



# CERTIFICATION REGULATION

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<b>Changes</b>	Better definition of the field of application and other formal changes, inclusion of the subsystem coordinator. New regulatory framework.		
<b>Status</b>	<b>Prepared</b>	<b>Verified</b>	<b>Approved</b>
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## 1. SCOPE

This document describes the relationships between CERTIFER Italia SrlU and the Customer and the methods with which CERTIFER Italia carries out the assessment / inspection activities.

**CERTIFER Italia SrlU** (hereinafter CERTIFER Italia) is an independent assessment body that provides services for assessing compliance with the reference standards of the sector of projects and / or products in the railway transport sect.

## 2. APPLICATION AREA

It is applied to the following CERTIFER Italia activities:

- Certifications as a Notified Body
- Certifications as Designated Body
- Certification of Maintenance Management (ECM)
- Certification as an Independent Railway Body (OIF)

## 3. REFERENCES

Assessment activities will be carried out according to the following national and international reference standards and regulations:

- UNI CEI EN ISO / IEC 17020 Conformity assessment - Requirements for the operation of various types of notified bodies that perform inspections
- UNI CEI EN ISO/IEC 17065 Conformity assessment - Requirements for organizations that certify products, processes and services
- MNB - Assessment scheme 000MRA1044 Requirements for conformity assessment bodies seeking notification
- DIRECTIVE (UE) 2016/797 Relating to the interoperability of the European Union railway system
- DIRECTIVE (UE) 2016/798 Railway safety
- Decreto Legislativo 50,14/05/2019 Decree IT transposing directive (UE) 2016/798
- Decreto Legislativo 57,14/05/2019 Decree IT transposing directive (UE) 2016/797
- EU Regulation UE n. 779/2019 Relating to a certification system for the subjects responsible for the maintenance of vehicles
- European commission decision - Technical specifications for interoperability (TSI) applicable to the high-speed and conventional railway system
- Decrees collection and directives of the National Agency for railway Safety (ANSF)
- CEI EN 50126 The specification and demonstration of reliability, availability, maintainability and safety (RAMS)
- CEI EN 50128 Telecommunication, signaling and processing systems, software for railway command and protection systems

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- CEI EN 50129 Telecommunication systems, signaling and processing, electronic security systems for signaling
- Accredia RG-01 Regulation for the accreditation of Certification and Inspection Bodies - General Part
- Accredia RG-01-03 Regulations for the accreditation of Product Certification Bodies
- Accredia RG-09 Regulations for the use of the ACCREDIA trademark
- Accredia RG-01-04 Regulation for the accreditation of Inspection Bodies

#### 4. TERMS AND DEFINITIONS

The definitions cited in the standards applied are:

- UNI EN ISO 9000 Quality management systems - Foundations and vocabulary, December 2005 edition.
- CEI UNI EN 45020 Standardization and related activities - General vocabulary
- UNI CEI EN ISO / IEC 17000 Conformity assessment - Vocabulary and general principles

and the following terms used in the text:

**Customer:** Organization that requires the activity of Inspection / assessment.

**Assessor:** Personnel qualified and appointed by the organization to perform the Inspection / assessment activity.

**Body:** company that carries out assessment activities.

#### 5. GENERAL CONDITION

1. This Regulation contains the provisions for governing the relationship between the Notify Body and the Customer. The Regulation can be supplemented by additional provisions that must be specifically included in the contract between the Body and the Customer.
2. The contractual relationship between CERTIFER Italia and its Customer will be governed exclusively by the order / contract concluded between the parties, drawn up in accordance with these Assessment Rules. In the event of discrepancies between this regulation and the contract, what is indicated on the order / contract prevails.
3. The object of assessment activity must be defined within the contract.
4. CERTIFER Italia and all the personnel performing the assessment activity are not involved in situations of: planning, realization, supply, installation, acquisition, possession, use and maintenance of the objects inspected or objects like these, without prejudice to the time clause (2 years).
5. CERTIFER Italia is responsible for the inspections even if the inspection activity is carried out by suitably qualified independent collaborators who carry out this activity on behalf of CERTIFER Italia.
6. Depending on the agreements that will be made, the inspection activity can be carried out, depending on the type of assessment activity, on the site, at the premises of the Customer, or even at the headquarters of CERTIFER Italia.

