GENERAL REGULATION FOR CONFORMITY ASSESSMENT IN ACCORDANCE WITH EUROPEAN DIRECTIVES

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1.0 PURPOSE AND SCOPE

This Regulation defines the conditions and procedures for conformity assessment (product certification, quality system certification and inspections associated with product certification) pursuant to the ISO/IEC 17065, ISO/IEC 17021-1, ISO/IEC 17020 only for the mandatory field in compliance with the applicable European directives as transposed by the Italian State and listed below:

- Pressure Equipment Directive (PED) 2014/68/EU
- Gas Appliance Regulation (GAR) 2016/426
- Boiler Efficiency Directive (BED) 92/42/EEC
- Electromagnetic Compatibility Directive (EMC) 2014/30/EU
- Radio Equipment Directive (RED) 2014/53/EU

The term 'conformity assessment' means an assessment performed by a neutral third party which certifies that the products covered by the activity meet some specific requirements, generally contained in international standards or other regulatory documents.
The impartiality that characterizes the assessments, and the nature of the operational processes that make them up, are the prerequisites for the results of the assessments to be reliable.
Precisely to assure consumers, producers and all other interested parties that the evaluations are reliable, the body in charge of carrying them out must carry out its activities in accordance with the aforementioned standards.
This regulation defines the conditions, procedures and all other elements necessary for the conformity assessments performed by UL International Italia S.r.l. as Notified Body NB 2052 (hereinafter UL NB) are in compliance with the ISO/IEC 17065, ISO/IEC 17021-1, ISO/IEC 17020 standards requirements.
This regulation applies to all conformity assessment activities in the mandatory field.
For anything not provided for in these Regulations, and where useful for integration, reference is made to the general contract conditions established in the 'Service Terms and conditions ' of each program available at the web address https://italy.ul.com/direttive-ue-e-certificazione-ce/.

2.0 REFERENCE DOCUMENTS

The normative documents that constitute the basic references for this Regulation are those reported in the ACCREDIA reference document 'LS-02 - List of standards and reference documents for the accreditation of Certification Bodies' and 'LS-03 - List of standards and reference documents for the accreditation of Inspection Bodies' available on the website www.accredia.it, limited to the activities listed in § 1 of these Regulations.
These also include the reference documents issued by ACCREDIA accreditation body (regulations, technical reports, circulars, etc.) in the version applicable at the time of execution of the activities; in fact, these documents contain provisions that are additional to the aforementioned regulations and mandatory for UL NB as an accredited Certification and Inspection Body.

3.0 RESPONSIBILITY

The responsibilities related to the conformity assessment are shared among the resources actually involved in the conformity assessment activities. For a detailed examination of this element, please refer to the Division Manuals and the system documentation relating to the individual certification schemes. The responsibility for updating this Regulation lies with the Management of UL NB, supported by the Quality Manager.

4.0 DISTRIBUTION

This Regulation is available on the website https://italy.ul.com/direttive-ue-e-certificazione-ce/.

5.0 CONTRACTUAL PROCESS

5.1 Conformity assessment application

In order to access conformity assessment services provided by UL NB, the customer must complete the certification application form provided by UL NB.
The application form contains at least the following information:

- Customer details: company name, name, address and legal status;
- A description of the products to be evaluated;
- The certification system and the applicable standards for each of them, if known by the applicant;
- Declaration of acceptance of UL NB Service Terms and Conditions for the specific program (also published on the website https://italy.ul.com/direttive-ue-e-certificazione-ce/) and these Regulation.
- Declaration of not having submitted an application for the same device, product or equipment, to another Notified Body.

5.2 Conformity Assessment application review

The conformity assessment application form completed by the customer is forwarded to the Technical Department of the pertinent Division for the activity requested for review.
The review of the request is performed by UL NB in order to ensure that the requirements for the conformity assessment are clearly defined, documented and understood, to resolve any difference of interpretation between the applicant and UL NB, to ascertain and guarantee that ability to carry out the conformity assessment activity in relation to the field of application, the headquarters of the applicant's operating units and any particular requirement expressed by the applicant (for example, timing for obtaining the certification).
If the review has a positive outcome, UL NB communicates to the Sales Department all the information necessary for the preparation of the quotation; in the event of a negative outcome, the customer is duly informed in writing of the reasons.

5.3 Preparation of the quotation and acceptance by the customer

Based on the information received by the Technical Department, the Sales Department prepares the quotation containing the description of the service offered complete with all the information relating to the activities and the prices determined on the basis of the tariffs in force.
By accepting the quotation, the customer accepts the contractual conditions and undertakes to:

- Always operate in compliance with the provisions of the conformity assessment programme;
- Comply with and enforce the obligations established by the reference Directive(s) relating to the economic operators involved;
- Provide all the facilities necessary for the performance of the assessment activities, including those for the examination of the documentation and access to all the areas assessed, to the records (including reports of internal audits) and to the personnel involved and in the resolution of complaints;
- Make claims regarding the certification only with reference to the purposes for which the certification was issued;
- Cease, in the event of any suspension or withdrawal of the certification, the use of all advertising material that contains the relative references and to return, upon request by UL NB, any certification document;
- Use the certification only to indicate that the products are certified in compliance with specific reference standards;
- Ensure that no certificates or reports, or parts thereof, are misused;

- Behaving in compliance with these and any other UL NB requirements when referring to the certification in communication media such as documents, illustrative and/or advertising material.

5.4 Conformity Assessment Project Opening

After acceptance of the quotation by the customer, a certification project is opened in customer's name in the fulfillment process tool and assigned to qualified personnel to carry it out. Through the MyUL platform (https://my.ul.com/), the customer can view all ongoing projects, the persons to whom they are assigned, and can also share documentation through the platform.
Furthermore, should inconsistencies emerge during the document evaluation or conformity assessment phase with respect to what is stated in the request, the quotation may be subject to review by UL NB. Apart from this exception, the terms proposed and accepted together with the quotation are generally no longer modifiable. This phase includes the planning of activities (possible assessment of the applicability of the quality plan) and billing conditions. The contract signed with UL NB generally has a predefined duration, which includes the verification activities for certification and, if planned, a defined number of inspections or surveillance audits.

5.5 Selection and assignment of the evaluation team

UL NB selects and appoints the evaluation team. The appointment process takes into account the competence necessary to achieve the evaluation objectives and the requirements for impartiality.
For product/production conformity assessment procedures, the selection includes an evaluator, or combination of evaluators, whose competence to perform the product assessment, as applicable for that assessment, has been confirmed by UL NB.
For management systems conformity assessment procedures, the selection includes a Lead Auditor and a Technical Expert, if required. The two roles may coincide if the Lead Auditor also has the technical expertise required for the assessment.
For all listed conformity assessment procedures, the selection includes a Reviewer and a Decision Maker. The two roles may be held by the same person.
In deciding on the size and composition of the assessment team, UL NB considers the following:

- the evaluation objectives, scope, criteria, and estimated evaluation time;
- for management system conformity assessment procedures, whether the audit is combined, joint, or integrated;
- the overall competence of the assessment team needed to achieve the assessment objectives;
- certification requirements (including any applicable statutory, regulatory or contractual requirements);
- language and culture.

