Title	**IMQ REGULATION FOR THE CERTIFICATION OF MEDICAL DEVICES** CE Marking – Directive 93/42/EEC
Reference	Reg. IMQ/ON/MDD-E
Date of entry into force	Rev. 0 of 22 April, 2016
Approved by	IMQ S.p.A. – Product Function (FP)

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Art. 0. FOREWORD

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

Each modification or 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, in its capacity as Notified Body, is required to operate.

Art. 1. SUBJECT MATTER OF THE REGULATION

1.1. This Regulation establishes the procedure followed by IMQ, in its capacity as Notified Body, to issue certificates of conformity and to carry out the related activities of surveillance and renewal, foreseen for "medical devices" by Legislative Decree 46 of 24 February 1997 and as amended (hereinafter "**Leg. Dec. 46/97**"), implementation of Directive 93/42/EEC of 14 June 1993 as amended (hereinafter "**Directive**"), considering in particular the Regulation (EU) n° 920 /2013 of the Commission of 24 September 2013 *related to the designation and surveillance of notified bodies in accordance with Council directive 90/385/EEC on active implantable medical devices and the directive 93/42/EEC of the Council on medical directives*.

1.2. This Regulation is applied to medical devices and related accessories (hereinafter "**devices**"), as defined in article 1 of Legislative Decree 46/97 for which IMQ has attained the suitable authorisation to carry out the relevant conformity assessment procedures.

1.3. For the purposes of this Regulation, EC certification is considered to encompass all the activities to assess and attest conformity, according to the different procedures laid down in art. 11 of Legislative Decree 46/97. The documents issued by IMQ within this scope are:

- Declaration of Conformity (Full Quality Assurance System), according to Annex II of the Directive;
- EC Type Examination Certificate, according to Annex III of the Directive;
- EC Verification certificate, according to Annex IV of the Directive;
- Declaration of Conformity (Production Quality Assurance) according to Annex V of the Directive;
- Declaration of Conformity (Product Quality Assurance), according to Annex VI of the Directive.

Art. 2. GENERAL TERMS AND CONDITIONS

2.1 The contract is considered to be in force and binding with full legal effect, as long as the manufacturer will have accepted the estimate in writing by the relevant term of validity and IMQ will have confirmed in writing the order of the manufacturer (hereinafter "**Contract of certification**"). This Regulation, signed by the manufacturer, constitutes an integral part of the Contract of Certification.

2.2 The manufacturer which intends to avail of IMQ to issue EC certification relating to his devices is responsible for the destination assigned to each device and for the relevant classification, according to the criteria set out in Annex IX of Legislative Decree 46/97. IMQ is responsible for verifying whether the information indicated by the manufacturer is correct and conforms to the reference requirements.

2.3 In the event of disagreement between the manufacturer and IMQ on the application of the classification rules, after informing the manufacturer, IMQ sets out the terms of the matter in hand to the competent Authority so it may be resolved, in accordance with art. 8, paragraph 2 of Legislative Decree 46/97.

2.4 It is the prerogative of the manufacturer to choose the conformity assessment procedure to follow in order to be able to affix the CE marking to its devices, in relation to their classification, in accordance with art. 11 of Legislative Decree 46/97.

2.5 The manufacturer cannot publicize the request underway until the positive result of the relevant tests, verification and assessments. In cases which are duly motivated, IMQ can grant an exception to this ban.

2.6 The tests and verification on the devices and the assessments of the Quality System of the manufacturer are performed by IMQ which, in addition to its resources, can also avail of laboratories or external assessors, in compliance with the requirements established by the technical standards of reference and by the competent Authority.

2.7 During its activity, IMQ reserves the right to recognize the documents issued by other Notified Bodies pursuant to the Directive, such as certificates, declarations of conformity, test reports, reports which attest conformity of the devices or production systems.

2.8 The EC type examination certificate, EC Verification certificate and Declarations of Conformity are issued and updated against payment:

- of the amount to handle the request and documentation;
- of the amount for the tests, the verification and audits,

according to what is set out in the relevant estimate formulated by IMQ.

2.9 The maintenance of any type of Declaration of Conformity and carrying out of any surveillance activity are provided against payment of the amount foreseen for the surveillance phase, in accordance with the IMQ fee schedule in force.

2.10 Otherwise, IMQ suspends the surveillance activity, giving communication of this to the competent Authority and to the other Notified Bodies. If the Quality System is approved according to Legislative Decree 46/97, persistence of the suspension of the surveillance activity implies the subsequent revocation of the Declaration of Conformity, since the conditions to guarantee the suitability of the production system cease to exist.