Note: the order / contract means the document that describes and regulates the reciprocal obligations of the Parties; it can be made up of a dedicated document specifically prepared by the Customer as well as by the formal acceptance of the offer presented by CERTIFER Italia

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## 6. ASSESSMENT PROCESS

Assessment activities can be requested from all companies operating in the rail and tram transport sector.

### 6.1. *Domanda di certificazione e riesame*

To start the assessment activity, the Customer sends to **CERTIFER Italia** an offer request. The offer contains the information necessary to identify the assessment object and the specifications / standards with which to carry out the assessment.

To facilitate the information collection, CERTIFER ITALIA can send the Customer organized forms for the collection of information, to be completed and signed by the Customer (eg. AP 07.1.5 Request for SRM certification).

CERTIFER Italia may request the additional documentations if they are not enough.

Furthermore, when required by applicable legislation, the offer will require a declaration in which the Customer, specifically states that no similar assessment activity has been demanded to another Body for the same object or alternatively that an assessment has already been carried out and assessment reports will be provided with results and open points (alternatively CERTIFER Italia can supply the model AP 07.1.6 "Model for univocal assignment declaration").

The contractual relationship between CERTIFER Italia and the Customer will be governed exclusively by what is indicated in the order / contract signed between the parties and by these Regulations.

With the order / certification contract the Customer also undertakes:

- Always comply with certification requirements. Should these requirements be modified, the Customer undertakes to implement the changes necessary to maintain the certification with the times and methods agreed with CERTIFER Italia or envisaged by the certification requirements.
- To ensure the maintenance of product / service / process requirements over time.
- To provide access to its sites and the documentation required for certification and subsequent supervision when applicable.
- To keep a claims records concerning the certified product / service / process, make them available to CERTIFER Italia, carry out the appropriate actions to restore compliance, document the management.
- To promptly inform CERTIFER Italia of all changes with an impact on the certification requirements (changes relating to the product / service / process, organizational changes, ownership, legal status, operating site, etc.).
- The use certificate use certification within its field of application and in any case in compliance with what is described in chapter 7 of this document.

As result of the signing of the order / contract, CERTIFER Italia notifies the Client of the names of the inspectors / assessors appointed (after a Start-up meeting with the interested parties).

If the offer is not issued, CERTIFER Italia informs the Customer with the reasons.

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## 6.2. Procedure for the documentation submission

To carry out the assessment activities, the Customer sends to CERTIFER Italy the documentation in electronic format and, where not available, in paper form. The accepted formats are: ".xls", ".doc", ".pdf" and ".dwg" (unless otherwise agreed).

## 6.3. First certification

Following the conclusion of the certification review application and the stipulation of the contract, CERTIFER ITALIA identifies the commission, updates the program prepared in the previous phase and starts the assessment activities.

### 6.3.1. Assessment performing

The following main management and assessment activities are carried out under the coordination of a project manager:

- Designation of assessors and obtaining acceptance of the assignment with a commitment to confidentiality and impartiality.
- Possible stipulation of contracts with external parties.
- Possible stipulation of contracts with laboratories.
- Update of the assessment program.
- Carrying out of the assessment (documentary or in the field) as described in the Assessment Program.
- Report review for the by the project Manager and sent to the Customer.

CERTIFER Italia notifies to the Customer the assessor names assigned and the Project Manager (**RC**) who constitutes the first interface for the Customer. The Customer has 10 days available, since the communication receipt, for a possible rejection of one or more assessors. The Customer must provide documented reasons, which will be verified by **RT (Technical Director)**. If the Customer's requests are adequate, RC will carry out the assessor(s) change.

The same approval process is also subject for the selection of the external laboratories by CERTIFER Italia, if these are necessary for the performance of the assigned activity.

CERTIFER Italia also notifies to the Customer the presence of ANSF or Accredia inspectors, as observers. The Customer has the obligation to accept the presence of such Inspectors.

The Customer has the obligation to make the assessors aware of the safety regulations and the site risks of interest for the assessment place.

In the event of an assessor prolonged absence, to maintain continuity of service, CERTIFER Italia replaces him with an assessor of equal professional competence, whose name is promptly communicated to the Customer.

