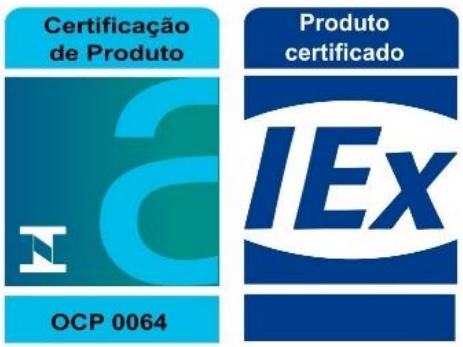
Associação IEx Certificações

Product Certification Program
General Requirements



1. General

1.1 This Program provides basic information about the Associação IEx Certificações's Product Certification Program.

1.2 It is considered eligible to obtain a product license, any company that has capacity to meet the requirements of the law, the Regulation of Conformity Assessment and technical standards related to products.

1.3 The certification aims to provide a high level of confidence that the certified product complies with the applicable requirements.

1.4 All companies that have products certified by Associação IEx Certificações, according to its accreditation by Coordenação Geral de Acreditação do Inmetro, will be authorized to use the Conformity Mark in their products.

1.5 Certification will be issued for each product (including the product family).

1.6 The maintenance of the certification is ensured by the conducting of agreed inspections in the manufacturer site.

1.7 Inspection is established by the Conformity Assessment, not exempting the applicant and the manufacturer of responsibility for the manufacture or production of certified products in compliance with this document and the relevant requirements.

1.8 All and any change in the product certified by IEx should be assessed, before the product is considered able to bear the Conformity Mark. If the applicant has no interest in continuing with the certification, shall request its cancellation.

2. About Associação IEx Certificações

The Associação IEx Certificações is a nonprofit association, accredited by Coordenação Geral de Acreditação do Inmetro, registered in the RCPJ, under the number 212667, located at Alameda Tocantins, 75, group 609 - Alphaville - Barueri – SP – 06455-020, inscribed in the National Directory of Legal Entities (Cadastro Nacional da Pessoa Jurídica – CNPJ) under the number 12.845.838/0001-65.

IEx has financial stability and resources required for its operations, resulting from its certification activities. The products under mandatory certification process are listed in the below categories:

- Equipment for hazardous locations, according to the Inmetro regulation N° 115:2022.
- Household appliances and similar, according to the Inmetro regulation Nº 148:2022.
- Medical Devices according to the Inmetro regulation Nº 384:2020**.**
- Plugs and wall sockets for domestic and analog use, according to the Inmetro regulation Nº 090/2022.
- Plugs and wall sockets adapters according to the Inmetro regulation Nº 009:2022.
- Switchers for electrical fixed installations domestic and analog according to the Inmetro regulation Nº 028/2022.
- Electrical Wire, Cables, and Flexible Cord, according to the Inmetro regulation Nº 131/2022.
- Low Voltage Electrical Installations, according to the Inmetro regulation N° 051/2014.
- IT Equipment, according to the Inmetro regulation N° 304/2023.

- Microwave ovens, according to the Inmetro regulation N° 268/2021.
- Noise Level Labelling for Household Appliances, according to Inmetro regulations N° 006/2022.
- Fans, according to Inmetro regulation N° 299/2021.
- Commercial Electric Ovens, according to Inmetro regulation N° 267/2021.
- Circuit breakers, according to Inmetro regulation N° 129/2022.
- LED Lamps with integrated driver, according to Inmetro regulation N° 069/2022.
- LED luminaries for public road, according to Inmetro regulation N° 062/2022.
- Spin Extractors, according to Inmetro regulation Nº 144/2021

This document aims to provide basic information on the certification of all products that IEx will certify.

The products are certified by IEx according to the following certification models, according to the specific Regulation:

- Assessment of the manufacturer Quality System and type tests of product – model 5.
- Certification of lot - model 1b.
- Certification of Special Situations, for explosive atmospheres products imported.

3. Product Certification Procedure

3.1 Requesting a certification

The company that wants the IEx certification must complete an application form, providing information about itself and the product to be certified.

