Title	**GENERAL RULES FOR ASSESSING CONFORMITY TO COMMUNITY DIRECTIVES FOR WHICH IMQ OPERATES AS NOTIFIED BODY N°. 0051**
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Approved by	*IMQ S.p.A. – Competent B.U. FP and FV*

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GENERAL NOTE: THIS DOCUMENT IS A TRANSLATION TO ENGLISH LANGUAGE BASED ON THE ORIGINAL DOCUMENT REG. ON/GEN – REV. 4 (IN ITALIAN LANGUAGE). IN CASE OF DISCREPANCY, SUCH ORIGINAL DOCUMENT PREVAILS

Art. 1. FOREWORD

This document is considered to be applicable unless exceptions are specifically agreed upon between the parties.

Each exception will be valid only if previously agreed in writing between the Parties. In the case that one or more of the articles were to prove null or ineffectual for any reason, the nullity or ineffectualness will not be extended to other requirements of this Regulation.

Any specifically agreed exceptions cannot in any way concern the conformity assessment procedures according to which IMQ, acting as Notified Body, is required to operate.

Art. 2. SUBJECT MATTTER OF THE REGULATION

2.1. Assessment of Conformity to European Directives or Regulations

This Regulation approved by IMQ S.p.A. (hereinafter, "IMQ") establishes the General Requirements for the provision of one or more services by IMQ to assess conformity (hereinafter "Service" or the "Services") to the European Directives or Regulations (hereinafter "Directives") for which IMQ is authorised to operate as Notified Body (hereinafter "NB").

Within this Regulation, are also defined the applicable conditions to the Certification Contract stipulated for the aforementioned conformity assessment services , taking as essential elements of this Contract:

- by the Customer side, the acceptance of the IMQ offer, the presentation of the application and the acceptance of the applicable IMQ Regulation;
- by IMQ side, the order confirmation, once the documentation has been received from the Customer.

2.2. Special requirements for each Directive

The Special Requirements applicable to each Directive for which IMQ is authorised to operate constitute an integral part of this Regulation.

2.3. EC /EU certification

The Applicant (hereinafter "the Customer") entrusts IMQ with the relevant Service to issue the pertinent documents attesting conformity (for example: EC/EU Type Examination Certificate, Declaration of Conformity) foreseen by the specific applicable Directive (hereinafter "EC/EU Certificate" or the "EC/EU Certificates").

2.4. Result of conformity assessment

Upon conclusion of the Service, in case of positive outcome of verification activity, IMQ issues the Customer with the relevant EC/EU Certificate requested. In the case of a negative result, IMQ issues the Customer with the specific communication describing the non-conformities found,to be resolved by the Customer in compliance with the specified deadlines in the relevant sections of this document.

In case of failure on solving the non-conformities in the specified deadlines, IMQ issues to the Customer a communication with the negative result of the evaluation activity conclusion and gives course to the communications to the Authorities and / or the other ONs, according to the applicable legislation.

In the event of an explicit request by the Customer, IMQ also sends the relevant Evaluation / Test Reports to the same.

Art. 3. GENERAL TERMS AND CONDITIONS

3.1. Attaining the certification

The certification, and its maintenance, where applicable, depend on:

- the availability of the Customer to submit itself to the ordinary, supplementary and documental assessments at the premises of the Customer itself and/or other premises involved (for example, the sites of the critical suppliers and subcontractors of the Customer) within the timeframe envisaged and indicated by IMQ;
- the positive result of the aforementioned conformity assessment activities, performed by IMQ;
- the payment of the amounts due, on any basis, to IMQ (e.g. for the activities of issuing, maintenance and renewal of the certification, for the variation/re-issue of the certificates, etc.).

3.2. Samples

If required, the samples must reach the laboratory indicated by IMQ accompanied by a delivery document showing the reason "Technical tests", suitably labelled with the indication of the order number or quotation number. All the transport expenses are borne by the Customer. It is the responsibility of the Customer to collect the samples at the end of the tests, unless the appeal procedure referred to in par. 13.2 hereinafter is begun. If fifteen (15) days have elapsed since the communication of the conclusion of the tests without the samples being collected, IMQ can dispose of the materials and the expense will be borne by the Customer. In case of destructive tests, the resulting materials will be immediately disposed of by IMQ, but the costs for this are borne by the Customer.

3.3. IMQ personnel

IMQ assigns the verification activities to personnel - IMQ employees or to those who have a collaboration relationship with IMQ – however in possession of the specific expertise and preventively qualified according to specific procedures, in accordance with the applicable accreditation provisions.

3.4. Confidentiality

All the documents relating to the assessment activity (documentation, recordings, communications, assessment reports, etc.) are considered confidential, without prejudice to what is provided for by legislative provisions and/or by the provisions of the Accreditation Bodies and Competent Authorities.

Access to and consultation of the documents relating to the activities in hand is reserved to IMQ personnel involved in the conformity assessment process. In the event that this information must be communicated or disclosed due to legislative/accreditation provisions, IMQ will give communication of this to the Customer.

Documents property of the Customer, when acquired by IMQ in relation to the subject matter of this Regulation, will be maintained by IMQ for the whole period of validity of the Contract and at least for 10 years, unless stricter specific rules apply (see also Specific Requirements applicable for the specific Directive).

3.5. Impartiality

IMQ, in its capacity as NB, is required to guarantee impartiality during all the conformity assessment activities; in this respect, IMQ avails of a process to assess and manage the risks of impartiality.

IMQ is not – and undertakes not to be - connected to a party directly involved in activities/situations of: design, manufacturing, supply, installation, acquisition, marketing, possession, use and maintenance of the products assessed or similar to those assessed and competitors of these.

In its capacity as NB, IMQ cannot in any way provide consulting services regarding the activities object of this Regulation.

3.6. IMQ Ethics Code and Legislative Decree 231 of 8 June 2001

IMQ has adopted an Ethics Code pursuant to Legislative Decree 231 of 8 June 2001 on the liability of legal persons, of companies and of associations, including those that do not have legal personality. The code is available on www.imq.it. Consequently, in conducting business with IMQ, the Customer is required to view the code and behave in a manner that is based on the highest ethical standards.

By signing the Certification Contract, the Customer declares to have viewed and to be familiar with the content of the IMQ Ethics Code.

The Customer also declares to be familiar with the provisions set out in Legislative Decree 231/01, to undertake to respect the IMQ Ethics Code and to fulfil its contractual obligations in accordance with an appropriate manner to avoid the occurrence of relevant behaviour according to Legislative Decree 231/01.

In particular, failure of the Customer to observe any one of the provisions of the Ethics Code will imply a serious breach of the obligations of this Contract of Certification and legitimate IMQ to terminate this with immediate effect, pursuant to article 1456 of the Civil Code. To this end, IMQ must communicate to the Customer, by registered letter with notification of receipt, or other modality valid for all purposes and effects of law, the motivated intention to avail of the termination clause.

Furthermore, Customer behaviour which results in the initiation of judicial proceedings to ascertain its relevance according to Leg. Dec. 231/01, of which IMQ has become familiar with in any way, will legitimate the latter to withdraw from the Contract of certification for just cause.

3.7. Accreditation and Authorization of IMQ as NB

3.7.1. Obligations related to accreditation

In the activity subject matter of this Regulation, IMQ is qualified by the competent Authorities as NB for each applicable European Directive.

In particular, within the scope of the Directives for which the qualification as NB is granted on the basis of the accreditation issued by ACCREDIA (Italian Accreditation Body), according to the international standard UNI CEI EN ISO/IEC 17065, IMQ must operate in conformity to this standard and to the specific provisions issued by ACCREDIA, applying the relevant reference documents, which are considered to be specifically referred to.

