STRMTG

NB ◆ 1267

# General terms and conditions of sale for assessing 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 - Scope - Intended recipients**

The purpose of this document is to define the general terms of intervention of STRMTG-NB1267 for assessing 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 the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC.

This document is intended for manufacturers who apply to STRMTG-NB1267 to assess the conformity of a safety component or subsystem.

It constitutes, along with the financial proposal, the “contract” which governs the relationship between STRMTG-NB1267 and the manufacturer, from the start of the service and for the entire period of validity of the certificates issued in this respect. This “contract” supersedes all other documents as soon as the manufacturer accepts the financial proposal.

**History of updates:**

| Version number | Date | Description |
|---|---|---|
| A | 03/10/2018 | Creation |
| B | 11/10/2022 | Addition of Section 7.3 “Language of documents issued and approved by STRMTG-NB1267” and update of Sections 4.1.1, 4.1.3, 7.1.3 and 7.6 |
| C | 13/03/2024 | Update of section 4.1.3 Testing and section 5.1 Audits |

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**Distribution:**
This document is available on the STRMTG website and referenced in all new financial proposals.
The associated documents (intervention request, declaration form) are available on the STRMTG website.

# Contents

# 1 - General

## 1.1 - Reference documents

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

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

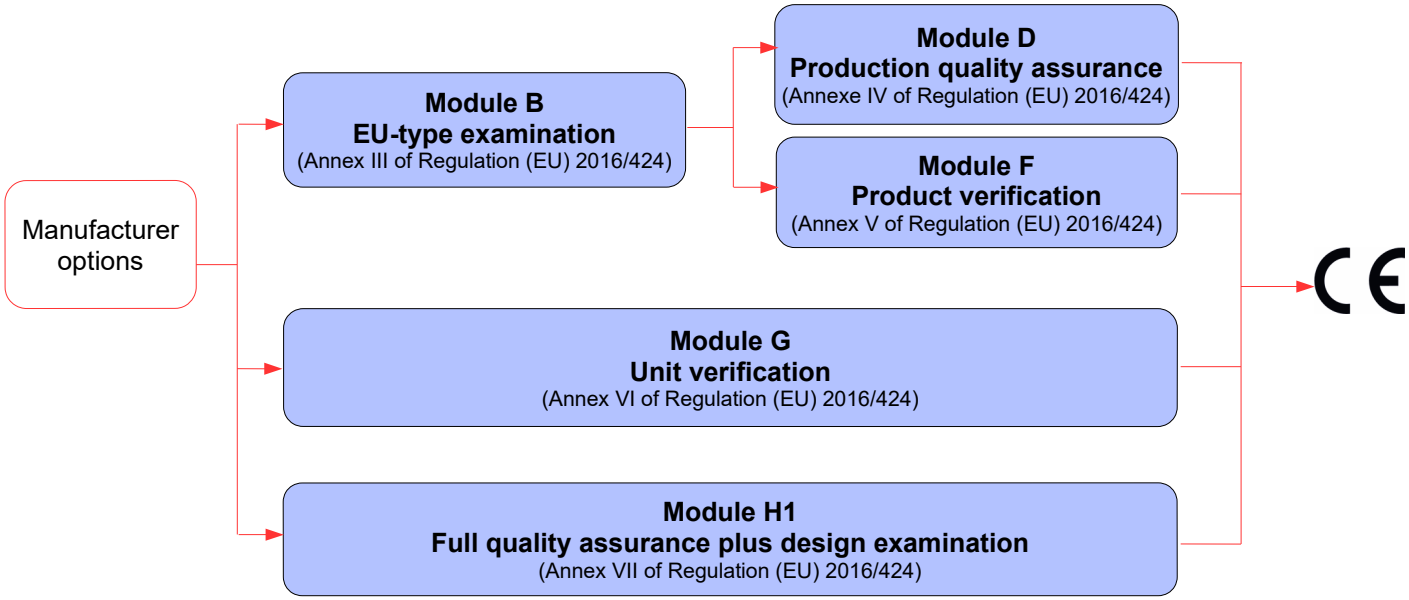
## 1.2 - Definitions

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

# 2 - Principles of intervention

## 2.1 - General principle

The interventions of STRMTG-NB1267 are carried out in accordance with the module(s) requested by the manufacturer.