UL NB shall inform the client of the composition of the evaluation team, with adequate notice to allow the client to raise objections about the composition of the evaluation team.
Objections must be submitted within a specific period of 1 week after receipt of the notice and in any case well in advance of the planned date of execution of the activity, in writing, including by simple communication (e-mail), addressing it to the evaluator and/or the audit manager and/or UL NB management (MIL.ULInternationalItaliaNB@ul.com).
Exceptions are those activities whose planning takes place in reduced time terms with respect to execution, due to agreements between the client and UL NB; in such a situation the applicant accepts, even tacitly, the composition of the evaluation team.
UL NB handles only relevant and substantiated objections made in writing.
Evaluators and/or Lead Auditor shall ensure that the objection has been forwarded to UL NB management, which determines whether the objection is relevant and substantiated. UL NB may

follow up on the objection by reformulating the composition of the evaluation team or reject it giving reasons in writing.
If there is no consensus with UL NB's judgment, the applicant may file a complaint and/or appeal in the manner described in §20.

6.0 PLANNING AND CARRYING OUT CONFORMITY ASSESSMENT ACTIVITIES

Depending on the type of conformity assessment required, and consequently the applicable standards, the following different types of verifications and inspections can be configured:

- laboratory or field tests;
- inspections of production lines and plants;
- audits concerning management systems;
- review and evaluation of technical documentation.

In accordance with the requirements of the applicable regulations, the above activities, all encapsulated in the term "verification," can be carried out alternatively or be complementary to achieve the specific objective of conformity assessment.
The activities may be carried out either by employees or by qualified external contractors in accordance with the requirements of the reference documents and UL NB procedures.
Should the need arise to subcontract part or all of the contracted activity, UL NB will implement all necessary measures to ensure that the subcontractor complies with the requirements of the reference documents and the management system documentation, and will inform the client, who shall give explicit consent.
However, responsibility for any subcontracted activities remains with UL NB.
Verification activities are planned taking into account, where possible, any specific needs of the client.
In some cases conformity assessment activities include a production audit: the client ensures that the production schedule on the days of the audit is as representative as possible of the products included in the scope of assessment. Where productions have a periodicity, activities may also be conducted on several non-consecutive days, and will be weighted closed only at the end of the verification of all products/product groups included in the scope of the certificate.
The leader of the verification and inspection team prepares an activity plan that is forwarded to the client. In accordance with the rules regulating the activities of Conformity Assessment Bodies, the client is bound to accept the possible presence of observers from UL NB and/or the ACCREDIA Accreditation Body: the non-acceptance of the performance of monitoring/observation activities by UL NB or the above-mentioned Bodies results in the non-granting of the certificate, or its suspension or withdrawal. Verification activities are generally preceded by a document analysis. In some circumstances, the client may request that the document review take place at its premises. Both at the planning stage and during operational activities, the client is required to provide UL NB with all necessary support. In particular, it is required to make available all items and all documentation (such as, for example, the technical file of the product it intends to certify as described in the Reference Directive, procedures, instructions, manuals, programs, etc.), necessary for the proper conduct of the audits; allow the inspection team to have access to the areas where the activities involved in the conformity assessment take place; and to interview the people involved; to provide the availability of personnel involved in the processes and production of the products under assessment; to provide, in accordance with the legislative requirements on occupational health, safety and hygiene, detailed information on the specific risks existing in the environment in which the assessment team will be working, and on the prevention and emergency management measures adopted; to provide any personal protective equipment, or to inform UL NB of the type of personal protective equipment with which the inspection team is to be equipped.

In cases where the contracted activities include laboratory testing, carried out directly by the client, and where the client subcontracts part or all of the planned compliance testing to an external laboratory, they shall provide evidence that:

- the chosen laboratory holds accreditation according to ISO/IEC 17025 to perform the tests included in the contracted activities, or
- the chosen laboratory is among the laboratories already qualified by UL NB to perform the tests covered by the contracted activities (the list of UL NB qualified laboratories is available upon request).

In the event that neither of the above conditions is met, UL NB shall also schedule a visit to the laboratory chosen by the customer (the verification will be paid for by the customer and will be billed on an hourly basis) to verify that the tests comply with the requirements of the applicable standards. More details regarding any specifics regarding the mode of operation, documentation to be provided and personnel required for the proper conduct of the verification activities are provided by UL NB when planning and communicating the activities to the client. A brief description of the individual verification activities listed above is provided below.

6.1 Testing and field activities

Where required by the Directive/Regulations, the client is required to provide one, or more, representative samples of the production that will be subjected to the tests, analysis and verifications required by the applicable regulations. Such samples shall be accompanied by all accessories, options and documents normally supplied to the end user. The products shall be delivered in their original packaging and accompanied by the set of documents required by the applicable regulations. More details with respect to the above aspects will be provided to the client at the time of quotation, or at the time of planning, in accordance with the specific requirements of the individual certification schemes. The samples supplied, properly prepared, processed and conditioned, will then be subjected to the tests, analyses and verifications required by the applicable regulations. Such tests and verifications may sometimes be destructive; in such cases the customer will be notified in advance of this possibility. Under no circumstances shall UL NB be held liable for damage to the samples subjected to the tests and verifications, except in cases, properly documented, of malicious intent on the part of the personnel involved. During all phases of the tests and verifications, the customer, or his representative, is authorized, upon express request, to actively participate in the conduct of the tests and verifications, supporting the technical personnel in the various phases of the activities. If non-conformities are found, the client will be promptly notified and, following analysis of the non-conformity and the client's proposed solution, an evaluation of the possible impacts on the modified product will be carried out in consultation with the client. Based on the results of the above evaluation, a repetition of the test(s) that generated the nonconformity or the repetition of any other tests that, in the sole judgment of UL NB, could be affected by the modification introduced to remedy the nonconformity or the suspension or permanent termination of certification activities will be carried out. A test report meeting the requirements of the applicable standards and ISO/IEC 17025 will be issued following the testing activities, if requested by the customer.

6.2 Inspections of production lines and plants

The inspections of production lines and plants will be carried out as indicated in paragraph 6.3 with the difference that only manufacturing activities related to the product subject to conformity assessment will be considered. Any other company activities, or company functions, involved in the production process will also be interviewed and assessed solely with regard to the certificate applied for. Particular emphasis will be placed on end-of-line testing and on the acquisition and

management phases of components and sub-assemblies necessary for the realization of the finished product (procurement, incoming inspection, final testing).