The assessment, according to the procedure requirements, can be conducted by a single assessor or an assessor group. In the case of an assessor group, CERTIFER Italia will appoint a manager.

The Customer shall give available all the documentation necessary for the inspections that will be necessary for the CERTIFER Italia assessment.

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RT is responsible for the technical coordination of all assessment processes. In the event of unavailability of RT or in the case of direct assessment activities as assessor, the responsibility lies with SRT (Deputy Technical Manager); in case of unavailability of SRT, the activity is suspended.

Where there is a Subsystem Coordinator, it is responsible for the technical coordination of all the assessment processes relating to the subsystem.

Where applicable, the Customer must submit a Test Plan to CERTIFER Italia, which is submitted for approval. Once approved, the Customer can perform the tests at laboratories. The tests acceptability must still be submitted to CERTIFER Italia. If the contract provides for it, CERTIFER Italia itself may organize the tests at laboratories selected in consultation with the Customer. The tests result in an independent external laboratory are transmitted to the CERTIFER Italy coordinator. If during the tests emerges a "Not-Conformity" to the applicable requirements, the assessor coordinator evaluates the opportunity to interrupt the test.

### **Sub-Contractor**

If CERTIFER Italia were to subcontract any part of the assessment, it will ensure and demonstrate that the selected subcontractor is competent to provide the service in question and, when applicable, is able to meet the criteria set forth in regulation 17020 or 17025.

In the event of subcontracting, CERTIFER Italia informs the Customer the intention to subcontract part of the assessment and the subcontractor will be submitted to the Customer for acceptance.

### **Assessment / inspection / audit reports**

At the end of each assessment activity, CERTIFER Italia releases a final assessment / inspection / audit report, which describes the outcome of the assessment, as reported below.

The reports issued by CERTIFER Italia contain all the results and conclusions of the assessment activities carried out.

In case of corrections or changes to an Assessment Report made after the issue, CERTIFER Italia provides for the release of a new document that cancels and replaces the previous one. Within the new document, the changes that led to the new issue will be indicated and justified.

#### **6.4. Remarks, Not conformities, corrective actions**

In the assessment operations, non-conformities can be detected, remarks can be made, or clarifications can be requested:

**Non-conformity:** they are issued in the event of failure to meet a requirement on the product, project or management system being assessed. They are also issued against a deficiency of the Customer's management system, such as not to guarantee the conformity of the product.

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**Remarks:** they are issued against a deficiency of the Customer's product, process or management system, even if not such as not to guarantee the conformity of the product.

**Comments:** they are issued if a possibility of improvement of the Customer's product, process or Management system is detected, to guarantee the conformity of the product to the reference technical standard.

All Not-Conformities and Remarks are promptly communicated to the Customer

Following this communication, the Customer will inform CERTIFER Italia about the corrective actions to be taken and the times within which to execute them (decided in relation to the specific complexity of the case), times that the Customer undertakes to comply with.

The remark does not compromise the release of the Final Assessment Reports with the result of conformity and the Assessment Certificates on the condition that the Customer engage to resolve the deficiencies found, and in any case fulfills the corrective action.

In the case of Not-Conformities that would preclude or render impracticable the continuation of the activity, CERTIFER Italia reserves the right to evaluate the temporary suspension of the activity, until the Not-Conformity is resolved.

#### **6.4.1. Certification decision**

The commission decides positively or negatively about the certification.

RC communicates the decision to the Customer.

#### **6.4.2. Certificates releasing and sending**

the event of a positive assessment the certificates are released and sent to the Customer.

#### **6.4.3. Certificate list update**

CERTIFER Italia will maintain an updated list with the certifications released and the related deadlines. These lists must be updated promptly within 7 days of the certificate release.

For example, CERTIFER Italia will maintain a list of ECMs for which certificates have been released, the updating of these lists will be made within 7 days of the commission's decision and will be promptly communicated to the ERA.

#### **6.4.4. ANSF communication**

When required, CERTIFER Italia will send the summary list of the certificates / certificates to the control bodies (ANSF and / or ACCREDIA). For example, CERTIFER Italia will send ANSF an annual summary list of the certificates released, and the surveillance activities carried out, attaching the assessment reports made.