IMQ is also required, according to applicable standards requirements, to communicate to the Accreditation Authority and to the competent Authorities the validity status of the certificates issued (e.g. certificates issued, limited, suspended and revoked).

Accreditation bodies and competent Authorities also have the right to carry out audits at the following premises: of IMQ and/or of its Customers and/or of Suppliers/critical Subcontractors of its Customers in order to verify the work of IMQ within the scope of the accredited certification schemes.

Note: Updated information on the accreditation status of IMQ is available on the websites www.imq.it and, for accreditations issued by ACCREDIA, on www.accredia.it.

3.7.2. Suspension, renunciation, revocation of accreditation and/or qualification of IMQ

In case the accreditation and/or qualification required to IMQ to operate as NB for the specific Directive is suspended or revoked – or in case of renunciation - IMQ will inform the Customer of this, as well as support it in the possible transfer to other NB.

Except in cases of fraud and gross negligence, IMQ is in no way responsible for any damage caused to the Customer by the suspension, renunciation, limitation of extension or revocation of accreditation and/or qualification; in such cases, the Organisation has the right to renounce to the certification issued by IMQ, without prior notice and without additional charges.

3.8. Subcontract

Upon notice to the Customer, IMQ reserves itself the possibility to subcontract part of the Service requested to third parties, for example performing tests at external laboratories. The Customer, who will be informed of the detail of the outsourced activities as well as of the references of the subcontractor, has the right to refuse this outsourcing for justified reasons, within five (5) working days from the communication date.

IMQ is anyway fully responsible for every outsourced activity and retains the responsibility for issuing, maintaining, extending, limiting, suspending or withdrawing the EC/EU Certification.

IMQ guarantees that the subject to which the subcontract is entrusted is competent and conforms to the applicable regulatory provisions and is not involved in the design and manufacture of the product, so as not to compromise impartiality as set out in par. 3.5 above.

Art. 4. CONFORMITY ASSESSMENT PROCESS

4.1. Presentation of the Request

The Customer has the right to request a quotation for the service in advance, in which IMQ gives a detailed description of the activities carried out in its capacity as NB and of the relevant fees applied.

It will include the following information:

- description of the Service;
- references to the Regulation and Special Requirements applicable to the specific Directive (documentation available on the web site www.imq.it);

- the timeframe in which the Service is provided;
- amount due, according to IMQ Price list in force, detailed for the single activities requested;
- invoicing and payment procedures.

In case of acceptance of the quotation, the Customer is required to send IMQ:

- quotation countersigned to show acceptance of the same;
- acceptance of the Regulation, of the Special Requirements applicable to the specific Directive and of severability clauses for the specific Directive, by the Legal Representative or its Attorney;
- any purchase order, if required by Customer's administration department.

Each Directive specifies the relevant conformity assessment procedures. For the applicable requirements, including the documentation requested and rights and duties of the Customer, refer to the specific Directive, to the relevant legislative provisions of national implementation and to the Special IMQ Requirements specific for the Directive (as set out in par. 2.2 above).

The request to access the Service is presented by the Manufacturer [1] or by its Authorised Representative [2] (hereinafter "Customer") and occurs by presentation of a specific Request to IMQ, containing the following minimum information:

- general information about the Customer (company name, name, address, legal status, etc.);
- description of the product to certify and the relevant production site;
- applicable Directive and assessment procedure envisaged and/or chosen by the Customer;
- declaration which shows that the same request has not been presented to any other NB;
- documentation to assess the conformity of the product to the applicable requirements of the specific Directive.

[1] *«Manufacturer»: physical or legal person who manufactures a product or has it designed or manufactured and places it on the market attaching its name or brand or puts it into service for its purposes;*

[2] *«Authorised Representative»: physical or legal person established in the Union which has received a written mandate from a manufacturer that authorizes him to act on his behalf in relation to specific tasks.*

For each Directive for which it works in its capacity of NB,,IMQ puts at the Customer's disposal specific application forms for use by the Customer to request the Service. The Request must be presented on the IMQ form, filled out in all its parts, stamped and signed by the Customer.

Where the application form includes the acceptance of the Regulations, of the applicable Particular Requirements and of the vexatious clauses, such acceptance requires the signature of a legal representative (or attorney) of the Customer.

The Manufacturer is allowed to appoint a person or company to act as its agent to assist him in all phases of the certification process, but the request, the contract documents and all the documentation must be signed and stamped by the Manufacturer. IMQ must have evidence of the relevant delegation of power.

The Request must be presented in a distinct manner for each type of product, or rather for each representative sample of a specific production. The type may also include product variants, as long as these do not imply

different types of risk with regard to the essential requirements of the Directive. The product variants must be indicated in an attachment to the request.

If the Customer has already obtained one or more EC/EU Certificates from another NB and requests IMQ to take over as new NB for the surveillance activities, the Customer itself is required to provide IMQ with a copy of these EC/EU certificates.

Acceptance by IMQ of the Request presented by the Customer depends on the positive result of the review of the request itself by the competent IMQ personnel; the Contract of certification is executed by IMQ sending the order confirmation to the Customer.

This is followed by the planning phase of the activity by IMQ, with particular reference to the activity carried out at Customer premises; such planning includes the communication to the Customer of the method, confirmation of the timeframe and dates on which the activities will be carried out, the appointment of the verification team, any specific requests to agree.

IMQ does not and cannot guarantee in any way the positive result of the verification activity and, consequently, the issue of the relevant certificate.

The Customer is not allowed to publicise the Request underway until the positive result of the relevant tests, verification activities and assessments. In cases which are duly motivated, IMQ can grant an exception to this ban.

In the case in which subsequent Requests are presented for types similar to others already covered by EC/EU type examination certificate or for variations to types already covered by EC/EU type examination certificate, it is up to IMQ to judge, at its own discretion, if the documentation provided and the tests to which the product must be subjected can be reduced, as well as the extent of this reduction.

IMQ reserves the right to recognize documents issued by other certification bodies, namely certificates, declarations of conformity, test reports, reports attesting the conformity of the products.

If the product for which EC/EU certification is requested has already been issued with a relevant IMQ voluntary certificate, IMQ reserves the right to define criteria of possible reduction of the tests according to the suitability of the tests and verification activities already carried out in a voluntary scope by IMQ.

4.2. EC/EU type examination

4.2.1. Requested documentation

In case the conformity assessment procedure chosen by the Customer includes EC/EU Type examination, the Customer is required to provide IMQ with the representative samples of production envisaged and the Technical File, indicating specifically:

- the list of applicable harmonised standards and/or of other relevant technical specifications, applied completely or in part, and the descriptions of the solutions adopted to satisfy the Directive requirements, if these harmonised standards have not been applied. In the event of partial application of the harmonised standards, the specific technical documentation of the parts which have been applied;

- the design, method of manufacture and operation of the product including a general description of the product, drawings related to the general design and manufacture, schemes of components, sub-systems, circuits, etc.;
- the results of the design calculations carried out, of the analyses carried out, etc.;
- the reports of the tests carried out on the product.

This documentation must be provided in Italian or English language; any other language is accepted only if this has been envisaged in the quotation phase.

For any additional documentation to be presented by the Customer, see Specific Regulation applicable to the specific Directive.

4.2.2. Verification of Technical File

IMQ verifies that the Technical File complies to the applicable Directive requirements.