## 2.2 - Intervention request

The manufacturer can request STRMTG-NB1267's intervention:
– for a new product, via a specific request or the intervention form;
– for a change in the design of a product which has already been assessed (Module B, Module G and Module H1 Section 3.6), via the declaration form (DOC OP 58).

## 2.3 - Documents to be provided by the manufacturer

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

### 2.3.1 - 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 Section 4.3.1) in order to describe the product. Its contents must include:
– a description and 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 reference of the “conditions of use” document;
– the references of the documents required for identification, commissioning, use and maintenance, etc.

### 2.3.2 - 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**<br>**for the design, manufacture, final inspection and testing** | **Module D**<br>**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.*<br>*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 that will 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 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 at the time of the intervention request. The manufacturer provides it or makes it available to STRMTG-NB1267 as part of the preparation and execution of the audit (see Section 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 - Assessment work conducted by STRMTG-NB1267

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

| | | B | D | F | G | H1 |
|---|---|---|---|---|---|---|
| **DESIGN EXAMINATION and SPECIFIC EXAMINATIONS** | | | | | | |
| Standards used | See Section 4.1.2, Section 4.2 | X | | X | X | X |
| Examination of the technical documentation | See Section 4.1.1, Section 4.2 | X | | X | X | X |
| Testing | See Section 4.1.3, Section 4.2 | X | | X | X | X |
| Examination of the representative specimen | See Section 4.2 | X | | | | |
| Intervention during manufacturing | See Section 4.2 | | | | X | |
| Final verification | See Section 4.2 | | | X | X | |
| **ASSESSMENT OF THE QUALITY SYSTEM** | | | | | | |
| Examination of the documentation related to the quality system | See Section 5 | | X | | | X |
| Initial assessment | | | X | | | X |
| Monitoring / Re-assessment | | | X | | | X |
| **ISSUANCE OF CERTIFICATES** | | | | | | |
| EU-type examination certificate | See Section 4.3.1 | X | | | | |
| EU design examination certificate | See Section 4.3.1 | | | | | X Section 3.6 |
| Certificate of conformity | See Section 4.3.2 | | | X | X | |
| Notification of decisions (quality system approval) | See Section 5 | | X | | | X |
| **CE MARKING and non-use of logos** | | | | | | |
| Affixing of the STRMTG-NB identification number (1267) by the manufacturer | See Section 7.4 | | X | X | X | X |
| Non-use of the STRMTG-NB and COFRAC logos | See Section 7.5 | X | X | X | X | X |

# 4 - Assessment work carried out for modules outside the quality system

## 4.1 - Design examination (Modules B, G, H1 Section 3.6)

### 4.1.1 - Examination of the technical documentation

This examination pertains to the technical documentation defined in Section 2.3.1, which allows 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 dimensions (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 paragraph below).

**Subcontracting**

STRMTG-NB1267 may use subcontracting for a limited part of the assessment of electrical components (design analysis and testing of the control-command software) and for some design calculations for mechanical components. In such cases, the manufacturer will be informed before the start of the service.

The certificates issued by STRMTG-NB1267 following assessment involving subcontracting will explicitly mention the use of subcontracting.

STRMTG-NB1267 asks to be a recipient of all exchanges between the manufacturer and the subcontractor. The subcontractor's services are monitored and approved by the STRMTG-NB1267 inspector in charge of the project. STRMTG-NB1267 retains responsibility for the assessment decision.

For the contractual provisions with the subcontractor, refer to Section 7.1.3 and for the payment conditions regarding its services, refer to Section 8.4.2.