### **6.5. Certificate surveillance, modification, suspension, revocation, reduction and cancellation**

#### **6.5.1. Surveillance**

If it is foreseen depending on the type of certificate, a surveillance activity is carried out.



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A few weeks before the surveillance deadlines the customer will communicate any changes with impact on the certification. If only the need for surveillance is confirmed (without changes), the surveillance activity is carried out according to the provisions of the assessment program.

In the case of a positive outcome of the assessment activity, the certificate remains valid.

In the case of a result that is not completely positive (in the case of remarks carried out during surveillance activities, which could jeopardize the certification / certification), the commission is asked to decide on the maintenance of the certificate that can decide on the maintenance, revocation or suspension of the certificate (see following paragraphs).

### **6.5.2. Certificate modification**

In the event of certificate modification requests, the same must be requested in writing form by the Customer. In the case of formal modifications, CERTIFER Italia will assess the impact of these on the certificate and will proceed with reprinting the certificate, updating the lists and, when required, communicating the change to the interested parties.

In the case of substantial changes (eg modification of the operational headquarters, extension of the scope of the certificate etc.) a specific assessment program will be drawn up which includes the activities to be carried out in order to verify the possibility of modifying the certificate. In these cases, the commission will be asked to express its opinion regarding the certificate modification. In the event of a positive outcome, the updated certificate will be released, and the lists will be updated and, when required, the change will be communicated to the interested parties.

### **6.5.3. Certificate suspension**

The decision to suspend a certificate can be taken in the following cases:

- The customer quality management system has constant or serious failures to comply with the certification requirements.
- The Customer has not allowed the realization of supervision audits according to the required frequency.
- Customer requests it voluntarily.
- Presence of non-compliance during the activity certification supervision / reassessment.
- Complaints and appeals in progress or closed with impact on the certificate.
- Nonpayment.

The suspension decision is communicated by CERTIFER Italia to the Customer, together with a supporting document, which also indicates to the Customer the elements necessary to revoke the suspension and a maximum time within which to provide them or alternatively a maximum time within which CERTIFER Italia can make a reassessment to verify the corrective actions made. The Customer is also informed with this communication that he must not use the certificate for the duration of the suspension.

The suspension status is updated on the certificate list. When applicable, the interested parties are informed.

If the Customer does not provide feedback and the cause of the suspension is not eliminated, the certificate will start the procedure for the withdrawal of the certificate (see the following paragraph).



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#### **6.5.4. Certificate revocation**

The decision for the certificate revocation can be taken in the following cases:

- if the Customer does not provide feedback following a suspension and the cause of the suspension is not eliminated;
- as result of serious non-conformities;
- as result of serious failures to comply with the rules on the use of the certificate.

The commission is called in this case to decide on the revocation of the certificate. The decision on revocation is communicated by DG to the Customer, together with the supporting documentation. The Customer is also informed with this communication that he must not use the certificate.

The revocation status is updated on the certificate list. When applicable, interested parties are informed.

#### **6.5.5. Certification scope reduction**

The decision to reduce the certification scope can be made in the following cases:

- the Customer requests it voluntarily;
- if the Customer does not provide feedback following a suspension and the cause of the suspension is not eliminated (applicable only to a part of the certification purpose).

The decision on the reduction is communicated by CERTIFER ITALIA to the Customer, together with the supporting documentation. The Customer is also informed with this communication that he must not use the certificate in its previous version.

The certificate list will be updated. When applicable, the interested parties are informed.

#### **6.5.6. Certification cancellation**

A certificate is canceled either upon its natural expiry or in the case of a voluntary request received in writing by the Customer.

In the event of a voluntary request, CERTIFER Italia will cancel the certificate by updating the lists and by notifying the parties concerned, if applicable.

### **6.6. Use of certificates verification**

If CERTIFER Italia becomes aware (either from its own personnel or from third parties) of the non-compliance with the conditions of use of the certificate indicated in this regulation, it performs the following actions:

- certification reminder in writing form of compliance with the conditions of use;
- requires that all necessary measures be taken to bring them back to compliance with these rules;
- requires that these actions be promptly communicated to CERTIFER Italia in writing form.