2.11 All the documents on the conformity assessment activity according to Legislative Decree 46/97, in particular the tests, verification and assessments, are considered confidential, except what is required by Legislative Decree 46/97 as specifically regards the competent Authority and the other Notified Bodies.

The access and consultation of certification documents are reserved to IMQ personnel involved in the certification process.

2.12 In the case that IMQ avails of external collaborators, as experts, it will send prior communication of this to the manufacturer. This is allowed to oppose the choice of the expert, showing any conflicts of interests of the same with the activities subject to assessment.

2.13 IMQ, in its capacity as Notified Body, is required to guarantee impartiality during all the certification activities: in this respect, IMQ avails of a process to assess and manage the risks of impartiality.

In carrying out the activities foreseen by this Regulation, IMQ in no way provides consulting services on products/management systems for which certification is requested or has already been obtained.

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

2.14 IMQ will inform the manufacturer of any suspension, renunciation or revocation of its notice as regards the EC certification issued to the manufacturer itself (conformity assessment procedures, families of medical devices); in this case, it will support the same in the move to another Notified Body. IMQ is in no way responsible for any damage caused to the manufacturer by the suspension, renunciation, limitation of extension, suspension or revocation of the qualification.

2.15 IMQ has adopted an Ethics Code according to Legislative Decree 231 of 8 June 2001 on the liability of legal persons, of companies and of associations, including those 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.
The Customer declares to have viewed and to be familiar with the content of the IMQ Ethics Code, 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 Legislative Decree 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.

Art. 3. CERTIFICATION PROCESS

3.1 - Presentation of request for certification

3.1.1. The manufacturer must make a request by filling out the specific form distributed by IMQ.

In particular, the manufacturer must specify in said form the classification of the devices subject of the request (art. 8 and Ann. IX of Legislative Decree 46/97) as well as the chosen procedures to assess conformity (art. 11 of Legislative Decree 46/97).

3.1.2. Each request must be accompanied by the documents as foreseen by the procedure chosen to assess the conformity evaluation, as clarified in the relevant Annexes of Legislative Decree 46/97.

Further documents (e.g.: certificates, declarations of conformity, test reports, reports attesting conformity of the devices or of their production systems to one or more of the essential requirements of the Directive) may be annexed to the request; IMQ will accept these according to the principles set out in paragraph 2.7. above.

3.1.3. Upon receipt of the request, IMQ examines the same for the purposes of its acceptance.

3.2 - EC type examination

3.2.1. Where the EC type examination is required according to the procedure described at Annex III of Leg. Dec. 46/97, the manufacturer must provide the documentation referred to in point 3 of the same Annex as well as a written declaration which attests that the request has not been presented to another Notified Body.

3.2.2. A separate request must be presented for each type of device, or rather for each sample which represents a specific production. The type can also include product variations, as long as these do not imply different types of risk with regard to the essential requirements of the Directive.

3.2.3. Once the request has been accepted, if necessary, IMQ draws up a specific test protocol and communicates to the requesting party the number of samples of the type which must be provided free of charge for the conformity examination. On these samples and on the relevant documents, IMQ carries out the appropriate tests and verification as well as the necessary examinations, in accordance with point 4 of Annex III of Legislative Decree 46/97.

If the type conforms to the requirements of the Directive, IMQ issues the manufacturer the EC Type Examination Certificate.

If, on the other hand, the result of the tests, verification and examinations is negative, IMQ informs the manufacturer on what has been found. The manufacturer must present, within the term indicated by IMQ, another or other samples and the relevant documents appropriately modified; the cost to repeat the verification will be borne by the manufacturer. In case the manufacturer does not proceed in this way, the request will be considered lapsed and IMQ will inform the competent Authority of this.

3.2.4. Whatever the result of the exam, IMQ will keep a copy of the documentation annexed to the request. The devices subjected to testing, if returned, are delivered to the manufacturer – at his expense – in the condition in which they are found after the tests.
IMQ reserves the right to ask the manufacturer to keep the samples subjected to testing, or parts of them, duly marked or sealed, at its premises.

3.3 - EC verification

3.3.1. Where EC verification is requested according to the procedure described in Annex IV of Legislative Decree 46/97, the manufacturer must specify if it intends to proceed with the verification by control and test on each device or with the statistical verification.

3.3.2. Depending on the choice made, the manufacturer proposes a time schedule in which to carry out the verification, a programme which IMQ reserves the right to accept.

3.3.3. In the event of acceptance, IMQ carries out the controls within the time set; in the event of non-acceptance, IMQ communicates the relevant motivations to the manufacturer and asks for a new schedule to be submitted.