### 4.1.2 - Technical specifications

On the basis of the technical solutions adopted by the manufacturer and the other information provided by the manufacturer in the technical documentation, in particular *"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"* (see Annex VIII, point C of Regulation (EU) 2016/424), 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 with the essential requirements that they aim to cover. STRMTG-NB1267 verifies compliance with every relevant normative requirement.

Note that a deviation from a requirement of a harmonised standard does not systematically result in non-conformity with the essential requirements of Regulation (EU) 2016/424. Therefore, STRMTG-NB1267 can accept such deviations as long as they are supported by an analysis provided by the

manufacturer to verify that an equivalent level of safety has been achieved, if necessary after establishing compensatory measures or verifications. Similarly, if the manufacturer relies on technical specifications other than harmonised standards, it must provide a specific analysis to demonstrate the level of safety achieved.

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

### 4.1.3 - Testing

Tests can either be required by standards, or requested by STRMTG-NB1267 as substantiation of a requirement which cannot be demonstrated by other means.

The manufacturer must submit the definition of these tests (protocol, service provider, procedures, installation of gauges for strain measurements), to STRMTG-NB1267 for approval. The reports for these tests are included in the technical documentation.

For vehicle tests to be carried out by laboratories as required by EN13796, the admissibility of test reports can only be accepted in the following cases:
- the laboratory performing the tests and issuing the report is accredited under EN ISO/IEC 17025 for the test concerned;
- the competency of the laboratory has been established through an audit by an external service provider recognised by STRMTG-NB1267, the frequency of which is defined by STRMTG-NB1267
In the latter case, the audit shall be carried out on the basis of the relevant provisions of ISO/IEC 17025 and shall demonstrate that the laboratory uses qualified personnel, equipment whose metrological traceability is ensured and procedures that guarantee the accuracy of data.

STRMTG-NB1267 may request to be present at 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, whether it is meant to improve the existing design, or results from a change in the applied standards[1].

STRMTG-NB1267 shall examine the changes, without necessarily re-conducting all the initial examinations.

Similarly, if STRMTG-NB1267 detects a change in the generally acknowledged state of the art[2] that could affect the conformity of the approved design, it shall determine if further investigation is required and shall inform the manufacturer accordingly.

1 Obligations of manufacturers (Art 11, paragraph 4 of Regulation (EU) 2016/424), Module B paragraph 7, Module H1 Section 3.6.4 of Regulation (EU) 2016/424:
*Module H1 Section 3.6.4: The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Regulation or the conditions for validity of the certificate. Such modifications shall require additional approval from the notified body that issued the EU design examination certificate in the form of an addition to the original EU design examination certificate.*

2 Module B paragraph 7, Module H1 Section 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 design 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.*

## 4.2 - Examinations specific to Modules B, F and G

<table>
<tr><th colspan="2"></th><th>STRMTG-NB1267 examination</th></tr>
<tr><td rowspan="3">The manufacturer provides information on where the product can be examined, and documents related to its manufacture and inspection.</td><td>Module B (followed by Module D or Module F) = a representative specimen (Annex III Section 4.2 of Regulation (UE) 2016/424)</td><td rowspan="3">– verifies the provisions and results of the manufacturing and inspection operations,<br>– carries out a visual inspection of all accessible parts of the product and ensures it conforms to the drawings.<br>As this visual inspection is not relevant for all types of subsystems or safety components, STRMTG-NB1267 may have to carry out an inspection based solely on the manufacturing, examination and test documents.<br>– has additional tests and checks carried out, if necessary.</td></tr>
<tr><td>Module F (follows Module B) =<br>– either each subsystem or safety component (Annex V Section 4 of Regulation (EU) 2016/424);<br>– or a random sample taken from each batch of subsystems or safety components (Annex V Section 5 of Regulation (EU) 2016/424).</td></tr>
<tr><td>Module G = the unique safety component or subsystem (Annex VI Section 3.1 of Regulation (EU) 2016/424);</td></tr>
</table>

## 4.3 - Documents issued by STRMTG-NB1267

### 4.3.1 - EU-type examination (Module B) or EU design examination certificate (Module H1 Section 3.6)

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

- issues the following to the manufacturer:
  - an “EU-type” examination certificate for Module B,
  - an “EU design” examination certificate for Module H1 Section 3.6,
- validates the conditions of use document for the subsystem or safety component by signing it and affixing its seal.
  The conditions of use document accompanies 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 Section 3.6 is valid for an unlimited period whereas the “EU-type” examination certificate for Module B is valid for up to 30 years from the date of issue.