6.3 Management system audit

In the case of conformity assessment product activities that include quality modules (e.g.: PED, GAR and BED) the certification audit takes place in two phases, Stage 1 and Stage 2, under the supervision of UL NB personnel qualified as Lead Auditor. The purpose and methods of execution of each phase of the audit are detailed in the audit plan which is sent to the organization well in advance of the date of execution of the activities. Each audit includes the opening meeting, in which the objectives and methods of carrying out the activity are defined, the applicable evaluation criteria, the confidentiality obligation to which the UL NB staff is subject and the closing meeting, in which communicates the outcome of the verification and the clarifications of the results, detailed in the report and in the list of findings, including the methods and times for resolving them. The audit report is delivered to the organization during the closing meeting unless otherwise required by UL NB procedures or previously agreed with the client.
During the activities, the audit team collects objective evidence by examining documents, directly observing the activities, holding interviews with managers and operating personnel. To this end, evaluators use the appropriate checklists prepared by UL NB, which are to be considered a guide and not a binding document. The team can therefore also carry out investigations not expressly provided for in the check-lists. Any external consultants of the client can participate in the audits at the request of the latter, provided that they do not replace the company managers in carrying out their role. In particular, the applicability of a Quality Plan is assessed before carrying out the audit. This can be a document developed for the specific purpose, or be represented by a procedure or by a set of management and operational documents, which as a whole cover the requirements; moreover, the organization's Quality Management System manual, if already present and specified in relation to the requirements of the legislative and regulatory references, may be acceptable for the purpose. If the evaluation team detects the non-conformity with one or more requirements, it formulates a finding (see 6.5 in this regard). The finding is immediately notified to the client and treated as described in point 6.5. The checks end with a final meeting, in which the audit team presents the summary of the results of the checks to the customer.

6.3.1 Stage 1 audit

The Stage 1 Audit includes the verification of the descriptive documentation of the system and, if necessary, the visit to the site(s) of the organization. The purposes of this audit are:

- evaluate the suitability of the management system documentation in consideration of the requirements of the standard(s) adopted;
- assess the location of the organization and the specific conditions of the site(s);
- identify the applicable mandatory provisions and assess their compliance;
- initiate in-depth study, analysis and dialogue with the organization's personnel, in order to determine the degree of application of the system;
- evaluate whether the internal audits and the management review have been effectively planned and carried out;
- gather the information necessary to formulate the scope of the management system (processes and activities) and the site(s) subject to assessment;
- review the necessary resources and agree with the organization the details to perform the Stage 2 Audit;
- provide clarifications on the details of the conformity assessment process. The findings resulting from the Stage 1 audit can be classified according to severity, as reported in point 6.5.

6.3.2 Stage 2 audit

The Stage 2 Audit must be performed within 6 months of the Stage 1 audit. If this is not possible, UL NB will evaluate the need to repeat all or part of the Stage 1 Audit, possibly on a documentary basis.
The Stage 2 Audit is always carried out at the organization's site(s) and has the purpose of ascertaining the consistency of the defined policy with the related objectives in order to evaluate the effectiveness of the system both in accordance with the (to the) reference standards and to the documentation prepared. During the Stage 2 Audit the following is verified:

- the resolution of the findings that emerged during the Stage 1 Audit;
- information and evidence regarding compliance with all requirements of the standard(s) or other regulatory document applicable to the management system;
- monitoring, measuring, reporting and reviewing performance, with reference to the defined objectives and targets;
- the management system and its performance, with reference to compliance with legal requirements;
- the procedures for managing and keeping processes under control;
- internal audits and management reviews where required by the reference standard.

The findings, both documentary and operational, resulting from the Stage 2 Audit, can be classified according to severity, as reported in point 6.5, i.e. as non-conformities or comments. At the end of the Stage 2 Audit, the relative report is delivered, possibly supplemented by the list of findings.

6.3.3 Surveillance Audit

Surveillance audits are intended to ascertain that the organization maintains an effective management system in compliance with the requirements of the reference standard(s) and the specific provisions established by the accreditation bodies. The surveillance audit is mandatory and is based on a sampling of the activities subject to certification, guaranteeing complete verification of the management system throughout the certification cycle. During the surveillance audit, the effective implementation of the observations arising from the previous audit is verified. UL NB carries out periodic surveillance audits on an annual basis in accordance with the contractually agreed reference program and communicated to the organization and reserves the right to examine requests with different frequency from the one indicated above. The reference date for planning the surveillance audits is that of the certification decision (generally coinciding with the one shown on the issued certificate), therefore the first surveillance audit must be performed within 12 months of the reference date, while the second within 24 months in accordance with the reference scheme, unless otherwise contractually agreed. As a rule, no exceptions to the dates of execution of the surveillance are applied if not limited to serious situations communicated in writing by the organization and evaluated and authorized by UL NB. In any case, the derogations granted cannot exceed 3 months from the date envisaged for the execution of the surveillance. The carrying out of the surveillance audits foreseen in the certification cycle is subject to the regular payment of the previous activities by the organization. Otherwise UL NB reserves the right not to carry out the envisaged activities and proceed with the suspension of the certificate. If the organization does not intend to carry out the surveillance audit, it must promptly notify UL NB in writing, which will proceed with the suspension of the certificate. At the end of the surveillance audit, the relative report is delivered, possibly supplemented by the list of findings.

6.3.4 Renewal Audit

The purpose of the renewal audit is to ascertain that the organization maintains an effective management system in accordance with the requirements of the reference standard(s) and specific provisions established by the accreditation bodies. The renewal audit shall be concluded, with a positive outcome (possible post-audit or approval of the proposed Corrective Actions, if any, received by the Organization), within the expiration of the validity of certificate, with reference to the date of issuance of the certificate and the terms of validity indicated in Annex 1, in order to maintain its validity and historicity. The audit is based on the complete verification of the system, including the descriptive documentation prepared, at the organization, and the effective implementation of the findings and comments from the previous audit is verified. At the time of renewal, the performance over the three-year period of the management system is reviewed. As a rule, no derogation is applied to the renewal performance date unless limited to serious situations communicated in writing by the organization and evaluated and authorized by UL NB. However, such derogations may not exceed 2 months from the expiration date. In the event of a derogation and for the entire period of the derogation, product manufactured after the certification expiration date may not be marketed until the renewal is resolved. If the Organization does not intend to carry out the renewal, it shall give prompt written notice to UL NB.
Renewal made after the expiration date will be considered as a new certification, so the contract conditions will have to be revised accordingly. The performance of the renewal audit is subject to the organization's regular payment of previous activities, otherwise UL NB reserves the right not to perform the activities scheduled for the renewal audit. At the end of the renewal audit, the relevant report, supplemented by the list of findings if necessary, is delivered.

6.3.5 Supplementary Audits

UL NB reserves the right, giving written reasons for the decision to the organization, to carry out additional audits not included in the certification cycle. These audits may be of the following types:

- audits to lift the suspension of the certificate;
- audits to extend or change the scope;
- audits at short notice, if necessary, justifying the reasons during the audit, in cases where it is necessary to carry out an in-depth management of complaints received from clients of the certified organization, verification of changes made by the organization to its management system, verification of the management system following the receipt of information on serious incidents, emergencies, accidents or malfunctions.

At the end of the supplementary audit, the corresponding report is delivered, supplemented if necessary by the list of findings.