3.3.4. Without prejudice to other agreements, the EC verification will be performed at the manufacturer's premises. IMQ is entitled to request that some or all of the tests are performed at its own laboratories (see also preceding paragraph 2.6).

3.3.5. In this case, the manufacturer undertakes to send IMQ the products involved free of charge; these samples will be returned, after the tests, in the condition in which they are found after the tests, with the risk and expense borne by the manufacturer.

Verification to control and test each device

3.3.6. Upon acceptance of the request, IMQ plans the verification and defines the specific test schedule.

3.3.7. In the event of a positive result of the tests carried out, IMQ issues the manufacturer with an EC Verification Certificate, which will state to which products it refers.

3.3.8. If one or more of the products tested were found not to conform to the essential requirements of the Directive, IMQ will inform the manufacturer of this in writing and takes the appropriate measures to avoid the same being put on the market.

Statistical verification

3.3.9. Upon acceptance of the request, IMQ plans the verification and defines the specific test schedule. The criteria for batch acceptance are those established by the Directive.

3.3.10. If a batch is accepted, IMQ issues the Manufacturer with an EC Verification Certificate, relating to the same batch.

3.3.11. If the batch is rejected, IMQ informs the manufacturer of this in writing and takes the appropriate measures to avoid the same batch being put on the market.

3.4 - Approval of the Quality System

3.4.1. Where the approval of the Quality System is requested according to one of the procedures described in Annexes II, V, VI of Leg. Dec. 46/97, the manufacturer must provide the documentation referred to in points 3.1. and 3.2 of the relevant annex as well as a written declaration which attests that the request has not been presented to another Body.

3.4.2. The presentation of the request according to one of the procedures above implies automatic acceptance by the manufacturer of the activation of the continuous surveillance procedures, including unannounced audits.

It is possible to present a single request for homogenous types of devices, as long as the request is accompanied by suitable documentation to support the homogeneity criteria applied. The final judgment on the possible aggregations in the same request is the responsibility of IMQ.

3.4.3. Once the request is accepted, IMQ examines and assesses the technical documentation of the product (where applicable) and the Quality System implemented to determine if the provisions of the relevant Annex of Leg. Dec. 46/97 are satisfied.

In the case of devices placed on the market in sterile packaging or class I measuring devices, assessing conformity according to Annexes V or VI respectively relates to:

- the sole manufacturing aspects which deal with achieving and maintaining the sterile status:
- the sole manufacturing aspects which deal with conformity to metrological requirements.

3.4.4. If the technical documentation (where applicable) and the Quality System comply with the requirements, IMQ issues the manufacturer with the relevant Declaration of Conformity.

If, on the other hand, the result of the verification is negative, IMQ informs the manufacturer on what has been found, inviting him to provide evidence of the consequent corrective actions adopted; the cost for the repetition of the verification will be borne by the manufacturer. In the event that the manufacturer does not adopt appropriate actions to adapt the technical documentation and/or its Quality System within the agreed timeframe, the request will be considered lapsed and IMQ will communicate this to the competent Authority and to the other Notified Bodies.

3.5 - Interruption of certification process

If twelve months have passed since the acceptance of the request, without the requesting party being able to show conformity, including in more activities of integrative assessment, the process is interrupted and the contract with the Organization is cancelled.

In the event of failure to issue the Certification the motivations are communicated to the manufacturer and the minimum timeframe considered necessary before proceeding with a new assessment is indicated.

Art. 4. USE OF EC CERTIFICATION AND AFFIXING OF CE MARKING

4.1. On products which have obtained EC certification from IMQ according to the procedures indicated below:

- Declaration of Conformity (Full quality assurance system), as referred to in Annex II (excluding point 4) of the Directive;
- EC verification, as referred to in Annex IV of the Directive;
- Declaration of Conformity (Production quality assurance) as referred to in Annex V of the Directive;
- Declaration of Conformity (Product quality assurance) as referred to in Annex VI of the Directive,

the CE marking is affixed by the manufacturer according to the methods laid down in article 16 of Leg. Dec. 46/97.

Said marking must be followed by the number 0051, which identifies IMQ as a Notified Body, to attest the intervention of IMQ in the production surveillance phase.

4.2. For products that have obtained EC certification from IMQ according to the procedure laid down in Annex III of the Directive (EC type examination), the manufacturer must subsequently obtain a further certification according to one of the procedures relating to the production phase (Annexes IV, V and VI of the Directive, considering the classification of the devices), before affixing the CE marking.