If the Technical File examination ends with positive result, certification process continues to the following stages.

If, instead, Technical File examination shows Non-conformities with reference to Directive essential requirements or part of the documentation received results to be lacking or incomplete, IMQ informs in writing the Manufacturer and waits for resolution of Non-conformities / integration of the same documentation.

Non-conformities related to documentation are classified in the following way:

- M = Major Non-conformity: evidence of non-conformity with reference to applicable Directive essential requirements and/or lack of one of documents requested in Technical file. Manufacturer must integrate the documentation before the beginning the product evaluation process;
- m = Minor Non-Conformity; requested documentation is available, but is clearly incomplete or inconsistent to allow a complete product evaluation. Minor Non-conformities are allowed to be solved during the process of evaluation and don't require to postpone the product verification.

Manufacturer has three (3) months of time to send to IMQ the missing documents or documentation, referred to Major Non-Conformities; in absence of this reply, IMQ keeps the right to stop the evaluation process and ask the payment of all the activity carried out till that time.

4.2.3. Verification of the product

In case of positive result of the Technical File assessment, the EC/EU Type examination is conducted according to the specific Directive and includes the following activities:

- verification that the Type has been manufactured in a way that conforms to the Technical File transmitted and identification of the elements which have been designed in conformity to the applicable provisions of the harmonised standards, as well as the elements whose design is not based on the applicable provisions of the aforementioned standards;
- controls, measurements and tests necessary to verify if the adopted solutions satisfy the essential health and safety requirements envisaged by the specific Directive, if the harmonised standards have not been applied;

- controls, measurements and tests necessary to verify, if the harmonised standards have been used, that their application has been effective.

4.2.4. Tests and controls

IMQ, if necessary, draws up a specific test protocol and communicates to the Customer the number of samples of the representative type of production envisaged which must be provided free of charge for the conformity test. IMQ can request other samples of the same type if necessary to carry out the test programme. The samples to be tested must be sent by the Customer accompanied by documents required by the legislation in force according to par. 3.2 above.

4.2.5. Result of assessment

If the assessment has a positive result, the process will continue with the phase of Review and Final Decision (see par. 4.5 under) and, in case of positive decision, with the issue of an EC/EU Type Examination certificate.

In case of negative result, the two following situation may present

- IMQ-appointed personnel requests or carries out supplementary tests/verification activities. The costs to carry out the supplementary activities are understood as payable by the Customer and communicated through an appropriate quotation, according to the IMQ Price list in force; the process continues with the performance of supplementary tests/verification activities;
- situations have been identified for which the product cannot in any way be considered as conforming to the requirements of the applicable Directive or it is not manufactured according to the Technical File and consequently it is not considered possible to proceed with the issue of the EC/EU type Examination certificate. IMQ communicates the negative conclusion of the certification process to the Customer, requests payment for the activity carried out to this point and communicates this to the Authorities and/or other NB envisaged by the specific Directive.

4.2.6. Periodic renewals of EC/EU type certificates

Where foreseen by the specific Directive, the renewal of the certification is carried out according to the relevant Particular requirements rules.

4.3. Assessment of Quality System

4.3.1. Documentation requested

If the conformity assessment procedure chosen by the Customer includes assessment of the quality system (production quality assurance, product or total quality assurance), IMQ will act in compliance with international standard ISO / IEC 17021-1 requirements.

The Customer is required to provide the relevant documentation on its quality system. This documentation must specifically include a suitable description:

- of the quality objectives, of the organisational structure, of the responsibilities to manage design quality and product quality;

- of the specific design techniques, including the standards which will be applied and, if the harmonised standards are not fully applied, instruments which will allow to guarantee that the essential requirements of the specific Directive are satisfied;
- of the techniques, of the processes and of systematic actions on the matter, where applicable; control and verification of the design, manufacture, quality control, quality assurance;
- of the controls and tests which can be carried out before, during and after the manufacture, with indication of the frequency with which it is intended to carry them out;
- of the quality documentation, i.e. audit reports and the test data, the calibration, the reports on the qualifications of the personnel involved;
- of the control equipment to obtain the quality required in design, as well as the efficacy of the operation of the quality system.

This documentation must be provided in Italian or English language; any other language is accepted only if this has been envisaged at the quotation phase.

For any additional documentation to be presented by the Customer, see Specific Regulations applicable to the specific Directive.

On documentation receipt, IMQ provides to:

- preliminarily, examine the form of request and the documentation presented by the Customer;
- ask further documentation, in addition to the above indicated documentation, as far as considered necessary to conduct the activities;
- contact the Organization for the planning of audit activities.

IMQ implements appropriate practices to guarantee the traceability of the Client's QMS documentation (or by keeping, in IMQ archives, the Client Documentation, or by keeping the same Documentation, duly signed by IMQ, in the Customer's archives); this guarantee of traceability is required both for the Documentation in force and for the Documentation outdated. Any operational details for the management of the documentation within the single Directive are reported within the Particular Prescriptions referring to the individual Directives.

4.3.2. Assignment of audit team and audit activities planning

Once completed the preliminary stage, IMQ will assign the certification job to an Audit Group (or "Audit Team"), composed of one or more individuals, providing an adequate skill for the activity to be performed.

The Customer is entitled to request replacement of one auditor or expert; such request must be made in writing within five (5) days after the Customer receives the information, and must be adequately motivated.

IMQ reserves the right to confirm or substitute the person in question, depending on the importance of the motivations expressed by the applicant.

IMQ contacts the Customer to set the dates of audit; after confirmation of such dates, the head of the Audit Group (or "Team Leader") sends to the organization the Audit plan.

If the Customer requests a change of date of an audit in the ten (10) working days before the planned date, IMQ reserves the right to charge an amount for the resulting costs, according to the current fees.

4.3.3. Conducting the audit

Audit activity involves assessment of the conformity of the Organization of the Customer Management System to the requirements of the applicable standards; such assessment is conducted using the sampling method and is based on interviews with staff, direct observation of activities and processes and inspection of locations, documents and records.

Audit activity is conducted according to the requirements of the specific Directive (see also Specific Requirements).

At the audit beginning, the Audit Team must have a meeting (Initial meeting) with the Organization's Direction.

Such meeting is aimed to the presentation of participants, to the confirmation of the scope of certification and of the audit plan, to the definition of formal communication channels between Audit Team and the Organization, to the confirmation of the existence of adequate occupational safety conditions, emergency and safety procedures; in addition, the same meeting is aimed to give every other clarification / useful indication for the conduction of the audit.

Organization is committed to put at auditors' disposal all the necessary instruments for a correct evaluation, assuring, in particular, the availability of:

- Documents related to the Managing System for which certification is requested;
- Records, including internal audit reports;
- Updated list of yards / external activities (for activities included in the certification scope but carried out outside the Organization's place).

During the audit, auditors must be assisted by the Organization's staff. Organization must permit safe access to all areas where activities relevant for the object of certification are carried out and, in addition, must allow to interview the staff involved in such activities and, in general, must put at disposal all necessary information for audit conducting.

Moreover, the Organization is aware that audit includes direct observation of operative activities in progress (production, service delivery) and that the impossibility of verification of such activities on the occasion of initial audit and, later, during the three years of certification may result – depending on the cases – in a refusal to issue the certificate, in a suspension, in a withdrawal or reduction of the scope indicated in the certificate.