6.4 Examination and evaluation of the technical documentation

This verification method requires the client to present the Technical File containing all the technical documentation required by the applicable legislation to UL NB and request its evaluation. In some cases, where required by applicable legislation, the client has the right to specify the aspects of the essential requirements that shall be assessed. This verification method is normally accompanied by other verification methods, for example the verification of the management system or the verification through laboratory tests or the verification of the production site. Such circumstances, if foreseen, are always indicated in the quotation. UL NB examines the technical documentation and evaluates whether the technical documentation adequately demonstrates that the requirements of the applicable legislation, subjected to its

evaluation, are met. If the conformity of the product is confirmed, UL NB prepares a declaration certifying the conformity of the same and transmits it to the customer. In the above-mentioned case of partial evaluation of the documentation, as indicated in the applicable legislation, this declaration will be limited to the aspects of the essential requirements that have been submitted for evaluation. The customer is required to integrate the UL NB declaration into the Technical File of the appliance being tested. If, on the other hand, the evaluation gives a negative result, UL NB draws up a letter containing the finding (see 6.5 in this regard) or a negative evaluation report and forwards it to the customer who, at its sole discretion, can decide whether to integrate or modify the documentation provided, or whether to terminate the conformity assessment process. When the client sends the supplementary documentation, or the modified documentation, UL NB proceed with a new evaluation of the documentation. This new evaluation can be partial or total in relation to the extent of the finding. Once the solution to the finding has been found, UL NB proceeds with the issue of the declaration of conformity previously described.

6.5 Classification of findings

For the provisions contained in these Regulations, the general term "finding" means the findings obtained by UL NB during the checks carried out on the product and formalized in the relative check reports.
For the purposes of this Regulation, the findings are divided into:

- Major Non-conformity: there is a major non-conformity if even one of the following situations occurs relating to non-compliance with the requirements:
    - the documentation envisaged by the Standard for which the Organization has requested certification and/or by the certification regulations and/or by the regulations envisaged by ACCREDIA;
    - documentation not expressly required by the standard, but assessed during the audit, can affect the compliance of the management system;
    - the implementation of the management system with respect to the Standard for which the Organization has requested certification and/or the certification regulations and/or the regulations envisaged by ACCREDIA (including the mandatory and specific requirements for the certification program) ;
    - missing or insufficient consideration of the requirement itself and/or missing or insufficient definition of the criteria and methods adopted to satisfy the requirement itself;
    - failure or insufficient practical implementation of the aforementioned criteria and methods, initially (implementation of the requirement) and over time (maintenance of the requirement).

  Failure to resolve the non-conformity for the examination and evaluation of the technical documentation or the persistence of the non-conformity at the time of the Stage 2 Audit will prevent the issue of the certificate.
- Minor non-conformities (or observations): there is a minor non-conformity when the non-satisfaction of the requirement - while being indicative of inadequate behavior on the part of the client and, as such, in need of correction - is not such as to immediately compromise the value of the certifications issued in the terms indicated above;
- Comments: the finding raised is classified as a comment when it is not consequent to the detection of an objective situation of non-fulfilment of a requirement, but is aimed at preventing this situation from occurring (since it is potentially achievable) and/or at providing indications for the improvement of customer performance. Comments will also be discussed during subsequent audits/verifications.

For the purposes of the provisions contained in this Regulation, a finding is classified as a major non-conformity:

- when failure to meet the corresponding requirement is such as to compromise the safety, fundamental performance, technical characteristics or functionality of the product;
- the modification of a previously certified product, even when the modification does not affect any of the characteristics mentioned above
- non-compliance with current legislative requirements.

The presence of non-conformities necessarily entails their treatment by the organization with a precise process clearly planned in the implementation methods and times. The organization shall communicate the methods of handling Non-Conformities, whether major or minor, within 1 month of performing the audit. It will therefore become mandatory to carry out subsequent verifications, of a documentary or field type depending on the contents of the non-conformity(s) issued, to verify the effectiveness of the corrective actions within the agreed times (in any case within a maximum time of 4 months) and in the event of a positive outcome of the verification, the certification process continues with the subsequent phases for issuing the certificate. The possible persistence of these non-conformities, as well as the failure to communicate the treatment of the non-conformity or its late communication, will prevent the issuance of the certificate in case of first certification or renewal (it will therefore be necessary to reactivate the procedure with a new request for conformity assessment) or suspension in the event of periodic surveillance audits, extraordinary or unannounced checks. In this case the organization shall define and implement the necessary corrective actions within a defined period (maximum 6 months) and a reactivation audit shall be performed by UL NB. In the event of a negative result of the reactivation audit or in the event that it was not possible to carry out this audit, the certificate will be definitively withdrawn.

For audits concerning management systems, in the case of only minor non-conformities, the audit has a positive outcome and the certification process continues with the subsequent phases for issuing the certificate, but the organization shall define adequate corrective actions in this regard which will be verified by UL NB in the next audit. Such corrective actions shall be communicated to UL NB within 1 month of the audit being performed. In the case of comments, the audit has a positive outcome and the certification process continues with the subsequent phases for issuing the certificate, but the organization shall declare whether or not it intends to accept the comments issued. In case the organization declares to manage such comments, the implementation of the latter will be verified by UL NB in the next audit. This statement shall be sent to UL NB within 1 month of performing the audit.

7.0 CERTIFICATE ISSUE

The process described in this paragraph is applied during all checks carried out by UL NB for the purposes of conformity assessment product, whether they are preparatory to certification, surveillance or renewal. The task of the Decision Maker (or of the Decision Maker Committee) is to express an opinion on the possibility of issuing, suspending or canceling the certificate subject to verification by examining the verification report and the other documents and data constituting the conformity assessment file. During the examination of the conformity assessment file, the Decision Maker may deem it necessary to request clarifications from the verification team or even a supplementary investigation through a new activity. Any different assessment by the Decision Maker compared to the team that performed the verification activities is promptly communicated to the customer and, where applicable, to the Member States and other notified bodies. The Decision Maker, although in possession of all the technical characteristics envisaged by the certification program, cannot in any way have taken part in the verification activities. When the Decision Maker issues a favorable opinion, UL NB issues a certificate of conformity, which is forwarded to the client. The certificate has a validity established from time to time by the reference standards for the certification program under which it operates and as indicated in Annex 1 of this regulation. The issuance of the certificate automatically entails the permission for the client to use the certificate itself, any numerical identification code of the Notified Body UL NB,

according to the procedures established by the reference standards and by this regulation. The document attesting the certification is a certificate bearing an identification number with the corresponding revision if the certificate has been reissued; the customer's company name with the reference contact details for the certification (registered office, production sites), the applicable reference standard, the field of application with reference to any exclusions, the category of the product subject to certification, the date of issue which generally coincides with the date of the decision, the date of first issue of the certification, the expiry date (where applicable), the logo of the Accreditation Body, the signature of the legal representative of UL NB or in person by them delegated and legally authorized to sign. The validity of the certification is subject to compliance with the technical and economic conditions described in this regulation. In the event that the Decision Maker does not decide in favor of issuing the certification, a new request for certification cannot be presented before a period of six months has elapsed.