It will be required the following information, except for the Certification of Special Situations for Ex products:

- List of models to be certified, including its technical description and the list of all marks to be commercialized.
- List of models that compose the products family to be certified according to the rules for products family composition as established by the Conformity Assessment Regulation, including its technical description and the list of all marks to be commercialized.
- Product Photographic documentation: internal and external photos from all product sides, detailing, logos, warnings, inputs, outputs, drive buttons, where applicable.
- Memorial descriptive contemplating the product design in their constructive and functional details and the list of its critical components, including its suppliers and possible existing certifications, translated into Portuguese, when in language other than English or Spanish.
- User manual in Portuguese language, including installation and safe use instructions.
- Drawing or artwork of packaging (primary, secondary and / or tertiary), where applicable.
- Model Certification Option, among those mentioned in the Inmetro Specific Conformity Assessment Regulation (RAC).
- Information about the Certification Applicant, including legal entity name, address, CNPJ (for Brazilian companies only) and the Social Agreement or other document that can prove its legal constitution.
- Applicant contact person data (Name, Phone number, e-mail).
- Manufacturer name, address and contact person, including all Production sites.

- Information about activities / outsourced processes that may affect the conformity of the product to be certified.
- Documentation that can demonstrate the compliance with Customer Complaint treatment as required by the Inmetro's Conformity Assessment Regulation.
- Manufacturer's quality system documentation, applicable for the product to be certified, in compliance with the Inmetro's conformity assessment regulation.
- ISO 9001 or ISO 13485 certificate that covers the production processes of the product to be certified.
- Identification of the certification Lot, in case of certification model 1b, including quantity and Lot number.
- Import license or Import Declaration, in case of certification model 1b, when imported products.
- Other documents required by the Inmetro Specific Conformity Assessment Regulation (RAC).
- Documentation proving the classification as micro and small enterprises – MPE (For Brazilian companies only).

It will be required the following information for the Certification of Special Situations for Ex products:

- Name and basic description of the product.
- Applicant name, address, CNPJ and contact person.
- Manufacturer name and address.
- The complete product certificate issued abroad.
- The ISO 9001 registration of manufacturing site.
- Documents for the product importation.
- Installation manual for safe use.

3.1.1 Information about charged fees

In possession of such information, IEx make a review of the application form and submit a quote for the applicant company. Fees included into the quote are regarding to the following activities:

- Technical analysis of the documentation received.
- Audit at the production Site.
- Testing plan preparation.
- Product Testing.
- Product Conformity Assessment based on the results of the testing and the production site audit.
- Product certification process reviewing.
- Certification decision and certificate of conformity issuing.
- Product certification data uploading in the Inmetro website.

3.1.2 Opening Project

If the quote is accepted, it will be opened a project to evaluate the product. Before the first issue of the certificate of conformity, it will be signed a contract for the Conformity Assessment Services.

3.2 Model with Assessment of the Quality System and type tests of product

The certification process of a product for this model includes the activities listed below (not necessarily in this order):

3.2.1 Initial audit

The plant will be audited to verify the implementation of items of the current version of the ISO 9001 or ISO 13485 standards, respecting the transition period established by the IAF and the additional requirements required by the Conformity Assessment Requirements.

IEx, after evaluating the Quality System documentation, will determines if the audit is required and the audit will be scheduled with the manufacturer on a mutually convenient date.

3.2.2 Delivery of prototype (When applicable)

The Applicant will send the sample prototype, when applicable, to the address previously defined, or will provide prototypes to assessment on their premises or the manufacturer (on site assessment). After completion of the type tests, IEx conducts an assessment of plant with the objective to verify the implementation of the approved product in the production process, which will be held in conjunction with the initial audit.

3.2.3 Constructive evaluation of the product

The verification of compliance to the requirements of the design standards is conducted before sending the product to the lab for testing, which can be performed in the facilities of the applicant or manufacturer.

3.2.4 Review and decision of the Internal Certification Commission

Once all requirements for the product certification have been met, IEx submits the results to its Certification Commission for final review before issuing the certificate.

3.3 Model with certification of lot

The process is similar but is not the initial audit and the need for the manufacturer share Quality System according to the current version of the ISO 9001 standard. Samples are selected and collected in accordance with the Conformity Assessment Requirements.

3.4 Model of certification for Special Situations (only for Ex Products)

This model differs from the previous ones, since it is a simplified process applicable exclusively for the importation of small quantities of Ex products already certified abroad. This modality cannot be used if the product is installed. The products must be inspected by IEx (even if abroad) to verify if they are in compliance with the information provided.