When changes are made to the design, STRMTG-NB1267 stamps the declaration form provided by the manufacturer (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 assessment is deemed satisfactory, STRMTG-NB1267 issues a certificate of conformity and authorises the manufacturer to affix its identification number.

Note: The design examination for Module G does not lead to issuance of an EU design examination certificate.

# 5 - Assessment of quality systems (Modules D and H1)

STRMTG-NB1267 services aimed at monitoring quality systems 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 production on one or more sites.

## 5.1 - Audits

To assess the manufacturer's quality system, STRMTG-NB1267 carries out audits at 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 assessed;
– confirming their compliance with all the requirements applicable to the scope of the quality system for the relevant module;
– confirming that the processes and procedures have been defined, implemented and maintained effectively to provide 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 with experience in quality management systems;
– one or more technical auditors with experience in assessing cableway installations and the technology of the subsystems or safety components concerned, and knowledge of the requirements applicable to Regulation (EU) 2016/424.

The audit team is proposed to the manufacturer, who may reject one or more members of the team. In this case, the manufacturer must send its duly substantiated request to reject the auditor(s) to STRMTG-NB1267. If the request is accepted, STRMTG-NB1267 will propose a new audit team.

STRMTG-NB1267 assesses the quality system on the basis of the essential requirements of Regulation (EU) 2016/424 and the requirements of standard EN ISO 9001:2015. It examines the documentation related to the manufacturer's quality system (see Section 2.3.2) while preparing and performing the audit.

If the manufacturer already has a certification under standard EN ISO 9001:2015, STRMTG-NB1267 deems that this confers a presumption of conformity to the chosen module with regard to the provisions of this module covered by standard ISO 9001:2015 and on condition that the specific characteristics of the assessed products are properly taken into account in the quality system.

3 If the manufacturer subcontracts all or part of the production process, STRMTG-NB1267 may also carry out audits at the facilities of the subcontractor.

The assessment shall pertain in particular to the following subject areas:

| Subject areas | Module | | Regulation (EU) 2016/424 | EN ISO 9001:2015 Correspondence |
|---|---|---|---|---|
| | D | H1 | | |
| Organisation and context of the manufacturer's business -<br><br>Quality system management | X | X | Quality objectives, organisational structure, responsibilities and qualifications of management personnel related to product quality (Section 3.2 Annex IV & VII) | Section 5.1.1, Section 5.2, Section 5.3, Section 6, Section 9.3 (excluding c-1 of Section 9.3.2) |
| | | | Means used to monitor the proper functioning of the quality system (Section 3.2 Annex IV & VII) | Section 9.1.1, Section 9.1.3 (excluding b), Section 9.2, Section 9.3 (excluding c-1 of Section 9.3.2), Section 10 |
| Skills management | X | X | - | Section 7.2 |
| Control of externally provided processes, products and services | X | X | - | Section 8.4 |
| Design and configuration/parameterisation process | | X | Technical design specifications, including the set of technical standards used to ensure that the essential safety requirements of Regulation are met (§ 3.2 ann. VII) | Section 8.3.1, Section 8.3.2, Section 8.3.3, Section 8.3.5 |
| | | | Design inspection and verification techniques for safety subsystems or components (Section 3.2 Annex VII) | Section 8.3.4, Section 8.3.6 |
| Production process | X | X | Manufacturing, quality control and quality assurance techniques (Section 3.2 Annex IV & VII) | Section 8.5.1, Section 8.5.2, Section 8.5.5 |
| | | | Examinations and tests carried out before, during and after manufacture (Section 3.2 Annex IV & VII) | Section 7.1.5, Section 8.6 |
| | | | Surveillance means used to check the required product quality (Section 3.2 Annex IV & VII) | Section 8.6, Section 8.7 |
| Traceability and archiving | X | X | Documented information: quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc. (Section 3.2 Annex IV & VII) | Section 7.5, Section 8.5.2, Section 8.6 |
| | | | Retention of relevant documents and information for 30 years (Section 6 Annex IV & VII) | Section 7.5 |
| CE marking management | X | X | CE Marking (art. 20 & 21) | - |
| Control methods and non-conformity management | X | X | - | Section 8.7, Section 10.2 |
| Material resources, equipment monitoring, calibration | X | X | - | Section 7.1.5 |
| Handling, packaging, storage | X | X | - | Section 8.5.4 |

