: fires, floods, strikes (including go-slow strikes or work-to-rule strikes), regulation or requirement of public authorities, or any other inevitable, unforeseeable event that is out of the control of STRMTG-NB1267, cannot be used as grounds for compensation.

8.4.2 - Payment conditions

As the STRMTG-NB1267 is a State body, it does not have its own accounting system. The invoices issued by the STRMTG-NB1267 are processed according to the public accounting rules, and it is the General Directorate of Public Finance that is in charge of processing their payments. A demand for payment received by the manufacturer gives the payment terms: reference to our invoice, bank details, payment deadline.

The STRMTG-NB1267 is not able to issue an invoice immediately after providing the service. It groups together the various services performed in order to create at least one invoice a year.Depending on the project, it may also issue intermediate invoices based on the state of progress of the works.

The invoices mention the applicable VAT rate as well as the price excluding tax and the all-inclusive price of the owed sum.

For manufacturers situated outside the territory of France, the manufacturer must settle the direct and indirect taxes and/or levies resulting from the invoices with the local authorities and/or administrations with the relevant jurisdiction.

Subcontracting
The subcontractor of STRMTG-NB1267 is paid directly by the manufacturer. The subcontractor shall send its invoices to the manufacturer via the STRMTG-NB1267, which will validate their compliance and then forward them for payment to the manufacturer.