4.3. Affixing of the CE marking and use of the EC certification are incorrect when they can mislead the buyers on the nature, quality and origin of the device and, in particular, when:

- the products are not manufactured according to the technical documentation referred to in Annex VII, point 3 of Leg. Dec. 46/97;

- the manufacturer has not satisfied the obligations specified by this Regulation.

It is forbidden to affix marks or inscriptions which can be confused with the CE marking to the devices.

The manufacturer must unequivocally distinguish its products provided with CE marking from those without it

4.4. Considering that the EC certification issued according to Annexes II, III, V, VI has a maximum validity of five years (art. 11 paragraph 12 of Leg. Dec. 46/97), the manufacturer must present IMQ the request for renewal of its validity within six (6) months from the expiry date.

Art. 5. OBLIGATIONS OF THE MANUFACTURER

5.1 - Transferibility of certification – Modification in organisational structure

5.1.1. The use of the EC certification issued by IMQ is reserved to the manufacturer and it is not transferrable, without prejudice to cases of sell-off, transformation, merger, split, transfer or rental of company or of a branch of the certified company.

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

5.1.2. In the cases described above, the Manufacturer must forward to IMQ a written request for maintenance of the certificate on the part of the subject which has modified its organisational structure described above, furnished with copy of the relevant certificate of registration in the Chamber of Commerce and of any further documents, if these are considered necessary. IMQ will ascertain, also through a supplementary verification, that the product and/or the Management System have not been subjected to modifications or, in any case, that it conforms to the requirements of law.

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

The costs of updating the certificate and any supplementary verification (documental and/or at the manufacturer's premises) are borne by the subject resulting from the modification.

5.2 - Obligations of the manufacturer

5.2.1. The manufacturer undertakes:

- to guarantee constant correspondence of production to the type recognized as conforming to the essential requirements of the Directive;
- to subject itself to the ordinary/extraordinary verification foreseen to maintain/renew the certificate, within the terms indicated by IMQ;

- to communicate without delay to IMQ any modifications which can be of importance to conformity to the essential requirements of the Directive, or of the field of application of the certificate (e.g. changes of registered office, activity, organizational changes, etc.); in these cases, IMQ can avail of one or more supplementary verification (the cost is borne by the manufacturer), proceeding, if necessary, with the formulation of an updated offer;
- not to make any declaration or publicize its certificate in a manner that can be considered misleading or unauthorized, or use his certificate to discredit IMQ;
- within the scope of the Management System, where applicable, to keep a record of the complaints and of the corrective actions and, where requested by IMQ, give evidence of their management;
- in relation to the qualification of IMQ, allow access to the inspectors of the competent Authority, so they can carry out the verification activities foreseen by the applicable provisions;
- communicate immediately to IMQ all the non-conforming situations found by the control Authorities, as well as any suspensions or revocations of authorizations, concessions, etc;
- communicate immediately to IMQ any judicial /administrative procedures underway regarding the subject matter of the certificate, without prejudice to the limits set by the legislative provisions and keep IMQ informed on the developments and management of such situations.

5.2.2. The manufacturer must establish and implement a systematic assessment procedure of the experience gained in the use of the devices subsequent to their production as well as provide for an appropriate system of corrective actions, especially in cases of accidents occurred during use of the same devices.

The manufacturer must immediately inform the competent Authority upon the verification of the accidents as identified in Leg. Dec. 46/97 (Annex. II point 3.1.; Ann. IV point 3; Ann. V point 3.1; Ann. VI point 3.1); said reports must also be simultaneously transmitted to IMQ by certified mail to the prodotto.imq@legalmail.it.

The manufacturer must allow IMQ-appointed personnel access to the production, control and inspection rooms and to the warehouses, accompanied, if necessary, by officials of the competent Authority.

5.2.3. In relation to fulfilling the obligations referred to in this paragraph, IMQ can, against payment, carry out extraordinary control visits and, if necessary, adopt measures to suspend or revoke certification, depending on the gravity of the situation and/or on the impact of the event which has taken place.

5.3 - Safety at work – Obligation of notice

The manufacturer, according to the legislation in force on safety and prevention of accidents at work, undertakes to provide IMQ with a full and detailed notice on the specific risks existing in the work environment in which the IMQ inspectors and any accompanying persons are intended to work.

The manufacturer 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 IMQ-appointed inspectors and which require the protection of both workers and of all other subjects who operate or who in any case are present in the same work environment

The manufacturer, according to any specific existing risks, will provide IMQ staff 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. CONTINUOUS SURVEILLANCE OF CERTIFIED PRODUCTION

6.1 - General information

The manufacturer must adopt the suitable procedures to guarantee the constant correspondence of production to the type recognized as conforming to the essential requirements of the Directive.