During the audit of each of the topics listed in the table above, particular attention will be paid to any **inappropriate use of the STRMTG-NB or COFRAC logos** by the manufacturer.

## 5.2 - Notification of decisions

### 5.2.1 - Audit findings

The findings of the audits may be as follows:

- **Strength**

Provision of the quality system in which the manufacturer:

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

- **Major Non-conformity (maj NC)**

Deviation from regulations or standards (internal and external), which directly compromises the safety of the safety components or subsystems, or the reliability of the quality system.

- **Minor Non-conformity (min NC)**

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

- **Weak point**

Provision that complies but could lead to a non-conformity in the short or medium term.

- **Area for improvement**

Suggestion to help the manufacturer improve the quality system.

### 5.2.2 - Processing the findings and especially non-conformities

The findings are taken into account by the manufacturer, processed and checked by STRMTG-NB1267 as follows:

- **Major Non-conformity (maj NC) and Minor Non-conformity (min NC)**

Each non-conformity (major and minor) is entered into a sheet that is given to the manufacturer and signed by it during the final meeting. The manufacturer then has 15 days to analyse the causes and impacts and to define the actions that it intends to take to resolve the non-conformity, as well as the implementation timeframes.

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

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

- **Weak point**

The manufacturer must take into account the weak point, the handling of which will be examined at the latest, at the next audit.

- **Area for improvement**

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

### 5.2.3 - Audit report

The audit gives rise to a report summarising the findings according to the aforementioned classification, and is sent to the manufacturer within 2 months.

### 5.2.4 - Approval of the quality system

All decisions concerning the approval of the quality system are taken by a person from STRMTG-NB1267 (the director or deputy director).

#### *5.2.4.a Initial audit / renewal audit*

STRMTG-NB1267 decides on whether or not to approve the manufacturer's quality system on the basis of the contents and findings of the audit report.

In the event of a positive decision, 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*

STRMTG-NB1267 decides on whether or not to uphold the approval of the manufacturer's quality system on the basis of the contents and findings of the audit report. The decision is issued by mail.

## 5.3 - Summary of the steps in a scheduled audit

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

| **Target date** | **Actions** |
|---|---|
| D – 6 weeks | STRMTG-NB1267 schedules the date of the audit with the manufacturer. |
| D – 4 weeks | STRMTG-NB1267 forwards the audit framework letter, including the proposed audit team. |
| D – 2 weeks | The manufacturer sends the requested documents.<br>The manufacturer may reject one or more members of the team. |
| D – 2 weeks | STRMTG-NB1267 sends the audit plan to the manufacturer. |
| D | Onsite audit.<br>Possible submission of non-conformity sheets. |
| D+ 2 weeks | The manufacturer must return the non-conformity sheets, updated with its analyses. |
| D + 2 months | STRMTG-NB1267 sends the report to the manufacturer with its decision. |