4.3.3.1 Certification audit conducting (initial audit)

Initial certification audit is divided in two phases, named Phase 1 and Phase 2 (or "Stage 1" and "Stage 2").

a) Stage 1 audit

In general, Stage 1 is conducted at the Organization premises, unless different agreements taken with the Organization. Main targets of such audit are as follows:

- Organization Managing System documents examination;

- Collecting all necessary information related to the scope of managing system, included sites, processes, applicable mandatory requirements, checks defined by Organization (in particular, for multi-site Organizations);
- Reviewing the status and the comprehension of Organization in relation to normative requirements, with particular reference to identification of key performance and to relevant aspects, processes, targets and operations of Managing System;
- Evaluation of the specific conditions of Organization site;
- Evaluation of the degree of preparation for Stage 2, identifying any deficiency that in Stage 2 would be classified as Major Non conformities (for classification of findings, see following clause 4.3.4). and that would thus determine the interruption of certification process;
- Acquire a sufficient knowledge of Managing System and of the activities carried out at the site to proceed to Stage 2 planning, agreeing with the Organization all its details and checking adequacy of allocated resources for its implementation.

Upon completion of Stage 1, the Leader of the Audit team prepares Audit report for Stage 1 and delivers copy to the Organization; such report outlines any deficiencies to be solved before conducting Stage 2 audit, but doesn't give a classifications of findings and is limited to identify situations precluding the continuation of certification process, i.e. critical areas to be solved before proceeding to Stage 2.

If during Stage 1 acquired information about the Organization (e.g. no. of employees, sites, processes) results different from the information previously provided by the Organization, the amount of work required to complete Stage 2 as previously determined may change.

b) Stage 2 audit

Stage 2 aim is to evaluate the execution – included efficacy – of Managing System. Stage 2 has to be conducted at Organization's site / sites and shall comprehend the following elements:
- information and evidences about the conformity to all the requirements of the Managing System applicable standard, and to other normative documents;
- check and review of performance, in relation to defined targets;
- system capability to manage the respect of applicable mandatory requirements;
- operative control of processes conducted by the Organization;
- internal audits and management review;
- Direction responsibility for Organization policies.

Stage 2 audit is conducted a sufficient amount of time after Stage 1; the duration of such amount of time is established according to the accreditation disposals applicable to the specific Directive and in a congruent way with the elimination of problems, if any, detected in Stage 1 and according to the features of the Organization (dimensions, complexity and criticality of aspects related to conducted processes).

In particular cases, depending on low complexity of processes and to limited dimensions of Organization, Stage 2 audit may be performed right after Stage 1; such option is applicable only after a positive outcome of Stage 1 audit and, however, only in case such option is allowed by the specific accreditation disposals.

Stage 2 audit may be conducted no later than 6 months later after Stage 1 closing; once exceed such time, a new Stage 1 audit. Costs related to such additional activity are charged to the Organization.

In case, due to an Organization will, audit is terminated before completion of activities indicated in Audit plan, the amount for the whole planned activity will be charged to the Organization.

4.3.4. Audit results

On conclusion of Stage 2 of audit, the Audit Group analyses all information and evidences collected during Stages 1 and 2, with the aim of reviewing audit results and of defining the conclusions.

Audit Group then fills up a dedicated Audit Report (hereunder, "Report"), which points out any situations of Non conformity (or "findings").

The final meeting of the audit is then organized, participated by the Direction and any further personnel of the Organization. During the final meeting, the Leader of the Audit Group presents the conclusions of the audit and the Organization is given the opportunity to discuss the contents of the Report, clarifying doubts, if any.

Later on, an Organization representative signs the Report and Non conformities, if detected, and receives copy of them; the Organization is allowed to express reserve about the contents of audit documentation, recording the reasons.

In case IMQ doesn't transmit to the Organization, within 30 days after the date of the end of the audit, a written communication of correction of audit results in the Report, the same Report is intended confirmed.

Findings (or Non conformities) represent situations of failure to meet / misalignment to normative requirements; such situations are formalized in audit documentation. Such findings are classified as follows:

- Major Non-conformity (M): situation which could significantly compromise the efficacy of the Quality System, making it impossible to satisfy the requirements; such finding – to be formulated also in case a high number of Minor Non-conformities are found – inhibits the certification issue;
  Minor Non-Conformity (m); though not compromising the overall efficiency of the Quality System, situations of dissimilarity / partial misalignment to normative requirements; such situations must be resolved to declare conformity.

Moreover, Audit Team may issue "Recommendations", to point out aspects that are not a failure to meet normative requirements, but may be considered as opportunities for improvement of the Organization Managing System.

The Customer must undertake to eliminate the Non-Conformities which may have been found during the audit, through the identification of the relevant Causes and adoption and implementation of adequate Corrections (or Treatments) and Corrective Actions.

The Causes of Non-Conformities, the Corrections and the proposals of Corrective Actions must be transmitted to IMQ by the term indicated in the Non-Conformity report/s, specifying the implementation times and relevant responsibilities; the Corrective Actions proposed are understood as accepted if IMQ does not send the Customer a specific request for integration or modification within 30 calendar days.

The implementation of the Corrections and Corrective Actions to resolve the Major Non-Conformities is verified according to documental evidence or through supplementary audits; obtaining/maintaining certification is dependent on the positive result of the verification.

In case adequate evidence of such carrying out is not made available within 6 (six) months from the end of Stage 2 audit, another Stage 2 audit has to be conducted to proceed in the certification process; the Organization will be charged of the costs of such additional activity.

The implementation of the Corrections or Corrective Actions relating to the minor Non-Conformities is instead verified during the subsequent audit; IMQ has in any case the right to request documental evidence, or to perform supplementary audits, where it is deemed necessary.

In case the Organization omits to send IMQ an adequate plan of Corrections and of Corrective Actions or, where requested, the evidences of implementation of the latter, IMQ is allowed to adopt provisions to suspend or limit the certificate (see par. 8.2 below).

For Recommendations, the transmission of corrective actions to IMQ is not requested; during the subsequent audit, the Organization is required to show evidence of having taken charge such findings, or to explain the reasons why no action was actuated.

The Report with any attachments, any further documentation and - in case Non-conformities were found – the relevant Corrective actions are subsequently subjected to an independent review, by a Decision Committee. This Committee is composed by qualified personnel and has the task to take a decision about the certification issue.

On the base of the results contained in the aforementioned documentation – and in every other pertinent information – IMQ takes a decision about the certification issue, according to criteria detailed in following par. 4.5.

If the quality system satisfies the set out requirements, IMQ issues the Customer with a Certificate of Approval of Quality System.

Such Certificate has a period of validity of 3 (three) years. Its validity, anyway, depends on the continuation of the contractual relationship with IMQ, on the positive result of ordinary / extraordinary surveillance audits, carried out on the Organization Managing Systems, according to the modes indicated in following par. 4.3.5.

After the positive result of renewal audit and of relevant decision activity by the Committee in charge, the certificate is re-issued. Lack of execution of such activity - such as lack of transmission and/or lack of execution of Corrective actions within the expiration date of the certificate – determine the loss of validity of the same certificate, the termination of the contract with IMQ and the consequent necessity to reactivate the certification process from the beginning.

At the end of the assessment process, ended with the issue of the Declaration of Approval of Quality System, all the documentation sent by the Customer and the one produced by IMQ are filed and remain at Competent Authorities disposal.

When certification is not issued, IMQ communicates such decision to the Organization in writing, detailing the reasons and asking the conduction of an additional audit to verify the resolution of found Non-conformities and / or the sending of the documentation adequate to have evidence of such resolution, specifying the deadline.

The positive result of such additional evaluations – the costs of which are charged to the Organization – allows the certification issue.