The choice made between the possible options (art. 11 of Leg. Dec. 46/97) must be communicated by the manufacturer to IMQ by means of the specific form (see paragraph 3.1. of this Regulation); the same method must be followed in the event that the manufacturer intends to modify the choice of option type.

6.2 - Surveillance of the Quality System and of the Product

6.2.1. IMQ periodically carries out surveillance visits, at least once a year, to ascertain that the manufacturer maintains and applies the approved Quality System.

The manufacturer is informed of these visits in advance so he can allow IMQ all the necessary inspections, at his premises and at those of his sub-contractors and critical suppliers, if considered necessary to guarantee an effective control; the manufacturer also undertakes to make all the useful information, in particular documents on the Quality System and the quality records, available to the auditors.

6.2.2. IMQ also carries out, in addition, unannounced audits (inspections without prior warning) at least once every three years, again to verify that the manufacturer maintains and applies the approved Quality System This frequency can be increased if the medical devices subject of the certification present a high level of potential risk, often prove to be non-conforming or if specific information lead to believe that the same or the relevant Quality System present non-conformities.

In general, unannounced audits have a duration of at least one day and are carried out by at least two auditors. They are conducted at the premises of the manufacturer or – in replacement or in addition to these – at the premises of the sub-contractors, critical suppliers and in the case of OBL contract at O.E.M., if this can guarantee a greater efficacy in the control process. If a visa is necessary to visit the country in which the manufacturer is located, an invitation must be provided with the date of the

signature and date of the visit kept open, to allow the audit to be conducted. Similar invitations must be issued by sub-contractors and critical suppliers.

To allow efficacy of the visit, the manufacturer must continuously communicate to IMQ the periods of the year in which the production of medical devices subject matter of the certification is not foreseen, with particular attention to company holidays, bank holidays, etc.

The manufacturer must equip himself with documented practices or procedures to manage unannounced audit in conformity with the Recommendation of the Commission of 24 September 2013 (2013/473/EU).

On the occasion of the unannounced audits, IMQ carries out controls on an adequate sample of recent manufacture, preferably a device taken from the manufacturing process underway, to ascertain its conformity with tests to the technical documentation and the legal provisions. These tests can also be carried out by the manufacturer, by a subcontractor or by a critical supplier, with monitoring by IMQ.

The costs of unannounced audits – including, if necessary, those for purchasing the device and for tests carried out on it and the security measures – are borne by the manufacturer according to IMQ fees.

Furthermore, in the case in which permanent access is no longer given, without prior notice, to the premises of the manufacturer, sub-contractors or critical suppliers , IMQ is authorized to terminate the existing contract.

6.2.3. Following verification referred to in points 6.2.1 and 6.2.2, IMQ issues suitable documentation (audit report, test report, verification report) with the results of the activities carried out and the conclusions reached.

6.2.4. If non-conformity is ascertained in the approved Quality System or in a device covered by EC certification, IMQ invites the manufacturer to adopt the appropriate corrective actions, within a fixed timeframe. All the expenses relating to the activities resulting from the negative result are borne by the manufacturer, according to IMQ fees. Verifying the adequacy and efficacy of the corrective actions will be carried out upon acceptance of the relevant estimate.

6.2.5. In the most serious cases or repetition of the negative result, IMQ warns the manufacturer against continuing the production and supply to the market of all the products covered by the Declaration of Conformity which is suspended; it also assesses if it is necessary to suspend or revoke the validity of any EC type examination certificate, co-ordinating itself with the Notified Body which issued it, if different to IMQ.

The warning will be cancelled only after IMQ will have been able to declare that the technical measures have been adopted to guarantee future conformity. If the warning is not cancelled within six (6) months, IMQ will revoke or limit the EC certification involved.

IMQ also informs the competent Authority of what has been implemented and, on request, the other Notified Bodies, in accordance with Leg. Dec. 46/97.

Art. 7. RENEWAL OF CERTIFICATION

7.1 - Presentation of renewal request

7.1.1. The manufacturer must present the renewal request by filling out the specific form distributed by IMQ and provide the necessary documentation for the renewal activity as indicated in the same form.

7.1.2. Upon receipt of the request, IMQ examines it for acceptance purposes.

7.1.3. Failure to perform the renewal activities within the validity term of the certification will result in termination of the contract from the date subsequent to that of certificate expiry.

7.2 – Renewal of EC type examination certificate

7.2.1. If the renewal of the EC type examination certificate is requested, IMQ verifies that the certified type continues to conform to the requirements of the Directive.