## 5.4 - Surveillance conducted during the quality system approval cycle

| | Initial audit | Surveillance (follow-up and renewal audits) |
|---|---|---|
| Module D | *Section 3.3 The audit shall include an assessment visit to the premises where the subsystems or the safety components are manufactured, inspected and tested.*<br>=> 1 audit | *Section 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.*<br>=> 1 audit every 2 years, including one at n + 4 years for renewing the quality system approval |
| Module H1 | *Section 3.3 The audit shall include an assessment visit to the premises where the subsystems or the safety* | *Section 4.3. The notified body shall carry out periodic audits of at least once every two years to make sure the manufacturer maintains and applies the quality system. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.* ⇒ |

| | | |
|---|---|---|
| | *components are designed, manufactured, inspected and tested.*<br>=> 1 audit | 1 audit every 3 years<br>⇒ depending on the size of the manufacturer and the technologies involved, an audit or other form of mid-cycle follow-up. |

Other forms of follow-up may include:
– follow-up meetings with the manufacturer, either in person or over the phone;
– exchanges with the manufacturer regarding the changes and progress of the actions undertaken to resolve the non-conformities identified during the audits;
– onsite visits/inspections of the installations containing the subsystems or components manufactured by the manufacturer, in the construction or testing phase or after commissioning.

Furthermore, STRMTG-NB1267 may conduct unannounced visits on the manufacturer's premises. The criteria for prompting such a visit are as follows:
– 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 on certified products that have already been released on the market;
– Significant organisational change at the manufacturer that was not voluntarily reported to 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, regulating authority, other cableways professionals).

The manufacturer is not informed of STRMTG-NB1267's visit. This visit will be the subject of a 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 ensure the safety of the auditors by providing them, if necessary, with the required personal protective equipment.

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

The manufacturer undertakes to fulfil the obligations deriving from its approved quality system and to maintain it such that it remains adequate and effective.

### 5.5.1 - Changes made to the approved quality system

The manufacturer is required to inform 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 receiving the approval;
– address of the legal entity receiving 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 takeover 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.

STRMTG-NB1267 assesses the impact of these changes on the originally approved quality system. It then decides if reassessment or an additional audit will be required.

### 5.5.2 - Regular information

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

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

# 6 - Defect detected in a product in service

In the event of a defect being detected or an accident or incident involving a safety component or subsystem already in service, the manufacturer shall inform STRMTG-NB1267 as soon as possible. This information is separate from the information that the manufacturer must provide to the proper national authorities of the countries concerned.

The manufacturer shall provide a technical analysis and a proposed action plan to:

– determine the causes of the problem;
– deal with the product and any similar products on the market which could be similarly affected;
– and prevent the same problem from occurring on future manufactured products.

STRMTG-NB1267 will send feedback to the manufacturer concerning its analysis and proposed actions. It also analyses the impacts on the validity of the quality system certificate and/or approval.

# 7 - The contractual provisions

## 7.1 - “Contract”

### 7.1.1 - First intervention or new product to be assessed

In response to an intervention request from a new manufacturer or from a manufacturer already under a contract with STRMTG-NB1267 for assessing a new subsystem or safety component, STRMTG-NB1267 prepares a commercial proposal that describes the specifics of the project, the timetable and the price quotation.

The same “contract” may cover the assessment of multiple products, especially when these products are intended for the same installation.

The “contract” which governs the relationship between STRMTG-NB1267 and the manufacturer requesting a conformity assessment consists of these general terms and conditions and the commercial proposal.

This “contract” supersedes all other documents.

It enters into force on the signature date of the commercial proposal 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 expiry of the certificate(s).

All “purchase orders” from the manufacturer must be made out in writing, and must reference the commercial proposal. In return, STRMTG-NB1267 shall issue an acknowledgment of receipt of the “purchase order” upon request.

### 7.1.2 - Assessment of changes

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

To inform STRMTG-NB1267 about changes made to the design, the manufacturer must use the declaration sheet (DOC OP 58), along with the technical documents required to demonstrate the continued conformity of the product in question, which shall be considered as an intervention request. If necessary, a commercial proposal will be drawn up.