8.0 CHECKS WITHOUT NOTICE

The purpose of unannounced checks is to ascertain that the client, the holder of the certificate, maintains an effective system to ensure the conformity of certified products with the requirements of the applicable regulations. The audits begin with a review of the client's documentation; in particular, those documents that, with respect to the previous audit, are newly issued or have been updated or revised are verified. Particular attention is paid to verifying the Corrective Actions (and their effectiveness) in relation to the previously identified findings, duly reported to the customer. In the event of a negative assessment of the effectiveness of a Corrective Action taken against a major or minor Non-Conformity detected during a previous inspection, as well as in the event of a repetition of a minor Non-Conformity against the same requirement, the inspection team assesses whether to "escalate" the finding to a major Non-Conformity. A further field of verification concerns the correct use of the UL NB certificate, as well as the correct handling of any complaints and reports from customers and interested parties. The results of the unannounced checks are submitted to the Decision Maker who examines them in order to confirm, or not, the validity of the certification. Once the result of the decision is obtained, UL NB informs the customer of the decision taken and implements the decided provisions: confirmation, suspension or withdrawal of the certificate. The customer is promptly informed about the decisions taken.

9.0 REGISTER OF CERTIFIED CUSTOMERS

UL NB updates its list of certified clients with each new issue or renewal of the certificate, and, where required by the applicable regulations for each certification scheme, informs the relevant authorities in accordance with the established timeframe.
The minimum information in the register is:

- Copy of the certificate
- Certificate number
- Type of module, in accordance with the Directive/Regulation
- Certification validity status
- Client company name
- Type of product
- Date of issue
- Date of revision
- Expiry date

Information on issued, suspended or withdrawn certificates is communicated to the competent Ministry through publication on a UL NB platform accessible to the Ministry officers. In addition, information on withdrawal or denied certificates is communicated to other NBs and ACCREDIA.

10.0 CHANGES AFFECTING CERTIFICATION

UL NB undertakes to provide its customers and interested parties with all the necessary information relating to the changes made to the certification requirements deriving from regulatory and/or legislative updates. Following the publication of the revised requirements, UL NB will verify that each customer implements all necessary adaptations within a pre-defined reasonable time frame.

11.0 METHOD OF REFERENCE TO THE CERTIFICATION AND USE OF MARK

The use of the UL mark and the ACCREDIA mark is not permitted in any case and for any certification obtained in accordance with these Regulations.
Once the certification has been obtained, the customer must implement a documented procedure relating to the management of the methods of reference to the certification itself (and in particular to the use of the certificate and the reference to UL NB) in all forms of communication. The procedure shall indicate the function or functions of the customer who are responsible for this management, and in particular how to use the certificate and the reference, so as to ensure compliance with the following requirements. As regards the certificates relating to the CE marking of products in compliance with the requirements of the EU directives, if required by the directives themselves, the customer must compulsorily indicate on each product manufactured (or on its packaging and on the accompanying documents if the nature of the product does not permits it), in a legible, indelible and clearly identifiable manner, the identification number of UL NB which issued the certification alongside the CE symbol as follows:

CE2052

Specific indications for affixing the CE marking can be found in the EU directives and on the European Commission website.
Once the certification has been obtained, and for the entire period of its validity, the customer can refer to it in his own technical and advertising publications in the manner defined by the different regulations. This on the sole condition that each reference is made correctly and in such a way as not to lead to erroneous interpretations; in particular, it must be clear that the certificate only concerns the certified product; it therefore means that particular piece of equipment, component or system expressly indicated on the certificate itself and not others, nor the organization's management system (for example the quality system or other type of system). The correct use of the certificate and in general the correctness of the references to the certification are elements that are analyzed during the surveillance and renewal audits. The conformity assessment team could detect non-conformity in this area, and incorrect use of the certificate could lead to its suspension. In the event of suspension or withdrawal of the certificate, the customer must cease using it and any other method of reference to the certification. If this does not happen, UL NB reserves the right to take legal action. Partial copies of the certificate are not allowed; enlargements or reductions of the same are allowed, provided that the structure is not distorted, and the certificate is in any case uniform and legible.

12.0 WAIVER OF CERTIFICATION

The waiver of certification (waiver) is the provision whereby, UL NB:

- at the direct request of the client, it cancels the conformity assessment process in progress; or
- at the direct request of the certificate holder or his/her delegate, it cancels the certificate already issued.

At any time, the client or the certification holder can submit a request for waiver of certification to UL NB.
The waiver involves the cancellation of the conformity assessment process and/or the end of the validity scope of the certification.
In the event of Withdrawal, the client shall submit a formal request to UL NB, giving reasons.
UL NB, following receipt of the waiver request, it will analyze the reasons and evaluate the effects of the waiver request in relation to the technical/regulatory aspects, including by investigating the documentation issued.
The outcomes of the decision are formally communicated in writing by UL NB to the client/certificate holder.
The certificate holder who does not intend to continue with the maintenance of the certification activities (surveillance of production or of the management system) shall give formal cancellation of the contract, at least 6 months before the date (month/day) of expiry of the certificate.
In the event of an ongoing waiver, UL NB reserves the right to evaluate the reasons for the waiver.
Where the reasons are attributable to deficiencies that emerged during the assessment, UL NB will inform the client that:

- for the same product, it is not possible to submit a certification request to another Notified Body;
- where required by applicable laws and regulations, UL NB will inform the interested parties of the waiver presented by the client.

In the case of certification that has already been issued, the certificate holder who submits communication of waiver of the certification shall:

- arrange to return the original Certificate to UL NB, unless otherwise communicated by UL NB;
- refrain from advertising the Certification;
- refrain from using the certificate for any purpose and action, starting from the date of waiver;
- stop using the UL NB identification number;
- remove any reference to the certification from the products, from the material relating to the products (e.g. packaging) or from the documentation.

The certificate holder of the certificate has the possibility of placing on the market the products whose manufacture took place within the waiver date. In such cases, UL NB reserves the right to carry out an inspection at the customer's warehouse to verify the actual stock of the products in the warehouse on the date of waiver. The Organization that intends to access the certification again shall submit a new application by repeating the entire process.

13.0 SUSPENSION OF CERTIFICATION

Suspension of certification (suspension) is the provision by which UL NB suspends the validity of the Holder's certification.
Through the suspension, UL NB suspends the validity of the certificates for the purpose of which the certificate holder, directly or indirectly, is unable to provide sufficient evidence of continued satisfaction of the regulatory and mandatory requirements.
The validity of the certification can be suspended at the request of the certificate holder for a maximum period of six (6) months, indicating the reasons, methods and timing envisaged through formal written communication.
UL NB, at its unquestionable judgement, suspends the validity of a certificate in all cases envisaged by current legislation, also following reports from the authorities or if it deems it appropriate for reasons arising related to the fulfillment of the essential safety and/or if you notice:

- the persistence of unresolved or resolved issues other than as indicated in the communications sent to UL NB;
- following the verification of serious reports from the market;