7.2.2. The renewal activity includes the general review of the technical documentation of the product and the repetition of the tests and controls carried out on the device in the initial certification phase.

If the type conforms to the Directive, IMQ renews the EC type examination certificate of the manufacturer; the costs of re-issuing the certificate are borne by the manufacturer.

Following the negative result of the certification renewal activity or if this activity is not completed by the expiry date of the certificate, the latter loses its validity.

7.3 – Renewal of Declaration of Conformity

7.3.1. Where renewal of the Declaration of Conformity is requested, IMQ re-examines the technical documentation of the product based on representative samples (where applicable) and verifies that the certified Quality System continues to conform to the Directive.

The following elements are assessed with particular attention:

- efficacy of the Management System overall, in light of the internal and external changes, and its continuous relevance and applicability to the application field of the certification;
- efficacy of the management system with reference to pursuing the objective of the Organization and the expected results;
- the commitment shown to maintain the efficacy and the improvement.

7.3.2. By the expiry date of the certification, the renewal audit must be completed and the Organisation must have implemented the Corrective Actions to resolve the major Non-conformities found; the aforementioned term is also applicable in cases in which the certification is suspended.

7.3.3. Following the positive result of the renewal activities, the certificate is reissued; the costs of each reissue of the certificate are borne by the manufacturer.

Following the negative result of the certification renewal activity or if this activity is not completed by the expiry date of the certificate, the latter loses its validity.

Art. 8. SUSPENSION, LIMITATION, REVOCATION AND RENUNCIATION OF CERTIFICATION

8.1 - Suspension of certification

8.1.1. The CE certificates can be suspended by IMQ following non-fulfilment of the manufacturer, and specifically:

- non-observance, implying serious negligence, of commitments undertaken as regards the maintenance of conformity of the product and quality system;
- non-fulfilment, by the Organization, of the obligations referred to in paragraphs 5.1. and 5.2 above;
- in case of undue affixing of CE marking (see article 4 of this Regulation).

8.1.2. The suspension provision will consider the principle of proportionality and can be cancelled as soon as the manufacturer shows to have satisfactorily adopted the appropriate corrective measures, or in the case in which the situation which had given way to the suspension has been resolved. Suspension of the certification and any provision to restore it are communicated to the manufacturer by registered letter with notification of receipt or other modality valid for all purposes and effects of the law.

8.1.3. During the suspension period:

- IMQ can suspend the surveillance activity at art. 6 above without prejudice to what is referred to in par. 6.2.2;
- IMQ communicates, where requested, the suspension to the Authorities and/or interested Bodies;
- the Organization cannot use the certificate/s obtained and the markings referred to in art. 4 of this Regulation, without prejudice to other indications by IMQ, or qualify itself as a certified Organization;
- the Organization is in any case required to pay the amounts due for maintaining the certification.

8.1.4. Before restoring the certification, IMQ can carry out documental verification and/or audits at the manufacturer to ascertain the effective resolution of the issues previously found; all the expenses for such additional verification are borne by the manufacturer.

8.1.5. The duration of the suspension, which cannot exceed six (6) months, is indicated in the communication referred to in point 8.1.2. above; if the suspension is not cancelled within this period, the certification will be revoked.

8.2 - Limitation and/or revocation of the certification

8.2.1. The CE certificates can be revoked or subjected to limitation by IMQ following non-fulfilment of the manufacturer and specifically:

- in case of bankruptcy of the manufacturer or termination of the activity;
- serious non-observance of the commitments undertaken at art. 5 and 6 above;
- failure to pay the amounts due to IMQ. In this case, before revocation, IMQ sends the manufacturer a warning notice; if a month has passed without the manufacturer having paid the balance of the amounts due, the certificate is revoked. During this period of prior warning all the verification activities are suspended, similarly to what occurs in the hypothesis of suspension;
- in the case of non-observance, implying serious negligence, of the commitments undertaken as regards the maintenance of product and/or quality system conformity;
- serious irregularities or abuse in the use of the certificate and/or of CE marking;
- failure of the Organization to adapt to legal and/or regulatory modifications;
- in cases referred to in 8.1.5 above.

8.2.2. The limitation or revocation of the certification are communicated to the manufacturer by registered letter with notification of receipt or other modality valid for all purposes and effects of the law.

8.2.3. In case of revocation, the manufacturer is required to immediately cease the affixing of the CE marking to the devices involved and to eliminate any reference to the relevant certifications in the catalogues and in advertising in general.

IMQ gives appropriate information of what has been implemented, in particular to the competent Authority and, on request, to the other Notified Bodies.