4.3.5. Surveillance, Renewal and Special audits

After issuing the Declaration of Quality System Approval, IMQ carries out a periodical check of the certified Organization, to verify the maintenance of the conformity of the Managing System to the requirements of reference standard/standards.

This check is guaranteed by periodic audits, carried out according to criteria and modes as shown in this paragraph and as required by applicable accreditation disposals.

The first surveillance audit must be carried out within a period of twelve (12) months from the date of issue of the certification; in particular cases, IMQ may define a shorter period of time, with the aim of verifying the resolution of Non-conformities found; in these cases, the Organization shall be informed in advance.

Surveillance audits subsequent to the first one are, in general, conducted within twelve (12) months from the previous one; anyway, they must be conducted at least once per year (calendar year).

Periodical audits guarantee the verification, in the arc of the three years certification cycle, of all the certified activities/processes; anyway, some areas/aspects considered significant/critical are subject to verification on the occasion of every surveillance audit.

Renewal audit (or "Re-certification") is oriented to a general review of the certified Managing System; it includes the verification of all normative requirements and, in particular, the examination of the following elements:

a) effectiveness of Managing System as a whole, based on internal and external changes, and its continual pertinence and applicability to the scope of certification;
b) effectiveness of Managing System, with reference to the achievement of Organization targets and to expected results
c) the commitment to maintain effectiveness and the improvement.

Within certification expiration date, renewal audit has to be completed and the Organization needs to have actuated Corrective Actions for the resolution of Major Non-conformities, if any; such deadline applies in cases of suspension of certification as well,

Following to positive result of renewal activities, certificate is re-issued; costs of each certificate re-issuing are charged to the Customer.

In case certification renewal activities are not completed within the certificate expiring date, the certificate loses its validity. The Organization intending to reacquire the certification must start the certification process from the beginning.

Based on the results of Audit Reports and of Non-conformities found, of received complaints and, in general, in all cases in which, for the Organization, a lack of fulfillment of requirements as required by reference standards, and also in the situations detailed in clause 5, IMQ is allowed to decide the conduction of additional audits. The cost of such activities, based on the current IMQ price list, is in charge to the Organization,

IMQ is allowed to conduct also short notice audits - i.e. conducted within five (5) working days from the date of notice – or unannounced audits, to investigate about received complaints, or following to Organization changes, or as an action subsequent to a suspension of certification for an Organization.

In such cases, right of objection described in the here above par. 4.3.2 may be inapplicable.

In case Customer wishes to extend the scope of certification (for instance, further sites / operational unit / processes, etc.) has to make a request to IMQ in writing; IMQ defines the further verification activities requested and prepares a dedicated quotation.

After quotation acceptance and after positive results for the activities of verification and of decision, the certificate is re-issued.

Cost related to additional verification activities and to certificate re-issuing are in charge of the Customer.

Certification, surveillance and renewal audits are announced with reasonable notice; in case Organization asks to move / to delete of an audit in the ten (10) working days before the planned audit date, IMQ keeps the right to charge the relevant costs to the Organization, on the basis of the current price list.

As far as ways of audit conducting, Report preparation, issuing of Non-conformities and of Corrective Actions sending, see requirements in parr. 4.3.3 and 4.3.4 here above; however, distinction of Stage 1 and Stage 2 activities applies to surveillance/renewal audits only in case of significant modifications in the Managing System, in the features of the Organization or in the operative site, in applicable requirements. etc.

For each of the here above audits, IMQ puts an Audit Report at the Customer disposal. In case such Report includes findings that compromise the conformity to applicable Directive requirements, the Customer will not be allowed to affix CE marking on the products covered by the Declaration of Quality System Approval, until they are eliminated.

4.4. Other conformity assessment procedures

If the conformity assessment procedure envisaged by the specific Directive and chosen by the Customer includes the assessment of the Technical File, what is set out at par. 4.2.2 above is applied, in addition to all that is requested by the applicable Directive.

In case the procedure requires a sample to be taken by the NB, IMQ takes samples of the product from the place of manufacture or deposit, for control purposes. IMQ assesses the number of samples to take, as well as the need to carry out or have carried out the final verification activity partially or fully.

If tests and verification activities cannot be carried out at the premises or a production unit of the Customer, the same are carried out at the IMQ laboratories or at subcontracted laboratories. In this case, the products selected by the IMQ appointed staff must be sent by the Customer to the laboratory indicated by the same appointed staff. The Customer is responsible for this movement of products. The Customer must take all the necessary precautions so that the products reach their destination in good condition and within thirty (30) days from the date of the surveillance visit. If the Customer does not comply with this obligation, IMQ reserves itself the right to repeat the visits for control purposes, against payment by the Customer. To manage the samples, what is set out at par. 3.2 above is applied.

If the assessment has a positive result, the process continues with the review and final decision phase, described in following par. 4.5 and, in case of positive decision, with the issue of the relevant EC/EU Certificate.

In the case of a negative result, if situations have been identified for which the product cannot in any way be considered conforming to the requirements of the applicable Directive, IMQ communicates to the Customer the

negative conclusion of the certification process, requests the payment of the activities carried out until that moment, and gives communication of this to the Authorities and/or to the other NB envisaged by the specific Directive.

4.5. Review and final decision on the issue of the Certification

The final decision on the issue of the EC/EU Certificate is the responsibility of a specific Deliberation Committee working at IMQ. All the documentation relating to the conformity assessment activities carried out are analyzed by this Committee which, based on the results contained in the aforesaid documentation, as well as any other relevant information, decides whether or not to issue the EC/EU Certificate.

If EC/EU Certification is denied, IMQ communicates this decision in writing to the Customer, indicating the reasons and the minimum conditions to restart the certification process. The Customer can request a supplementary assessment to verify conformity to these minimum conditions; the cost is borne by the Customer.

If EC/EU Certification is granted, IMQ issues the Customer with the specific attestation/certificate according to the assessment procedure carried out. The validity of the EC/EU Certificate issued is clarified in the Specific Requirements applicable to each Directive. This period of validity of the EC/EU Certificate issued is defined according to the applicable Directive considering any modifications which can intervene in the reference standard requirements. If the product changes or the production processes of the Customer change, the EC/EU Certificate issued is no longer valid.

Art. 5. OBLIGATIONS OF THE CUSTOMER

5.1. Obligations of the Customer

The Customer is committed to:

- prepare the requested Documentation in relation to the relevant conformity evaluation procedure;
- write UE declaration of conformity and affix CE marking on certified product (see also par. 7.1 of this Regulation);
- ensure - in the terms and with the exceptions according to the single applicable Directive - that the samples of certified product placed on the market bear the type identification number, batch, series, or any other element allowing their identification; ensure - in the terms and with the exceptions according to the specific Directive applies – that, on the same samples, the Manufacturer's name, their trade name or registered trade mark and the postal address to which the Manufacturer can be contacted are indicated; ensure that the contact information is in a language easily understandable for the end user and for the Market Surveillance Authority;
- ensure that the certified product put on the market is accompanied by appropriate instructions on safety, as provided by the applicable Directive; ensure that these instructions are clear, understandable, intelligible, and written in an appropriate language to be easily understood by the final user;
- keep the products subject to certification, and its quality system, where applicable, compliant with the requirements of the applicable regulations and / or stated in the relevant certificate; inform IMQ of any program of modification on certified product (both in terms of design changes and the characteristics of the product); in the group of changes, should be considered, as applicable, even those arising from changes in

the harmonized standards and other technical specifications with reference to which conformity is declared;