- improper use of the certificate or in any case in a way that does not comply with the provisions of the applicable rules and regulations;
- non-conformity with contractual obligations with particular reference to compliance with payment terms and economic conditions, signed with UL NB and with its contracting parties;
- where applicable, in cases where the management system does not ensure compliance with all applicable requirements and seriously and persistently demonstrates that there is no confidence in the effectiveness of its application, for example in cases where:
    - Non-conformities found during the audits, not adequately and promptly managed;
    - High number of Non-conformities emerged during a surveillance audit, such as to raise doubts about the conformity and effectiveness of the certified management system;
    - Failure to comply with the mandatory product/service requirements;
    - Failure to adopt and apply the treatments and/or corrective actions within the foreseen times;
    - Failure by the applicant/licensee to adapt its management system, within the established terms, to the changes to the Standard and/or Certification specifications;
    - Failure to handle complaints and/or reports connected with deficiencies in the management system;
    - Adoption of unsatisfactory treatments and corrective actions relating to improper use of the certification, logo and certificate;
    - Incorrect behavior and/or detrimental to the image of UL NB;
    - Involvement in legal proceedings such as to compromise the compliance and effectiveness of the management system;
    - failure to carry out the audit at one or more locations where the processes covered by the certification are carried out, for reasons beyond the control of UL NB (for example due to the prohibition of access to the areas, by the customer or its outsourcer), or failure to comply with the periodicity established for the surveillance audit, or refusal to support a supplementary audit;
- Where applicable, refuse the participation of observers from the Italian Accreditation Body ACCREDIA in the assessment activities of UL NB.

The suspension effectively interrupts the validity of the certificate.
Following the suspension, the certificate holder shall:

- refrain from advertising the certification until the end of the suspension period;
- refrain from using the certificate for any purpose and action, starting from the date of suspension;
- stop using the UL NB identification number.

The costs incurred by UL NB to carry out any checks or activities caused by Suspension measures are charged to the customer.
The suspension can be partial or total (e.g. when it concerns some or all of the offices/branches/plants of a certificate holder) or it can be in full or in part (e.g. when it concerns all or only a part of the certification object) .
The suspension provision ceases when the certificate holder removes the causes that generated it. Any resolution plan proposed by the client and communicated to UL NB within 30 days of the suspension communication must be completed within 6 months of the suspension date. The suspension period generally cannot exceed 6 months, unless there are causes of force majeure or extraordinary events.
If the client does not resolve the problems that led to the adoption of the suspension provision within the time established by UL NB, UL NB sanctions with the withdrawal or reduction of the

scope of certification, following up on the communications envisaged and informing the authorities opportune.

14.0 WITHDRAWAL OF CERTIFICATION

Withdrawal of certification (withdrawal) is the provision by which UL NB withdraws a certificate, effectively nullifying its validity.
UL NB provides for the withdrawal in cases where the certificate holder is not able to provide sufficient evidence of continued satisfaction of the regulatory and mandatory requirements and in all cases envisaged by current legislation also following reports from the authorities or if it deems it appropriate for reasons arising related to failure to meet the essential safety requirements.
Furthermore, UL NB provides for the withdrawal in cases where the time limits for the suspension have expired.
Following the withdrawaln, the certificate holder shall:

- arrange to return the original certificate to UL NB, unless otherwise communicated by UL NB;
- refrain from advertising the certification;
- refrain from using the certificate for any purpose and action, starting from the date of withdrawal;
- stop using the UL NB identification number;
- remove any reference to the certification from the products, from the material relating to the products (e.g. packaging) or from the documentation.

All withdrawal communications addressed to the certificate holder are sent in writing by UL NB.
Revocations are made public by UL NB in the manner required by applicable laws and regulations, and are always communicated (where applicable):

- to the competent authorities;
- to ACCREDIA in the times and ways established by it;
- any other entitled Entities and applicants in the times and ways established by them.

The certificate holder has 5 days from the date the withdrawal communication is sent, to notify UL NB that he has taken charge of the withdrawal, or to file an appeal.
Following the withdrawal process, the certificate holder is prohibited from placing the products subject to certification on the market regardless of their storage or warehousing location.
In cases where the withdrawal is consequent to the non-fulfilment of the essential safety requirements of the product subject to certification, the certificate holder may be subject to a recall by the competent authority of the product already placed on the market.

15.0 MANAGEMENT OF COMPLAINTS AND REPORTS BY CUSTOMERS AND INTERESTED PARTIES

UL NB's clients shall establish and implement a documented procedure for handling complaints and reports which ensures:

- the recording of complaints and reports received by its customers and interested parties related to the activities, implementation and delivery of the products to which the certification applies and affecting compliance with the certification requirements;
- carrying out appropriate investigations of such complaints and reports and recording them;
- taking, where necessary, of corrective actions and their recording.

The procedure and record shall be made available to the UL NB team during the various audits. In addition, these documents shall also be available for inspection by ACCREDIA representatives, if requested.

16.0 MODIFICATION TO THE CERTIFIED PRODUCTS

The client who intends to make changes to the certified product such that they may affect the conformity, safety and legality of the certified productions, including the modification of the production lines, processes and sites or the modification of the company management system, shall inform UL NB in writing. Before implementing the changes, the client shall await formal approval from UL NB.
For the purposes of certification, a product that is different from the certified product is considered a new product and, therefore, requires a new verification before it can be declared compliant.
UL NB evaluates the real need to carry out, on the basis of these changes, additional checks, possibly accompanied by a revision of the certificate, or to start a new certification process also taking into consideration the type of existing certificate.
Failure to comply with this provision may result in the suspension of the certification.
The client is also required to promptly inform UL NB in the event of exceptional events, legal proceedings, accidents, emergencies, legislative non-conformity. The information shall be related to the event that occurred and completed by a report describing the management of the event and what repercussions it had on the management system. UL NB examines the information and the report in order to evaluate its completeness and, therefore, decide what action to take:

- Confirmation of certification;
- Need to carry out an additional audit/verification;
- Suspension or withdrawal of certification.

17.0 CERTIFICATE VALIDITY

The certificates issued are valid for a period established by the reference standard, if reported, or established by UL NB, as indicated in Annex 1. The expiry date of the certificate is indicated on the certificate itself. Once they have reached their natural expiry, the client has the right to choose whether to keep the certification active or terminate it. Based on the decision made by the client, the following conditions can be configured:

- Waiver of certification: the client who does not intend to continue with the maintenance of the certification activities shall give formal cancellation of the contract, for certificates with expiry, at least 6 months before the date (month/day) of expiry of the certificate. Furthermore, it has the duty to remove any reference to the certification from the products, from the material relating to the products (e.g. packaging) or from the documentation. The client has the possibility of placing on the market the products whose manufacture took place within the expiry date of the validity of the certificate within a period of 6 months from the expiry date itself. The products not present in the warehouse on the date of expiry of the validity of the certificate will no longer be able to bear the reference to the certification and will no longer be able to be placed on the market. In such cases, UL NB reserves the right to carry out an inspection at the client's warehouse to verify the actual stock of the products in the warehouse on the expiry date of the certificate's validity. The Organization that after waiver intends to access the certification again shall submit a new application by repeating the entire procedure.
- Renewal of the certification: to renew the validity of the certificate, if granted by the reference legislation in accordance with what is reported in Annex 1, it is necessary to carry out a new verification activity. The consistency of this activity depends on the type of certification issued. For the renewal of certifications based on the application of a controlled management system, see § 6.3.4. For the renewal of certifications based on type verifications and/or laboratory tests it will be necessary to carry out a new evaluation of the product, including a new analysis of the Technical File. UL NB reserves the right to evaluate the extent of the verification to be carried out on a case-by-case basis, also

on the basis of the complexity of the product, the manufacturing process or the potential danger of the product itself.