8.2.4. If a device is present on the market for which the CE certification has been revoked due to defects which can be a hazard for users, IMQ can invite the manufacturer to withdraw from sale all the units of the same device, informing in any case the competent Authority and the other Notified Bodies.

8.3 - Renunciation

8.3.1. If the manufacturer wishes to renounce the permanent control by IMQ (surveillance of the Quality System), he will have to communicate this in writing with prior warning of at least one (1) month undertaking to:

- stop affixing the CE marking with the identification number IMQ (0051) and, in any case, making reference to the IMQ as Notified Body;
- use up in his plants or warehouses the products involved within the term which will be indicated by IMQ;
- communicate, three (3) days before the date of the last validity of the CE Certificate issued, the serial number or the batch of last products sold.

8.3.2. If the manufacturer wishes to cancel a CE type examination certificate issued by IMQ, he must make written communication of this. This communication automatically implies cancellation of the relative surveillance activity, if conducted by IMQ; in this case the provisions referred to in point 8.3.1. above are applied.

8.3.3. IMQ cancels the EC certification issued, informing the competent Authority of the renunciation and, on request, the other Notified Bodies in accordance with Leg. Dec. 46/97.

IMQ also removes the denomination of the relevant types from the list of CE certified products.

Art. 9. MODIFICATIONS TO THE LEGISLATIVE PROVISIONS OR TO THE REGULATION

9.1. If modifications which affect the EC certification issued are introduced to the Directive and/or Leg. Dec. 46/97, IMQ will communicate this to the manufacturer who will have the right to adapt its devices or its business Management System within the term which will be stated, or to renounce the certification attained from IMQ.

If the manufacturer intends to adapt to the new provisions, IMQ will have the right to repeat the tests and the verification on the devices or the Quality system assessments which it will consider necessary, and also to request new documentation.

The expenses for said activities will be borne by the manufacturer upon acceptance of the estimate formulated by IMQ.

9.2. IMQ reserves the right to make changes and integrations to this Regulation without the prior consent of the manufacturer; in this case, IMQ will communicate any modification to the Regulation through a notice to all the interested customers and/or through publication on its website www.imq.it.

If these modifications imply significant impacts on the activity carried out at the manufacturer, IMQ will inform the latter of this formulating a new estimate where required; the manufacturer will have

the right to renounce the certification within the thirty (30) days following the relevant communication.

Any costs for the assessment of documents and/or assessment in the work area, deriving from legal or regulatory modifications above are the responsibility of the Organization.

Art. 10. FINANCIAL TERMS AND CONDITIONS

10.1 - Amounts due to issue and maintain the certification

The amounts due for the activities of certification and of maintenance (and, where specified, the amounts for the renewal activity), together with the relevant payment conditions, are indicated in the estimate as accepted by the manufacturer; this estimate is formulated according to the fees indicated in the IMQ Fee schedule in force and on the basis of the information provided by the manufacturer.

The manufacturer is required to correctly communicate all the information requested during the formulation of the offer in order to issue the estimate, as well as update IMQ with regard to any modifications (see point 5.2 above); IMQ assesses if, on the basis of the updated data, it is necessary to review the financial conditions agreed.

In the case in which the formulated estimate does not include the renewal activities, IMQ will formulate a new estimate for the subsequent five-year period on request of the manufacturer and before expiry of the certificate. Upon receipt of the acceptance of this estimate, the certificate renewal activities will be planned and carried out.

As regards what is not specifically provided for by the estimate, as well as in the absence of same, the amounts indicated in the IMQ Fee schedule in force are applied which are intended as expressly referred to.

In the event of failure by the manufacturer to accept the estimate, at least four (4) months before the certification expiry date, the contract is understood as being terminated starting from the date subsequent to the certificate expiry. The organization is required to pay the amounts due for maintaining the certification until the certificate expiry.

10.2 - Variation to IMQ fee schedule

Any variations to the IMQ Fee schedule are communicated to all the IMQ Customers involved, if the same imply a significant modification to the financial conditions.

The manufacturer has, in any case, the right to renounce the certification within one (1) month from the receipt date of the communication. The manufacturer that avails of the aforementioned right to renounce the certification will be charged the fees prior to the variations, until the termination date of the relationship.

Art. 11. LIMITS TO THE RESPONSIBILITY

11.1 - IMQ breach – Limits of responsibility

11.1.1 Only in case of misconduct or gross negligence, the responsibility of IMQ for any damage deriving from the total or partial execution or non-fulfilment of its obligations will be limited to a sum which cannot exceed a total amount equal to five (5) times the total of the fee paid for the activity carried out, starting from the occurrence of the event which has determined the responsibility of IMQ.