This modality cannot be used for the following products: accessories for installations (for example: cable-glands, flexible conduits, plugs, etc.), luminaries, electronic ballasts for tubular fluorescent lamps, hand lamps, floodlights, empty enclosures, electrical motors, junction boxes, solenoid valves, signaling and command components, except when these products are part of process modular units (Skids).

4. Certification grant

After the product certification decision, IEx will grant the Applicant the authorization to use the Conformity Identification Mark, composed of the Inmetro logo of its property, associated to the IEx certification logo, for the application in the products manufactured as listed in the Certificate (s) of Conformity issued by IEx, under the following conditions:

- The use of Inmetro Iogo depends on the simultaneous use of IEx logo, both for application in products, as well as in advertisement.

- Authorization has full efficiency, provided that the manufactured units are in conformity with granted Certificate(s) of Conformity, according to Inmetro Regulations and its Conformity Assessment Requirements (RAC).

- Manufacturing unit(s), where product(s) authorized to use the Conformity Identification Mark is (are) those showed on the Certificate of Conformity.

- Full conformity with technical-administrative conditions set forth in related Inmetro Regulations and its Conformity Assessment Requirements (RAC) and Reference Term of Brazilian Certification System, approved by Resolution CONMETRO Nº 4, of December 2nd, 2002.

- Full adoption, by the Applicant, of all technical requirements and procedures set forth in applicable technical rules, which integrate related Inmetro Regulations and its Conformity Assessment Requirements (RAC).

5. Certification Maintenance

According to the Conformity Assessment Requirements established by Inmetro, should be periodically evaluated the Quality System and the manufacturer's production line. This periodic evaluation is considered part of the Program for Certification Maintenance and the frequency of this evaluation is also presented in the specific program for the product category.

In case of failures during the maintenance process, the Applicant and/or Manufacturer must implement corrective actions in the process and/or in the product to keep the certification.

6. Extension or reduction of the certification scope

The applicant may formally request an extension of its certification scope. IEx will review the request to verify the need for further testing and factory audit.
For certified products using the model with assessment of the Quality System and type tests of product, the applicant may request a certification of a new version of the product using the results of a similar product, currently certified and produced in the same factory and subject to the same certification requirements.
The applicant may formally also request a reduction of its certification scope. In this case, the applicant shall:

- Inform which products are involved in reducing the certification scope.
- Inform the quantity of products in stock, if any.
- Review its advertising material by removing references to the products involved in reducing the certification scope.

Based on the information received, IEx will decide if an extraordinary audit should be carried out at the manufacturer's facility and / or at the product storage unit.

7. Products certified by a foreign certification body

If an applicant wishes to use the results of a certification conducted by a foreign certification body, the following conditions are applied:

a) The foreign certification body must be accredited by an entity under the same accreditation criteria adopted by Coordenação Geral de Acreditação do Inmetro.

b) The laboratory conducting the tests must be accredited by a full member of ILAC or must be an ExTL from the IECEx System (in those cases related to Ex Products).

c) IEx must have Memorandum of Understanding (MoU) with the foreign certification body, except if the certification body is accredited by IECEx System (an ExCB for the case of Ex Products).

IEx may accept the tests results and the results of the evaluation of the quality system only after review of documentation to prove the equivalence of requirements used for certification. If any additional assessment is needed based on the review of documentation, this may be requested to the certification body that originally certified the product.

8. Cancellation

The applicant may request the cancellation of certification for any reason. IEx removes the certificate of its database and from the Inmetro database.

9. Suspension

The certification of a product may be temporarily suspended as a result of information (e.g. complaint of end users) received for a product license, non-conformities during the inspection, non-conformities with the certification requirements review, etc. During this period the product may not bear the Conformity Identification Mark under SBAC. Once the non-conformity is resolved, the manufacturer receives permission to reuse the Conformity Identification Mark.

10. Repeal

When a non-conformity is not solved during the suspension period, the certification may be revoked. If the applicant wishes to license the product again, a complete new certification process should be implemented.

11. Complaints

Complaints may be directed to any IEx employee that records and forward them to the Quality Department, aiming to evaluate them and make the appropriate corrections, if applicable.