- inform in advance IMQ of any planned changes applicable to the certified product in terms of production site, of Organization or the quality system, if applicable and wait for IMQ approval before implementing such changes;
- keep the technical documentation, the EU declaration of conformity and any approvals /certifications applicable for a period of at least 10 years from the date that the certificated product was placed on the market;
- guarantee to the assigned IMQ personnel access to the places of design, manufacturing, inspection, testing and storage of the products concerned, and provide the means and the necessary aid so that IMQ can conduct the required service, including access to the documentation and complaints received. In this regard, the inability to carry out the activities for fact and / or cause imputable to the Customer (example, inability to access to such places, lack of documentation), such as to prejudice the fulfilment of obligations by IMQ, will constitute cause for termination of contract;
- guarantee to IMQ personnel the possibility to conduct extraordinary audits, as far as needed; IMQ shall give advanced notice to the Customer the date of execution of these extraordinary audits;
- guarantee to IMQ personnel the possibility to conduct unannounced audits, in the terms they are contemplated in the relevant evaluation procedure of the Directive in question (see also par. 4.3.5 of these Regulations);
- guarantee to inspectors from the Accreditation Bodies and from Competent Authority the possibility to access the aforementioned places, in accompaniment to the IMQ personnel. Such visits, the purpose of which is overseeing IMQ personnel activity and not the Customer, are regularly communicated adequately in advance;
- where deemed necessary with regard to the risks associated to the certified product, in order to protect the health and safety of consumers, carry out a random test on a sample of certified product made available on the market;
- examine complaints related to the certified product; examine samples of certified product found not compliant; examine the recalls and / or withdrawals from the market, as related to the certified product;
- keep a record of such complaints, of such non-conformities and of such recalls / withdrawals from the market, as well as of the relative corrective actions; where required by IMQ, provide evidence of their management;
- If certified products placed on the market are considered or there is a good reason to believe that certified products placed on the market do not comply with the Directive under which they have been certified, immediately take the necessary corrective actions to make them compliant, to withdraw or recall them; furthermore, where the product placed on the market presents a risk, immediately inform the competent National Authority of the EU Member States in which the certified product in question has been placed on market, providing them with the details of non-conformities and related corrective action taken; in front of a motivated request coming from a competent National Authority, provide to such Authority with all the information and documentation, in paper or electronic format, as needed to demonstrate compliance of the certified product to the applicable Directive; they shall be in an easily comprehensible language for such Authority; cooperate with that Authority, on the basis of its request, for any action taken to eliminate the risks presented by certified products placed on the market;
- do not make any statement or advertisement about their certification in a way they may be considered as misleading or unauthorized, or inconsistent with the field of application of the same certification, and not use their certification so as to bring discredit to IMQ;

- fulfill the requirements contained in the Regulations for the Use of Marks IMQ, as applicable;
- Interrupt the use of advertising material containing references to the certification, in case the same has been suspended, revoked or has expired;
- reproduce in their entirety the certification documents, in case copies of them are provided to third parties;
- return to IMQ the obtained original Certification, if any, in case it decides to transfer to another Body.

In case of any changes at the production site, in the Organization or in the quality system approved by IMQ, the variation made to the documentation must provide guarantees of traceability similar to those indicated in par. 4.3.1 above.

In relation to fulfilling their obligations under this paragraph, IMQ will be allowed to conduct, adequately charged, extraordinary audits, and to take appropriate measures to suspend or revoke the certification, depending on the severity of the situation and / or impact of the event occurred.

5.2. Safety at work – Obligation of notice

The Customer, according to the legislation in force on safety and accident prevention at work, undertakes to provide IMQ personnel and any accompanying persons with a full and detailed notice on the specific existing risks in the environment in which they will work.

The Customer also undertakes to promote, through its own person empowered for that purpose, the cooperation and coordination to implement the measures and actions of protection and prevention from risks at work, which affect the work activities of the auditors appointed by IMQ and of any accompanying persons, and which require the protection of workers and of all other subjects who work or in any case are present in the same work environment.

The Customer, according to any specific existing risks, will provide IMQ personnel and any accompanying persons with the appropriate personal protection equipment and will put in place any protection to allow the activities to be carried out in total safety.

Art. 6. FINANCIAL TERMS AND CONDITIONS

6.1. Amounts due to issue and maintain the certification

The amounts due for the certification and maintenance activities, where specified, together with the relevant payment conditions, are indicated in the Quotation as accepted by the Customer; this Quotation is formulated according to the fees indicated in the IMQ Price list in force and on the basis of the information provided by the Customer (number of staff, production plan, etc.).

The Customer is required to correctly communicate all the information requested during the quotation formulation phase, in order to issue the Quotation, as well as update IMQ on any modifications; on the basis of the updated data, IMQ assesses if it is necessary to modify the audit times envisaged for the surveillance activities and review of the financial terms and conditions agreed.

For anything which is not specifically set out in the Quotation, as well as any absence of the same, the amounts indicated in the IMQ Price list in force, which is intended as specifically referred to, are applied.

The payments due for the Service requested are subject to VAT as required by law (article 3. Pres. Dec. 633 dated October 26, 1972).

6.2. Variations to IMQ Price list

Any variations to the IMQ Price list are communicated to IMQ Customers if the same imply a significant modification to the existing financial conditions applied.

The Customer has in any case the right to renounce the certificate within one (1) month from the receipt date of the first invoice updated to the new fees.

During the period of prior notice, the Customer who avails of the aforementioned right to renunciation will be charged the fees prior to the variations.

6.3. Payment of fees due

Upon conclusion of the Service, IMQ issues to the Customer all the documents set out at parr. 2.3 and 2.4 above, only on condition that all the fees due to IMQ have been paid.

In case of failure to pay the fees and/or related interests, or in the event of non-fulfilment of the Contract, IMQ has the right to interrupt the Services at any moment, until the Customer has paid and/or remedied to its non-fulfilment.

Art. 7. USE OF CERTIFICATION, CE MARKING, MARKS

7.1. CE marking

For products that have obtained the relevant EC/EU Certification from IMQ, the Customer must draw up a specific declaration of conformity and attach the CE marking, where requested and according to the requirements of the applicable Directive.

It is forbidden to attach brands or inscriptions which can be confused with the CE marking to the products. The Customer must unequivocally distinguish its products provided with CE marking from those which do not have CE marking.

7.2. Transferability of EC/EU Certification – Modifications in organisational structure

The use of EC/EU certification issued by IMQ is strictly reserved to the Customer and it is not transferable, without prejudice to cases of sell-off, transformation, merger, split, transfer of the company or a branch of the company involved.

In these cases the Customer must send a communication to IMQ in a timely manner and in any case no later than fifteen (15) days from the entry of the registration into the Business Register, where required; failure to observe this term can cause the application of the provision to suspend or revoke the certificate.

The Customer must also forward to IMQ a written request for maintenance of the certification on the part of the subject which has modified its organisational structure, with copy of the relevant certificate of registration in the

Chamber of Commerce and of any further documents, if these are considered necessary. IMQ assesses the need to carry out additional verification activities, the cost of which is borne by the Customer, upon acceptance of a quotation formulated by IMQ, according to the Price list in force.

The transfer of the certificate is dependent on the positive result of the assessments carried out, as well as payment of the balance of all the amounts due by the transferring Organisation.