To inform 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

STRMTG-NB1267 may have to outsource part of its assessment.

STRMTG-NB1267 shall have full control over its subcontractors by choosing them from among bodies which it has qualified on the basis of their expertise in the relevant fields and applications, the methodology applied, their technical resources and their independence from the projects involved.

These bodies can be:

- French Independent Technical Inspectors (*Contrôleurs Techniques Indépendants* - CTI) approved by STRMTG under the French Order of 9 May 2008 on the certification procedure for contractors and inspectors of lift and conveyor systems referred to in Article L. 342-17-1 of the French Tourism Code (these inspection bodies are known and recognised in the field of lift systems).
- bodies accredited for the relevant activities;
- bodies assessed by STRMTG-NB1267 through an analysis demonstrating the subcontractor's level of expertise in the relevant field(s).

Furthermore, STRMTG-NB1267 carries out surveillance (e.g. audits) of its subcontractors to assess their expertise and compliance with other applicable requirements of EN ISO/IEC 17020.

When STRMTG-NB1267's commercial proposal involves the work of a subcontractor, it separates STRMTG-NB1267's financial proposal from that of the subcontractor. The subcontractor's proposal is appended to the proposal.

Therefore, when a manufacturer accepts a commercial proposal that includes the intervention of an STRMTG-NB1267 subcontractor, it implies acceptance of the subcontractor.

If the manufacturer accepts the commercial proposal by issuing a "purchase order", it has two options:

1) The manufacturer sends two purchase orders:

- one to STRMTG-NB1267 for the financial sum of STRMTG-NB1267 with reference to the commercial proposal.
- one to the subcontractor for the financial sum of the subcontractor with reference to the subcontractor's quotation and STRMTG-NB1267's commercial proposal.
  STRMTG-NB1267 is issued a copy of the purchase order.

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

For payment of the subcontractor, see Section 8.4.2.

## 7.2 - Conditions for the validity of certificates

Some certificates have validity periods defined when they are issued:

- The EU-type examination certificate for Module B is valid for up to 30 years (subject to a quality system approval under Module D or a valid certificate of conformity under Module F),
- the quality system approval under Module D is valid for up to 4 years,
- the quality system approval under Module H1 is valid for up to 3 years.

Conformity certificates under Modules F and G are valid for an unlimited period. The same applies for the EU design examination certificate (Module H1 Section 3.6). However, it remains valid only for as long as the manufacturer has a valid quality system approval under Module H1.

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

- at the manufacturer's request;
- at its own initiative, if the manufacturer does not comply with the obligations of Regulation (EU) 2016/424 or the assessment conditions, such as:
  – refusal to carry out audits within the required period or at the required frequency;
  – refusal to provide 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;
  – if the subsystem or safety component has a defect that was not detected at the time of its certification;
  – if the normative standards and the generally acknowledged state of the art change;
  – the fraudulent use of the certificates and the STRMTG-NB identification number (1267);
  – non-payment of invoices.

## 7.3 - Language of documents issued and approved by STRMTG-NB1267

The certificates issued by STRMTG-NB1267 are bilingual, in French and English. They shall not be issued in any other language.

STRMTG-NB1267 signs the conditions of use for a safety component or subsystem in one language (French or English).

If necessary, it is therefore the manufacturer's responsibility to have these documents translated into other languages in accordance with the original.

## 7.4 - 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 as follows: "*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 STRMTG as a notified body is 1267, which is the property of STRMTG.

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

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

Regardless of whether it pertains to the use of its certificate or any other information on the misuse of the CE marking that it may be aware of, STRMTG-NB1267 shall inform the market surveillance authorities and Member States, and take appropriate measures. "Misuse" particularly includes the act of:

– referring to a certificate that does not exist;
– referring to a pending certificate that has not yet been issued;

– referring to a certificate when it has been suspended or revoked;
– giving the same trade name to certified and non-certified products.