12. Appeals

Appeals are not complaints. An appeal is made when the customer does not agree with the decision of IEx not to grant or cancel the certification. Apply the following criteria:

a) The right to make the appeal is provided when there is not an agreement in the decision with the IEx.

b) The appeals must be documented by the organization and sent to the President of IEx on letterhead with the signature of an executive of the Organization.

c) The documented petition will be accepted within five working days. The President of IEx will ensure a full investigation. A detailed assessment of facts is performed within 30 days of receipt of the appeal forwarding a proposal for a solution.

d) If the proposal is not accepted, the postulant must explain its reasons and the President of IEx submit the request for appeal to the other members of the Management IEx to be formed an Appeal team in accordance with the policies of IEx.

e) The Appeal Team will not include members with a personal interest in the decision. Both the IEx and the applicant (the individual / applicant of the appeal) must agree on the composition of the Appeal Team.

f) The Appeal Team meets on a maximum of 60 days after the request for reconsideration. The team's decisions are based on facts and information presented, and the decisions are consistent with the resolutions and actions arising from previous situations.

g) The appellant is free to defend its interests with the accreditation body and to the relevant regulatory body if it does not agree with the decision of the Appeal Team.

13. Transfer of Certification

13.1 IEx can accomplish the transfer of a certificate of conformity from another OCP accredited within the Brazilian System of Assessment Conformity (SBAC), according to Inmetro's General Requirements for Product Certification (RGCP), upon the request of the company licensed to use the Seal of Compliance Identification.

13.2 If any IEx customer desires to transfer its certificate to another OCP accredited within the Brazilian System of Assessment Conformity (SBAC), IEx will provided the necessary information to another OCP, if the certificate is still valid.

14. Obligations of the Applicant (Certificate Holder)

14.1 Comply with all provisions set forth in documents referred to in Clause 3 of this Program.

14.2 Submit to IEx, for prior evaluation and approval, all change which may be proposed for certified product(s).

14.3 Use the Conformity Identification Mark, only in products referred to in Clause 3 of this Program.

14.4 Directly pay IEx for services related to certification services.

14.5 Ease the personnel access formally set forth by IEx to manufacture lines and stock of finished products, during audits, inspections or samples collecting.

14.6 Arrange transportation, accommodation (if necessary) and meals for personnel set forth by IEx, during audits, inspections or samples collecting, bearing related expenses.

14.7 Maintain its Quality Management System updated and implemented.

14.8 Use granted Certificate(s) of Conformity and authorization only in products which were manufactured in installations referred to in related certificate(s), and approved by IEx.

14.9 Use promotional material, with references to the Conformity Identification Mark, only for certified product(s), settling any doubt between certified and not-certified model(s).

14.10 Accept and implement within agreed terms the recommendations of IEx, regarding corrective actions arising from nonconformity identified in technical audit or document reviews.

14.11 Correct nonconformities identified by IEx due to audit, document reviews and testing established by the Conformity Assessment Regulations.

14.12 Investigate and maintain records of complaints regarding certified product(s) make them available to IEx when required.

14.13 Take and document appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification.

14.14 Not to use the product(s) certification in such manner as to bring IEx into disrepute and does not make any statement regarding its product certification, that IEx may consider misleading or unauthorized.

14.15 Discontinue to use of all advertising matter that contains any reference about all certified product and return all procedure documents which are required by IEx, in the event of suspension, withdrawal, or termination of related Certificate(s) of Conformity; in the event on the contrary, it also undertakes to be subject to applicable civil and criminal injunctions.

14.16 Immediately notify IEx in the event of permanent cease of manufacture of certified model(s), as well as submit to analyses and approval by IEx of any change performed prior to marketing.

14.17 Comply with all IEx’s requirements when referring to the certification of product(s) in media, as documents, brochures, Web or advertisement.

14.18 Fulfil the certification requirements set out in Conformity Assessment Regulations (RAC) and implement appropriate changes when notified by IEx.

14.19 Ensure that the certified product continues be produced according to the requirements set out in the Conformity Assessment Regulations (RAC) and applicable standards.

14.20 Make all necessary arrangements for the conduct of the evaluation and surveillance by IEx, including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and subcontractors.