In the event of serious abuse or in the event of lack of presentation of corrective actions by the Customer, CERTIFER Italia initiates the procedure for the suspension or revocation of the certificate.

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## 7. USE OF ASSESSMENT REPORTS, CERTIFICATES, CERTIFER ITALIA LOGO, ACCREDIA BRAND

The Customer may make use permitted by the law of assessment report, which must be considered confidential documents that cannot be reproduced except for internal and official uses by the control bodies of the Agencies (European and National) and / or final Customers (users of the products being assessed).

The Companies that receive the CERTIFER Italy Certificates have the right to exhibit the Certificate and to use the reproduction, on its own bulletin boards and in its advertising documents, only in its entirety, so that it is clear which is the declared conformity and the limits of the certificate. It is forbidden the use of the Certificate outside the area for which the certification was granted, can cause the revocation or suspension of the certificate.

It is permitted to use the CERTIFER Italia logo within its own materials only if this is clearly related to the certification obtained, without the risk of misleading the user of the documentation on the type, nature and limits of the certification.

CERTIFER Italia uses the ACCREDIA trademark in its own certificates / assessment reports for the activities / services that fall under the Accreditation scheme:

UNI CEI EN ISO / IEC 17020 - as Type A Inspection Body in the sector: Railway sub systems and related components - Certificate 076E.

No other use of the ACCREDIA trademark is granted to the Customer, outside of these reports / certificates

## 8. CUSTOMER RIGHTS AND DUTIES

The Customer, by accepting this regulation, undertakes to:

1. Operate as reported in the regulation.
2. Allow access to permit and make available the resources necessary for the performance of the assessment activity, to those responsible for the activities being assessed and, possibly, to the inspectors of ANSFISA and / or Accredia, in compliance with the safety regulations current.
3. Ensure all the necessary conditions to allow the optimal assessment to be carried out even in the case of third-party assessment.
4. Comply with the payments provided for in the contractual documents.

The Customer is entitled before receiving the documents, with CERTIFER Italia, to issue a confidentiality agreement.

If the customer finds discriminatory and non-impartial behavior on the part of CERTIFER ITALIA, he has the right to contact CERTIFER ITALIA's Committee for safeguarding impartiality (CSA).

## 9. CERTIFER ITALIA RIGHTS AND DUTIES

CERTIFER Italia undertakes to:

1. Operate as reported in this regulation.
2. Guarantee the presence of the inspection personnel in charge during the assessment.
3. Respect the safety regulations in force in the premises owned by the Customer to which CERTIFER Italia personnel have access.

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4. Respect the scheduled agreed times for the performance of the assessment activities and for the delivery of the final documentation.
5. Guarantee the confidentiality of the information received from the Customer useful / necessary for the performance of the assessment activity.

## 10. RESPONSIBILITY

1. The Customer undertakes to guarantee the completeness and truthfulness of the documents and information made available to CERTIFER Italia.
2. CERTIFER Italia is explicitly exempted from any liability in the event of failure or incomplete communication of data, as well as they do not correspond to the actual business situation.
3. CERTIFER Italia is responsible for verifying what has been agreed at the contractual level by not assuming any direct responsibility for the adequacy of the technical choices made for this purpose by the Principal's Organization - which remains solely responsible - nor for ascertaining the compliance with legal requirements.
4. The assessment activity by CERTIFER Italia does not exempt the Customer from the legal obligations deriving from the products, processes and services provided by it and from the contractual obligations towards its customers, with the exclusion of any liability or guarantee obligation. In particular, it is agreed that no responsibility can derive to CERTIFER Italia for defects in products, processes and services provided by the Customer to third parties, in the cases contemplated by Legislative Decree 6.09.2005 n. 206 and subsequent amendments (Consumer Code) EEC Directive 85/374 (and / or subsequent amendments or additions), concerning liability for damage to defective products and for systematic or occasional behaviors of the Customer, not aligned with Laws and / o Regulations.
5. CERTIFER Italia is not responsible for inadequacies or damages of any kind caused by the Customer during the activity or by its products, processes or services.