18.0 REQUIREMENTS FOR CUSTOMERS ALREADY CERTIFIED BY ANOTHER BODY

There are no special constraints for the conformity assessment of products other than those already certified by another body. No special conditions apply for upgrading to UL NB except as stipulated in the applicable regulations.
An organization holding product certification issued by another Notified Body may apply for conformity assessment, for the same product, to UL NB provided that certification with the previous body lapses. The customer shall therefore provide UL NB with evidence of the cancellation sent to the previous Notified Body or a copy of the certificate showing that it has lapsed.

19.0 CONFIDENTIALITY OF INFORMATION

UL NB ensures that all information acquired during conformity assessment-related activities or in the course of surveillance audits is handled confidentially, unless otherwise required by:

- legal provisions
- provisions of accreditation and/or notification bodies;
- owners of the certification program.

In such exceptional cases, the client is informed of what information is disclosed to third parties. To this end, UL NB personnel involved in conformity assessment activities sign a formal undertaking of confidentiality.

20.0 COMPLAINTS, APPEALS AND DISPUTES

20.1 Complaints

For the purposes of these Regulations, the term complaint refers to a formal protest that is made in writing when it is believed that one has been the victim of an injustice or damage. Any client and any interested party can make complaints against UL NB and its operations. A complaint can be presented by organizations/clients (or from other sources) and can concern the operating methods adopted by UL NB personnel during the various phases of the certification activities and can also concern the certification of another organization than the reporting one.
UL NB duly takes this into account under the following conditions:

- complaints shall be submitted in writing (any support is accepted) and shall describe in detail the situation object of the complaint;
- the name and contact details of the complainant shall be reported;
- the reasons for the complaint shall be stated.

In the event that such information is not contained in the complaint, the complainant is contacted for the necessary clarifications. Complaints are managed through a special register, and an initial reply will be sent for each of them within two working days of notification of receipt. Complaints are examined by the UL NB Management and by the Technical Manager of the Division involved in the activity who, with the possible support of other colleagues (e.g. Quality Manager), carries out appropriate investigations and insights, interviewing, if necessary, also the technical and operational staff involved. In any case, the complaint will be evaluated by personnel who have not participated in the activity that is the subject of the complaint. If the situation makes it necessary, UL NB reserves the right to perform an additional verification in order to substantiate the subject of the complaint. At the end of the complaint management process, UL NB sends a written communication to the complainant, in which it reports the outcome of the investigation

and any measures taken. The information relating to the complaint and its resolution cannot be made public without the consent of the parties involved.
Complaints can be sent to any member of UL NB staff or through the Customer Experience Center (CEC@ul.com) as described at www.ul.com at the Customer Confidentiality and Complaint Process FAQ page or to UL NB email address (MIL.ULInternationalItaliaNB@ul.com).

20.2 Appeals

The term appeal defines a request forwarded to ask for the cancellation or modification of a provision that is considered harmful to one's rights or interests in relation to the decisions taken by UL NB during the certification activities. The client who makes use of UL NB's certification services has the right to submit written appeals with reference to the decisions and measures adopted by UL NB following a certification activity, so that these decisions are reviewed. When submitting an appeal, the appellant shall specify the references of his organization, the object of the appeal itself, the underlying reasons, any attachments in support of the above reasons and the signature of the legal representative of the organization. It should be noted that the lack of one or more of the elements mentioned constitutes grounds for rejection of the appeal. In such situations, UL NB will forward to the appellant a communication containing the reasons for the position taken. If, on the other hand, the appeal is acceptable, the UL NB Management, together with the Technical Manager of the Division involved in the certification activities, will start a phase of review of the appeal, and of the causes that led to the appeal itself, involving the interested parties. The appeal will be evaluated by personnel who did not participate in the certification activity object of the appeal. At the end of the investigation, within two months of receipt, the appellant will be informed of the outcome of the checks carried out.
Appeals can be sent through the Customer Experience Center (CEC@ul.com) or to UL NB email address (MIL.ULInternationalItaliaNB@ul.com).

20.3 Disputes

Should a dispute arise between UL NB, one of its customers or another interested party, it is established that the competent court is in Monza.

21.0 CONFORMITY ASSESSMENT FEE

UL NB defines the economic conditions applicable to conformity assessment activities in such a way as to obtain a sufficient profit to ensures independence in the performance of its activities and to enable continuous improvement of its services. UL NB's fee schedule includes the following elements (where applicable):

- Examination of documentation (Technical File);
- Inspections;
- Issue of certification;
- Activities associated with additional inspections;
- Possible verification at the laboratory for qualification purposes;
- Annual fee if foreseen by the program.

Travel expenses and extra expenses (board, lodging, car expenses) are charged at cost.
Urgency procedures expressly requested by the customer will lead to an increase in costs.

22.0 INVOICING

Invoicing of the services provided by UL NB shall take place in accordance with the conditions agreed upon in the quotation and the conclusion of the contract. The following shall also apply:

- In the event that the client cancels the scheduled activities within 20 working days prior to the date agreed in writing, UL NB reserves the right to charge the amount stated in the quotation and/or order confirmation;
- In the event of termination of the agreement by a client who has already been certified in connection with a surveillance audit, UL NB reserves the right to charge the amount of the audit fee if the written notice of termination is not received at least 4 months in advance.
- If certification activities are interrupted for any reason whatsoever, the client will receive an invoice from UL NB for all services rendered up to the time of interruption (in particular, if the client does not commence certification activities after signing the agreement, the client will nevertheless receive an invoice for the amount of the case opening).
- UL NB reserves the right to revise the contractual documents if, in the course of the certification activities, it discovers variations from the conditions declared by the client, on the basis of which the quotation was issued.

23.0 ANNEX 1 – CERTIFICATES VALIDITY

Directive PED 2014/68/UE			
Module	Description	Production type	Certificate validity
A2	Internal production control plus supervised pressure equipment checks at random intervals	Serial manufacturing	1 year
		Unit o production lot	No expiration
B	EU Type examination — production type	Famiglia o tipo	10 years
B	EU Type examination — design type	Famiglia o tipo	10 years
C2 (1)	Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals	Serial manufacturing	1 year
		Unit o production lot	No expiration
D (2)	Conformity to type based on quality assurance of the production process	based on management system	3 years
D1	Quality assurance of the production process	based on management system	3 years
E (1)	Conformity to type based on pressure equipment quality assurance	based on management system	3 years
E1	Quality assurance of final pressure equipment inspection and testing	based on management system	3 years
F (2)	Conformity to type based on pressure equipment verification	Unit o production lot	No expiration
G	Conformity based on unit verification	Unit	No expiration
H	Conformity based on full quality assurance	based on management system	3 years
H1 (3)	Conformity based on full quality assurance plus design examination	based on management system	3 years

(1) Associated with Module B EU Type examination — production type

(2) Associated with Module B EU Type examination — production type or Module B EU Type examination — design type

(3) Associated with Module B EU Type examination — design type. The validity of the certificate issued for Module B EU Type Examination – design type is linked to the validity of H1 certificate. Failure to renew or withdrawal of the H1 certificate implies the cancellation of all certificates issued for the linked Module B EU Type Examination - design type.