14.21 Allow the participation of observers during factory audits, when requested by IEx.

14.22 Make claims regarding certification consistent with the scope of certification.

14.23 Provide copies of certification documents for others, if necessary, reproduced in its entirety.

15. **Obligations of IEx**

15.1 Provide all technical coordination of all services regarding the maintenance of authorization for the use of Conformity Identification Mark.

15.2 Verify the conformity of product(s) according to the applicable technical rules, regarding tools for audit, inspection, documents reviews, and testing established by the Conformity Assessment Regulations.

15.3 Keep the Applicant informed about changes in basic documents controlling the Certificate(s) of Conformity and authorization now granted, as well as provide, in details, the results of audits, technical inspections, documents reviews and tests.

15.4 Not to provide any information regarding the manufacturing processes of products, including when regarding performed tests, or regarding the alienated or manufactures quantities, unless upon authorization by the Applicant.

15.5 Provide necessary information to a receiver Certification Organization (result of performed tests and audits and special conditions on which were based the granting of certification, when applicable) only due to a transfer request by the Applicant of certificate(s) now granted, to another Certification Organization accredited by Coordenação Geral de Acreditação do Inmetro.

Appendix A - Terms of Use for IEx Conformity Mark

A.1 General

A.1.1 After the completion of the certification, the client has the right to use the IEx Conformity Mark on its product, as illustrated below in A3.2.

A.1.2 IEx grants the right to use its Conformity Mark ("the Mark") in the product licensed. The mark given under the conditions of this document may only be used by the customer associated with the product certificate to indicate that this product is covered by the certification of IEx. The client must not, under any circumstances, make use of the mark, the name, the abbreviations or symbols, or any other form of reference that can link IEx with products that are not in accordance with this document and requirements.

A.1.3 The promotional material of the client should not conflict with the results of IEx and should not refer to IEx to create a misleading impression about the nature of the results of IEx.

A.1.4 The certificate of conformity and the mark should be used in the manner authorized by IEx, and subject to its control. The request for using the certificate and the mark should be made to IEx.

A.2 Requirements

A.2.1 The mark of IEx can only be used associated with the products described in the certificate of conformity. When the mark of IEx is used in a context where the scope of application is open to interpretation, the client must clearly identify which products are covered by the certificate of conformity.

A.2.2 The company agrees to discontinue any authorized use of the IEx mark considered unacceptable by IEx, which may generate misleading interpretations.

A.2.3 If the certifications are not valid anymore, whatever the reason, the applicant and the manufacturer should discontinue the use of the mark of IEx immediately.

A.3 Composition and elements

A.3.2 IEx Mark, when the product is used in conjunction with the record number of the Certification (OCP 0064)

A.4 Implementation

The information below describes the acceptable applications of IEx Mark:

A.4.1 Minimum size is not specified, provided it is clear and legible.

A.4.2 Colors that contrast with the front and the bottom allowing the details of the IEx mark are clearly visible and legible.

A.4.3 Highlighted so that the IEx mark is clear and legible.

Appendix B - Conditions for Use of Conformity Mark

B.1 General requirements

B.1.1 Under the Brazilian Conformity Assessment System, the use of the Inmetro mark in a product and packing must always be in conjunction with the certification body mark, as defined by Inmetro regulations listed item 2, in this procedure.

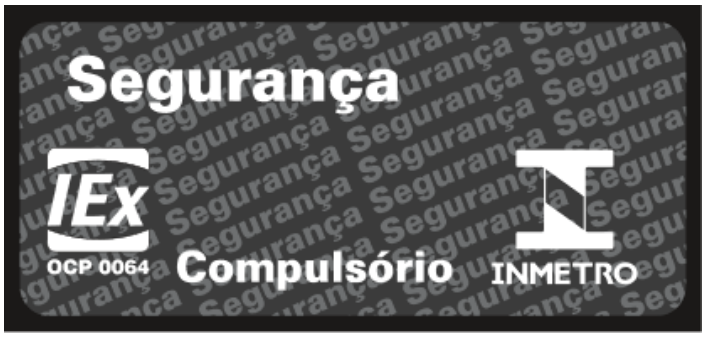
B.1.2 Some examples about Inmetro mark to be used on the products:

Compact Stamps

B.1.2 Some examples about Inmetro mark to be used on the packing:

Pantone 1235
100%
80%

CMYK
C2 M34 Y94 K0
C2 M27 Y90 K0



100%
90%
70%

Just one color