## 7.5 - Use of the STRMTG-NB1267 logo and accreditation marking

Any use or reproduction of the STRMTG-NB1267 logo is prohibited without its prior written consent.
Use of the accreditation marking is strictly prohibited.
STRMTG-NB1267 reserves the right to take any appropriate measures in the event of unauthorised use of its logo and accreditation marking.
This point may be observed during audits.

- **Reproduction of documents issued and approved by STRMTG-NB1267**

Documents issued or approved by STRMTG-NB1267 (certificate, audit report, conditions of use) may be reproduced. They must be reproduced in their entirety and must be true to the original (without modification or alteration of any kind)
They may be translated by the manufacturer. They must be translated in accordance with the original, under the full responsibility of the manufacturer.

## 7.6 - Claims and appeals

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

## 7.7 - After-sales technical support

STRMTG-NB1267 shall provide support to the manufacturer in case of any question regarding the use of the certificates that it issues for a product; 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 - STRMTG-NB1267 intervention conditions

## 8.1 - The tasks and duties of STRMTG-NB1267

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

- carry out the tasks of assessing conformity in accordance with the requirements of Regulation (EU) 2016/424 and take appropriate corresponding decisions;
- ensure that the other activities of its subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities;
- monitor the generally acknowledged state of the art;
- participate in standardisation activities;
- participate in the activities of the European coordination group of notified bodies;
- inform the notifying authority and other notified bodies of the certifications that it has issued, rejected, revoked, suspended or subjected to other restrictions;
- on request, provide the notifying authority with the conformity assessment activities carried out as part of the notification;
- provide the notifying authority with the relevant documents concerning the assessment of the subcontractor's qualifications and the work which it carries out.

To be accredited, STRMTG-NB1267 must comply with the requirements defined in Articles 26 and 34 of Regulation (EU) 2016/424. The French Order of 28 June 2004, amended by the Order 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.

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

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

## 8.2 - Impartiality and confidentiality

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

STRMTG-NB1267 undertakes 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 STRMTG-NB1267 is bound by law to disclose confidential information, the manufacturer in question shall be informed about the information disclosed, unless prohibited by law.

In the light of its accreditation, STRMTG-NB1267 mandates COFRAC evaluators as well as internal personnel or service providers to audit it. These persons may need to access the manufacturer's confidential information. As a matter of professional ethics, the evaluators and auditors will themselves treat this information confidentially.

## 8.3 - Language

STRMTG-NB1267 is able to handle projects in the following languages:

- French;
- English.

The conditions for issuing documents are set out in Section 7.3.

## 8.4 - Financial and payment terms

### 8.4.1 - Financial terms

The price owed to STRMTG-NB1267 is defined and detailed in the “contract” (see Section 7.1).

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

If, for any reason whatsoever, the procedure for issuing the certificate is interrupted, the sums corresponding to the work carried out or initiated by STRMTG-NB1267 shall be due or be forfeited to STRMTG-NB1267.

If an audit is postponed or cancelled by the manufacturer who has agreed to the audit dates, STRMTG-NB1267 reserves the right to charge the manufacturer 30% of the price that would have been invoiced to it if the audit had been carried out.

Delays or non-performance of orders resulting from events of force majeure - such as fires, floods, strikes (including slowdowns or work-to-rule strikes) - regulations or requirement issued by the public authorities, or any other unavoidable and unforeseeable event beyond the control of STRMTG-NB1267, shall not give rise to compensation.

### 8.4.2 - Payment terms

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

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

The invoices include the applicable VAT rate as well as the price Excluding VAT and the Total Price Including VAT for sum owed.

For manufacturers located outside France, the manufacturer must settle the direct and indirect national taxes and/or levies resulting from the invoices with the appropriate local authorities and/or administrations.

**Subcontracting**

STRMTG-NB1267 subcontractors shall be paid directly by the manufacturer. The subcontractor shall send its invoices to the manufacturer via STRMTG-NB1267, which will approve their conformity and forward them to the manufacturer for payment.