11.1.2 IMQ is in no way responsible for any damages caused to the manufacturer by the suspension, renunciation or revocation of its notice.

11.2 - Forfeiture clause

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

Art. 12. DURATION AND WITHDRAWAL

12.1. Without prejudice to the hypothesis set out at point 12.4 below, the Contract of certification is entered into for an indefinite time starting from the date of acceptance by the manufacturer of the estimate formulated by IMQ or of presentation of the first request for product certification.

IMQ and the manufacturer have the right to withdraw from the Contract of certification with prior warning of three (3) months with respect to the effective date of withdrawal, by registered letter with notification of receipt or other modality valid for all purposes and effects of the law.

12.2. The withdrawal by the manufacture implies renunciation of the certification for all the certified products. The period of prior warning set out at paragraph 12.1 above will be effective from the receipt date of the relative communication by IMQ.

12.3. The withdrawal by IMQ implies the revocation, at the end of the period of prior warning set out at 12.1, of the certification for all the certified products.

12.4. In all cases of withdrawal mentioned at paragraphs 12.2 and 12.3 above, all the provisions of this Regulation which are functional to maintaining the products conforming to the reference provisions, with particular regard to the right of IMQ to carry out verification and to obtain information if it has reason to believe that said conformity has ceased to exist, remain valid. IMQ will also be owed all the fees agreed for the activities carried out by the same until the effective date of withdrawal.

12.5. In any case, failure to execute the renewal activities within the term of validity of the certification implies termination of the Contract of certification starting from the day subsequent to that of the certificate expiry date.

Art. 13. PROTECTION OF PERSONAL DATA

13.1. Pursuant to Leg. Dec. 196/2003, the personal data (hereinafter "the data") directly supplied by the manufacturer or through third parties, are and will be processed by IMQ – and in particular recorded and stored in a database – to ensure correct performance of the contractual relationships with the manufacturer in legal (e.g. fulfilment of accounting, tax obligations, etc.) and commercial (e.g. to send catalogues, brochures etc.) terms.

With regard to the aforementioned purposes, the data is processed using manual and computerized tools with modalities that are strictly related to the purposes themselves and, in any case, to guarantee the safety and confidentiality of the data.

The provision of manufacturer data is therefore essential for the correct performance of the contractual relationships with IMQ, with the consequence that any refusal to provide it will make it impossible for IMQ to establish the relationships.

The data may be communicated by IMQ, within its respective and specific area of responsibility, to Bodies, Administrations, Associations and, in general, to any public and private subject, to internal subjects appointed as data supervisors or in charge of processing the data, as well as to those external subjects responsible and/or appointed by IMQ to whom communication is necessary to carry out tasks ordered by IMQ, including to debt collecting agencies which may be entrusted with the task of collecting debts.

The disclosure of data is finalised exclusively at guaranteeing institutions and consumers on the issue, existence, renunciation, suspension or revocation of the certificate.

13.2. "Data controller" is IMQ S.p.A., with registered office in Via Quintiliano, 43 - 20138 Milan.

Pursuant to art. 7 (Right to access personal data and other rights) of the decree at par. 13.1, the manufacturer can at any time have access to his data, asking the competent Data supervisor of the Function for information. This is to request, for example, the updating, rectification, integration or cancellation of the data, always without prejudice to the right of the manufacturer to oppose, for legitimate reasons, the aforementioned processing and uses.

The updated list of Data Supervisors is available by forwarding a request to the e-mail address:**info@imq.it**.

The list of debt collection agencies, external Data supervisors, is available through the website**www.imq.it**.

13.3. By signing this Regulation, the manufacturer agrees that his personal data is processed for the purposes set out above and that it is also subject matter of communication and disclosure within the scope of the purposes set out above.

Art. 14. COMPLAINTS AND APPEALS

14.1. The manufacturer, like anyone who is interested in doing so, can lodge 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.

14.2. The manufacturer can 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. The appeal will be examined by a Committee set up by people not involved in the activities of assessing conformity subject matter of the appeal, which will have the task of deciding on whether or not to accept the appeal. The relevant decision will be communicated to the manufacturer by IMQ within three (3) months from the date on which the appeal was received

Art. 15. APPLICABLE LAW AND COMPETENT COURT

15.1. The Contract of certification, of which this Regulation is an integral and substantive part, is governed by Italian law.

15.2. Any dispute regarding the application and/or interpretation of the Contract of certification, including those on its validity, performance and termination, will be subject to the exclusive jurisdiction of the Court of Milan.