Art. 8. SUSPENSION, REVOCATION OR RENUNCIATION

8.1. Renunciation

8.1.1. Renunciation of surveillance

If the Customer intends to renounce the surveillance by IMQ, it must give written communication of this with prior warning of at least two (2) months, undertaking also to:

- stop attaching the CE marking with the identification number IMQ (0051) and, in any case, making reference to IMQ as NB;
- communicate within a term no longer than fifteen (15) days from the renunciation date, the stock in the production sites and warehouses of the products which show reference to IMQ as NB (identification number 0051);
- use up said products in own production sites or warehouses within the term, following the expiry date, which will be indicated by IMQ.

8.1.2. Renunciation of EC/EU Certification

If the Customer wishes to renounce to EC/EU certification issued by IMQ, it must make a written request for this.

This communication automatically cancels the relevant surveillance activity if conducted by IMQ; in this case, what is set out at par. 8.1.1 above is valid.

IMQ cancels the EC/EU certificates issued informing the competent Authorities and the other Notified Bodies of the renunciation, if necessary.

8.2. Suspension of surveillance activity and/or validity of the Certification

8.2.1. Motivations to suspend certification

The continuous surveillance activity can be suspended by IMQ following non-fulfilment of the Customer, and in particular:

- in case of bankruptcy or termination of activity of the Customer;
- failure to pay the amounts due to IMQ;
- in the event of non-fulfilment of the obligations by the Customer set out at Art. 5 above;
- in the event of serious non-conformities or in a high number, lack of adoption of corrective actions and, in general, negative result of the surveillance verification activities; non-observance, implying serious negligence, of the commitments undertaken as regards maintaining production conformity;
- in case of reports from the market, upon ascertainment of the relevant severity;

- in the event of undue attachment of the CE marking (see Art. 7 above).

8.2.2. Suspension of EC/EU Certificates issued

The validity of the EC/EU Certificates issued by IMQ can be suspended in cases of non-fulfilment as set out in par. 8.2.1 above.

8.2.3. Communication of suspension

The suspension of the certification and any restoration of it are communicated to the Customer by registered letter with notification of receipt, or other modality valid for all purposes and effects of law. The communication shows the reason for the suspension and expiry dates by which the Customer must implement the corrective actions requested. The Customer has five (5) days in which to communicate to IMQ of having taken charge of the provision, adaptation to requirements, implementation times, which must not be longer than six (6) months, and any other useful information on the solution of the findings disputed. The communication must occur in written form. The suspension will consider the principle of proportionality.

8.2.4. Consequences of suspension

Following the suspension the Customer must interrupt the use of the EC/EU Certificates and abstain from publicising them until the end of the suspension period. The suspension implies the impossibility of attaching the CE marking and the consequent impossibility to put the related products on the market, starting from the suspension date.

IMQ communicates, where requested, the suspension to the interested Authorities and/or Bodies involved.

In the most serious cases, IMQ reserves the right to request the Customer to recall products from the market, including those stocked in warehouses.

The expenses borne by IMQ to carry out any verification activities or activities caused by suspension are paid by the Customer.

The Customer is in any case required to pay the amounts to maintain the certification.

8.2.5. Restoring certification

The suspension can be cancelled only when the Customer has satisfactorily resolved the Non-Conformities found or in the case in which the situation which gave way to the suspension has been resolved.

Before proceeding to restore the certification, IMQ can carry out further verification activities to ascertain the actual resolution of the issues previously found; all the expenses for these additional verification activities are borne by the Customer.

8.2.6. Duration of suspension period

The suspension, which cannot exceed six (6) months, is indicated in the communication set out at par. 0 above; if the suspension is not cancelled within this period of time, the certificate is revoked.

8.3. Revocation of certification

8.3.1. Motivations for revocation

The EC/EU Certification issued can be revoked by IMQ in case of:

- failure to remove the causes of suspension as set out at par. 8.2 above, within the period indicated by IMQ;
- serious non-observance of the obligations of the Customer, set out in Art. 5 above;
- fraudulent or illegitimate use of the EC/EU Certification;
- significant and systematic non-conformity of the product;
- adoption of significant modifications made to the product by the Customer, or variation of the production site, without the preventive involvement of IMQ;
- failure to pay the amounts due, for any reason, to IMQ;
- bankruptcy or termination of the activity of the Customer;
- failure to adapt the product to the requirements of the new review of the applicable standards;
- misleading use of the EC/EU certification, such to damage or discredit IMQ.

8.3.2. Communication of revocation

The decision of revocation is communicated to the Customer by registered letter with notification of receipt, or other modality valid for all purposes and effects of law.

8.3.3. Consequences of the revocation

In the case of revocation of the EC/EU Certification, the Customer undertakes to:

- redeliver to IMQ the originals of the EC/EU Certificates obtained;
- abstain from publicising and using the EC/EU revoked Certificates, removing the logo and the references to IMQ from the documentation in use;
- stop attaching the CE marking to products referable to the EC/EU Certificate revoked and, consequently, stop its marketing.
- pay the balance of all the amounts due to IMQ.

IMQ also:

- interrupts the surveillance activity;
- communicates the revocation to the competent Authorities and/or to other Notified Bodies.

Art. 9. LEGISLATIVE, LEGAL AND REGULAMENTARY VARIATIONS

9.1. Modifications to the legislative provisions and/or reference laws

If important variations affecting the validity of the EC /EU Certificates issued are introduced in the legislative provisions applicable to the single Service in hand or in the technical standards which provide the presumption of conformity to the essential requirements of the specific Directive, IMQ will give communication of this to the Customer. The latter will have the right to adapt its products or quality system, within the indicated terms, or renounce the EC/EU certification.

In case the Customer intends to adapt to the new provisions, IMQ will be entitled to repeat the tests and verification activities on the products or the quality system assessment, as also to request new documentation. The expenses for said activities will be charged to the Customer, according to a new quotation.

9.2. Modifications to the Regulation and/or to the General and Special requirements

In the case in which the requirements applicable to the certification activity, contained in standards (e.g. ISO /IEC 17065) and/or in other specific documents (e.g. applicable accreditation rules), are subject to variations, IMQ can update the procedure described at Art. 4 above to transpose the new provisions.

IMQ also reserves the right to make modifications and integrations to this Regulation without the preventive agreement of the Customer; in this case, IMQ will communicate the change of the Regulation by a notice to the Customers and/or through publication on its website www.imq.it.

9.3. Supplementary assessments following modifications

Any costs for documental assessment activities and/or assessment activities at the place of work, deriving from modifications to laws or to regulations above are borne by the Customer.

Art. 10. LIMITS TO CERTIFICATION AND RESPONSIBILITY

10.1. Liability of Customer – Hold Harmless

The Organization undertakes to comply with and maintaining compliance with mandatory requirements, such as laws, regulations, etc., of an international, national or local level, with particular regard to the products, processes and services inside the scope of certification.

The issue and maintenance of the certification do not constitute attestation or guarantee by IMQ of conformity to the compulsory requirements that weigh on the Customer and, in general, of the legislative conformity of the latter.

Therefore, the Customer is and remains the only responsible party towards himself and towards third parties of the correct activity and conformity of the same, and of its products/services, to the applicable standards as well as to the expectations of the Customers and third parties in general.

The Customer also undertakes to hold harmless IMQ and its employees, assistants and collaborators against any complaint, action and/or claim of third parties connected with activities preformed by IMQ according to this Regulation.

10.2. IMQ Breach – Limits of responsibility

IMQ can be held responsible by the Customer only for damages following wilful misconduct or gross negligence.

The responsibility of IMQ for any damage deriving from the total or partial execution or non-fulfilment of its obligations subject matter of the Contract will be limited to a sum which cannot exceed a total amount equal to three (3) times the sum of the amount paid for the activities carried out by IMQ in relation to the Service in hand, starting from the verification of the event which has determined the responsibility of IMQ.