## 11. COMPLAINTS AND APPEALS

All **complaints** relating to the activities of CERTIFER Italia must be submitted in written form by registered letter with acknowledgment of receipt or fax within three months of the occurrence of the claim. All complaints so received will be analyzed by the organization. The manager of the complaint management will verify the merits of the complaint and activate the relative procedure. The results of this verification will be communicated in writing to the Customer within thirty days of receipt of the complaint. If the complaint is founded, the corrective actions will be implemented promptly by CERTIFER Italia and communicated to the Customer.

**Appeals** can be presented by the Customer to CERTIFER Italia within and no later than three months from the delivery of the Final Assessment Report and / or the Certificate. Appeals must be received in writing by letter registered with acknowledgement of receipt or fax.

The appeal is taken in charge by the Legal Representative, who appoints a Responsible for the Appeal. The Complaints Manager must be a person of adequate technical skills and must be unrelated to the activity in question, independent and impartial in the expression of their judgment. The Customer will be notified in writing form for the Appeal and it will have 5 days to object, by documenting its decision in writing form.

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The results of the checks are communicated by CERTIFER Italia to the Customer in written form by registered letter with acknowledgment of receipt within sixty days from the presentation of the appeal.

CERTIFER Italia notifies the Customer of the appeal results, stating the reasons, taking care to also send any documentation relating to the checks carried out about the appeal.

A more detailed description of the complaints and appeals procedure can be sent upon request.

## 12. DISPUTES

In the event of disputes between the Customer and CERTIFER Italia, the Court of Pisa will have the jurisdiction.

## 13. PRIVACY

The information and documents required for the assessment activity will be considered confidential.

Access to this documents/information will be reserved for those involved in the assessment process, the Customer and, if necessary, the accredited body.

CERTIFER Italy and its employees / external collaborators undertake to:

1. no diffusion for data dissemination and uses in any information, data, documents related to the assessment of the activities in which they participate;
2. keep and manage the documentation received from the Customer in such a way as to prevent third parties from viewing it or making a copy;
3. the assessors also undertake to return the paper copies of the documents to CERTIFER Italia and to eliminate any IT (Information Technology) versions at the end of the assessment.

The commitment takes place through the signing of confidentiality agreements, in which employees and external suppliers undertake to avoid conflicts of interest and to remain impartial and free from external influences of both economic and psychological nature.

However, CERTIFER Italia operates in full compliance with the provisions of Legislative Decree 30 June 2003 n. 196 (processing of personal data).

## 14. REASON OF FORCE MAJEURE

CERTIFER Italia will not be forced by this regulation and will not be held responsible if external events defined as "force majeure" on which it has no influence should occur. The term "force majeure" means all unforeseeable events independent of CERTIFER Italia which occurred after the conclusion of the contract.

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## 15. SAFETY REQUIREMENTS

CERTIFER Italia undertakes to comply with the Customer Safety Plan, which is previously made available for CERTIFER Italia.

Compliance with the legislation for the safety of workers is stated pursuant to Legislative Decree 81/08 and subsequent amendments and additions, in particular observing the obligations pursuant to art. 20 of the aforementioned Decree, as well as the provisions of the prevention and protection service manager.

The obligations provided by the art. 26 of Legislative Decree 81/08 and the provision of personal protective equipment (PPE), in relation to the specific risks present in the host structures, are to be attributed to the subject at the top of the host structure (article 2 DL363 / 98).

In implementation of the provisions of Legislative Decree 81/08:

- In the event that there are interferences between the activities of the Customer and those of CERTIFER Italia, the personnel in charge of the Customer and that of CERTIFER Italia are to cooperate in the implementation of the risk prevention and protection measures for the activity; CERTIFER Italia draws up the document of assessment of the interferences bearing a recognition assessment of the standard risks with respect to the provision that provides derivatives from the execution of the contract. First, the beginning is foreseen for the specific risks of interaction in the places where the activity will be carried out; the integration, signed for acceptance by the executor, supplements the contractual deeds.
- Without prejudice to the fact that the coordination of the protection and prevention interventions against the risks that are the workers will always be up to the Customer, the manager in charge of the security of the Customer and that of CERTIFER Italia inform each other also in order to eliminate the risks of interference between the works of the various companies during the execution of the works contracted to CERTIFER Italia.