Regulation GAR 2016/426		
Module	Description	Certificate validity
B	EU Type examination — production type	10 years
C2 (1)	Conformity to type based on internal production control plus supervised product checks at random intervals	10 years
D (1)	Conformity to type based on quality assurance of the production process	3 years
E (1)	Conformity to type based on product quality assurance	3 years
F (1)	Conformity to type based on product verification	No expiration
G	Conformity based on unit verification	No expiration

(1) Associated with Modulo B EU Type examination — production type

Directive BED 92/42/EEC		
Module	Description	Certificate validity
B	EU Type Examination	No expiration
C (1)	Conformity to type	10 years
D (1)	Production quality assurance	3 years
E (1)	Product quality assurance	3 years

(1) Associated with Modulo B EU Type Examination

Directive EMC 2014/30/EU		
Module	Description	Certificate validity
B	EU Type Examination	3 years

Directive RED 2014/53/EU		
Module	Description	Certificate validity
B	EU Type Examination	3 years

24.0 ANNEX 2 – REQUIREMENTS FOR THE EQUIPMENT CALIBRATION

24.1 Purpose and Scope

This appendix provides the minimum requirements for the calibration of measuring equipment used for verifying the performance and safety characteristics of EC certified products.

24.2 Definitions

Calibration Reference Equipment/Material – An equipment or material with an accepted value that is used as a reference for comparison with similar devices having an unknown value. It is used to calibrate M&TEs and provide traceability of measurements to international standards.
Measurement and Test Equipment (M&TE) – All devices used to measure, test, inspect or otherwise determine compliance with prescribed technical requirements.
Accreditation – Recognition of competence in specific calibration practices as assessed by a conformity assessment body ILAC, APLAC or EA MRA signatory.
Traceability – The property of a measurement result or the value of a standard for which it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all with stated uncertainties.
Calibration interval – The defined period of time that elapses before re-calibration of equipment is performed.

24.3 Calibration requirements

All M&TEs used for verification of performance and safety characteristics of CE-certified products shall undergo periodic calibration. Calibration of M&TEs can be carried out:

- directly by an ISO/IEC 17025 accredited calibration laboratory by an accreditation body ILAC, APLAC or EA MRA signatory or by a national metrology institute (e.g., National Institute of Metrological Research I.N.Ri.M.);
- internally, through the use of reference equipmnt/materials with a calibration certificate issued by an ISO/IEC 17025 accredited calibration laboratory by an accreditation body ILAC, APLAC or EA MRA signatory or by a national metrological institute (e.g., National Institute of Metrological Research I.N.Ri.M.).

Accredited calibration of M&TEs or in-house calibration carried out with reference equipment/materials with accredited calibration enables the accuracy and traceability of measurements to be ensured.
In the case of in-house calibration, the reference equipment used for calibration must be used exclusively for this purpose.

24.4 Identification

M&TEs must be maintained in accordance with the following:

- Identity of the object and any related software (version and/or date of software)
- A unique identification number;
- Manufacturer's instructions or operating manual;
- Calibration and verification records including adjustments made, certificates, reports, next calibration date, and current calibration dates.

24.5 Calibration interval

All M&TEs requiring calibration shall undergo initial calibration before being put into service. The maximum allowable nominal calibration interval is given below:

- As specified by the equipment manufacturer;
- one year for electrical, electronic and mechanical equipment;
- three years for mechanical equipment consisting of solid materials not subject to deterioration.

Calibration intervals may be extended under the following conditions, and the reasons for the extension shall be documented:

- passive electrical test equipment, such as current shunts, current transformers, potential transformers, may be extended to 3 years if the initial calibration has been successful and if not subjected to severe conditions of use;
- weights may be extended to 5 years if there is a laboratory procedure that accounts for use and provides for physical examination and/or intermediate checks of the weights.
- where sufficient calibration data are available to statistically establish a trend in the test equipment to ensure good measurement results for a longer period.

Delicate test equipment that is subject to frequent use or severe conditions (e.g., shock and vibration, excessive heat or humidity, or transported) should be assigned reduced calibration intervals from the nominal intervals.

Test equipment used under variable conditions for which periodic calibration is not possible should be checked before use under the specific conditions (e.g., gas chromatograph checked with standard gas).

Test equipment used infrequently (e.g., once or twice between calibration cycles) can be calibrated before use instead of periodically.

Equipment that does not require calibration should be verified according to documented specifications and/or procedures.

24.6 Measurement Uncertainty evaluation

For all calibrations it is necessary to report the estimate of the measurement uncertainty. These calculations can be performed in accordance with JCGM 100:2008 (GUM 1995 with minor corrections) Evaluation of Measurement Data - Guidance on Expressing Uncertainty in Measurement.

All measuring equipment must be verified according to acceptability criteria for compliance with the requirements of accuracy and/or measurement uncertainty as required by the test methods.

24.7 Calibration certificates/reports

Calibration certificates/reports, whether issued internally or by external calibration service providers, shall meet the ISO/IEC 17025 requirements. Calibration certificates/reports shall contain at least the following information:

1. The title Calibration Certificate (or Report).
2. The name and address of the Laboratory
3. The place where the calibration activities are carried out
4. The unique document identification number given on all pages, the page number and the total number of pages to identify the end of the certificate/report
5. Business name, address, telephone number and/or email address of the client
6. An indication of the method used, including the number and revision
7. The description and, if necessary, the condition of the sample being calibrated
8. The date the calibration sample was received, if relevant to the validity of the results
9. The date the activities were performed or the start and end dates, in the case of activities requiring more than one day
10. The date of issuance of the certificate/report
11. The indication that the sample(s) was not selected by the Laboratory (only for external certificates/reports)
12. The statement that the results refer only to the sample(s) being calibrated
13. The results with the relevant units of measurement
14. Any additions, deviations or exclusions from the method used
15. The identification of the person(s) authorizing the issuance of the certificate/report

16. A statement that the certificate/report is not reproducible except in its entirety without the Laboratory's approval (for external certificates/reports only)
17. The logo of the accreditation body or a statement declaring the accreditation, if required and if the report contains at least one accredited calibration (if performed by an accredited lab)
18. The measurement uncertainty of measurement results presented in the same unit as that of the measurand or in a term related to the measurand (e.g., percentage)
19. The conditions (e.g., environmental, settings, etc.) under which the calibrations were made that affect the measurement results
20. A statement identifying the metrological traceability of the measurements
21. The results before and after each adjustment or repair, if available
22. If applicable, a statement of compliance with requirements or specifications.

24.8 Records

All records relating to M&TEs and reference equipment/materials (Certificates/calibration reports, verification reports, calculation of measurement uncertainty, etc.) must be kept for at least 10 years.