10.3. Forfeiture clause

Any complaint or claim for damages against IMQ must be brought by the Customer, on pain of forfeiture, within and no later than one (1) year from the event which has given way to the claim or to the complaint.

10.4. Exclusion of liability IMQ

Except in cases of fraud or gross negligence, even in cases of proven failure by IMQ, it remains excluded compensation in favor of the Organization for any loss of profit, such as business activity interruption, loss of profits, loss of business opportunities, of revenue, business start-up or of expected profits.

Art. 11. DURATION OF CONTRACT AND RIGHT TO WITHDRAWAL

11.1. Entry into force of contract

The Contract is considered to be in force and legally binding as long as the Customer has accepted in writing the IMQ Quotation within the time of validity and IMQ has confirmed the Customer's order in writing. Acceptance of the Quotation by the Customer constitutes an irrevocable Offer.

11.2. Duration of contract

Without prejudice to the hypotheses set out at par. 11.3 below, the contract of certification, of which this Regulation constitutes an integral and substantive part, is entered into for an indefinite time period, starting from the date of entry into force set out at par. 11.1.

11.3. Right of withdrawal

Each contracting party has the right to withdraw from the contract at any time, by certified e-mail, registered letter with notification of receipt, or other modality valid for all purposes and effects of law, signed by the Legal Representative or Attorney, giving a minimum prior notification of three (3) months from the effective date of withdrawal.

The Customer who withdraws is required to pay the balance of all the amounts due to IMQ until the date of communication of the withdrawal.

The Organization is allowed to withdraw from the contract before obtaining the certification. However, in this hypothesis:

- if the communication of withdrawal arrives to IMQ before the start of the activities, the Organization will be required to pay a penalty equal to:
  - for amounts of the offer up to 3,000 euros = 20% of the amount of the offer;
  - for amounts of the offer greater than 3,000 euros = 10% of the amount of the offer, with a minimum of 600 euros;
- in case the notice of withdrawal is communicated after the start of the test / verification activity, but before completing the assessment procedure, the Organization shall be obliged to the payment of an amount equal to fifty percent (50 %) of the amount due for certification;
- in case the notice of withdrawal is communicated after completion of the evaluation procedure, the Organization shall be obliged to the payment of the full amount due for certification.

The withdrawing Organization is required to the payment all the amounts invoiced by IMQ, according to the contractual terms, as well as to pay to IMQ the amounts for the maintenance related to the current period at the

date of communication of the withdrawal, if the latter occurs with at least 15 days notice from the invoice date of the maintenance amounts.

11.4. Renewal

Where applicable, and in cases in which the previously formulated Quotation does not include renewal activities, on request of the Customer and before expiry of the certificate, IMQ formulates a new Quotation for the subsequent certification cycle.

Upon receipt of acceptance of this Quotation, the activities aimed to the certification renewal are planned and carried out.

Art. 12. PROTECTION OF PERSONAL DATA

12.1. Processing of personal data

Pursuant to Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data ("General Data Protection Regulation") and Italian Legislative Decree 196/2003 as amended ("Privacy Code"), personal data provided directly by the Principal or via third parties are and will be processed by IMQ - and, in particular, recorded and stored in a database - in order to ensure proper execution of the contractual relations with the Principal. Special categories of personal data and personal data relating to criminal convictions and offences, pursuant to arts. 9 and 10 respectively of the General Data Protection Regulation, may be requested as a mandatory condition for the issue of certification. These data will be processed solely for the purpose of providing the service requested, applying appropriate, strengthened technical and organisational security measures.

For the above purposes, the data requested ("Data") will be processed using IT, manual and ICT tools, applying logic strictly correlated with the purposes of the processing and, in any case, in a manner that guarantees the security and confidentiality of the Data.

Proper execution of the contractual relations with IMQ therefore depends on provision of the Data by the Principal, with the consequence that refusal to provide the Data will prevent IMQ from continuing these contractual relations.

The Data will be processed for the time strictly necessary for execution of the contractual relations with the Principal, subject to a further period for which the Data will be stored of 10 years (dependent on whether specific EU regulations or directives require retention for a longer period) from completion of the last service provided, in order to comply with the established legal and regulatory obligations.

IMQ may disclosure the Data to accreditation and certification Bodies, Administrations, Institutions, Associations, Judicial Authorities and Public Security Authorities, for use to the extent of their respective specific responsibilities, as well as to all other relevant competent Authorities and, in general, to all public and private entities to which disclosure is required by law or necessary for execution of the services provided by IMQ. These parties will process the Data as independent Data controllers.

The Data are disseminated solely to guarantee institutions and consumers with regard to the issue, existence, waiver, suspension or withdrawal of the certification.

12.2. Data controller

The "Data controller" is IMQ S.p.A. with headquarters at Via Quintiliano No. 43 - 20138 Milan – Italy.

Pursuant to arts. 15-21 of the General Data Protection Regulation and art. 7 of the Privacy Code (Rights of the Data Subject), the Principal may at any time exercise the rights of access, rectification or erasure (so-called "right to be forgotten"), restriction of processing and to data portability by sending a specific request to the Data Protection Officer (DPO): dpo@imqgroup.it.

The Data may be disclosed and processed by third-party companies and other parties (including but not limited to suppliers of IT services, banks, professional firms, consultants) that perform activities outsourced by the Data controller in their roles as Data processors.

The list of specifically authorised Data processors is available from the Data controller.

12.3. Consent to processing personal data

By signing this Regulation, the Principal gives consent to the processing of the Data for the purposes stated above and, also, to be disclosed and disseminated in that context.

Art. 13. COMPLAINTS AND APPEALS

13.1. Complaints

The Customer, like anyone who is interested in doing so, is allowed to present a complaint regarding the work of IMQ, stating and motivating the reasons of the complaint, using the methods referred to in the website www.imq.it. IMQ will process the complaint according to its procedures, described in the specific section of the website www.imq.it.

13.2. Appeals

The Customer is allowed to lodge an appeal against the decisions taken by IMQ regarding the result of the conformity assessment within thirty (30) days from receipt of the relevant communication, stating and motivating the reasons for the objection, following the procedures laid down on website www.imq.it.

The management process of appeals by IMQ is regulated by a specific internal procedure - accessible to the Customer – detailing the procedures for registration and responsibilities of collecting and verifying necessary information for the managing of each individual appeal. This process, therefore, includes an initial phase of ascertainment that the appeal received refers to conformity assessment activities for which IMQ is responsible; it also contemplates the allocation of the appeal to a Committee composed of people not involved in the activities of conformity assessment subject to appeal; such Committee which will be responsible of deciding the acceptance/non acceptance of the appeal, and, finally, of defining the necessary consequential actions to solve the appeal. The relative decision will be communicated to the Customer by IMQ within four (4) months from date appeal.

IMQ will take care to manage the appeal according to its own procedures, described in a dedicated section of the aforementioned website. The decision on the appeal - taken by a Committee composed by persons not involved

in the conformity assessment activities subject to appeal - will be communicated to the Customer by IMQ within four (4) months from the date of receipt of the appeal.

Art. 14. APPLICABLE LAW AND COMPETENT COURT

14.1. Applicable law

The present Regulation, of which the quotation is an integral and substantive part, is governed by Italian law.

14.2. Competent court

Any dispute regarding the application or the present Regulation, including those on its validity, performance and termination, will be subject to the exclusive jurisdiction of the Court of Milan (Italy).