

FAQ – INMETRO

PRODUCT REGISTRATION

1. GENERAL INFORMATION

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FAQ REGISTRATION

CERTIFIED PRODUCT

1. GENERAL INFORMATION

FAQ REGISTRATION Certified Product

1. General Information

1.1 What is the Registration, what is it for ?

Registration is the procedure by which Inmetro authorizes, conditional to the existence of the Certificate of Conformity and, consequently, the sale of the product or the operation of a service, as defined by the Conmetro Resolution no. 05/2008, available at <http://www.inmetro.gov.br//legislação>.

1.2 What is a Certificate of Conformity?

The Certificate of Conformity is the document issued after a conformity evaluation procedure, indicating that a product conforms to a regulatory base. Examples of Certificates of Conformity are the Certificate of Conformity and the Statement of the Supplier.

4.4 Where can I find the definitions of the general procedures to Register an Object?

The procedure to grant continuity and renewal of the Registration of Object is defined by Administrative Rule. The Administrative Rule currently in force is the Inmetro Administrative rule no. 491, dated December 13, 2010, available at

1.4 How can I know what are the products and services ruled by Inmetro which are subject to the Registration Process ?

All Products and Services which conformity is compulsorily evaluated by Inmetro are subject to the registration process.

It is the Administrative Rule which publishes the Conformity Evaluation Requirements – RAC of the specific product determined for mandatory Registration prior to marketing.

The list of the RAC Administrative rules which establish the obligation of registration with Inmetro is available under <http://www.inmetro.gov.br/qualidade/regObjetos.asp>.

ATTENTION:

The non-observance of the Registration, within the terms established by the RAC Administrative Rule, subjects the Supplier to fine and seizure of the product sold.

1.5 How to find, in the Inmetro Administrative Rule, the information on the mandatory registration ?

The Administrative Rule publishing RAC institutes::

- a) the conformity evaluation mechanism;
- b) the compulsory nature of the regulation; and –
- c) the mandatory nature of the Registration, as in the following example:-

“Article 3 – to institute, under the Brazilian Conformity Evaluation System – SBAC, the compulsory certification for Metallic Pans, which shall be done by Product Certification Office – OCP qualified by Inmetro, as established in the Requirements now approved.

Article 4 – to determine that as of thirty (30) months counted as of the date of publication of this Administrative Rule, the Metallic Pans shall be manufactured and imported only according to the requirements established by the Requirements now approved and duly registered with Inmetro. (Administrative Rule no. 419/2012 – RAC for Metallic Pans).

1.6 How can I know if my specific product is included in the regulations?

The Administrative Rule publishing the RAC specifies the classification, that is, defines, for each product, what is covered by the regulations and, consequently, what is subject to the Registration.

See the following example:-

“Article 3 – Institute, under the Brazilian Conformity Evaluation System – SBAC, the compulsory certification of Metallic Pans, which shall be done by Product Certification Office – OCP qualified by Inmetro, as established in the Requirements now approved.

Paragraph 1 Do such Conformity Evaluation Requirements – RAC apply to the following products: -?

- A) *for use in ovens: dampers, roasters, shapes, trays and pie shapes, or other fixtures having such purpose;*
- B) *for use in stoves: boiling water heaters, beef grills, teapots, mugs, casseroles, pots, kettles, grills, steam cookers, crepe maker, “cuscus” pans, spaghetti pans, boilers, Closed Pizza shapes, shapes for direct heat source, pans, fryers, dairy heaters, lunch boxes, saucers, omelet pans, “paeja” pans, pressure cookers, pancake pans, popcorn pans, pudding pans, pots, and wooks, or other devices used for this purpose.*

Paragraph 2 – This RAC does not apply to exclusively electric pans and one-way devices. (Administrative Rule no. 419/2012 – RAC for Metallic Pans).

1.7 What are the basic registration documents ?

The basic documents for the Registration were defined by Inmetro Administrative rule no. 491, dated 12/13/20101, available at <http://inmetro.gov.br/qualidade/regObjetos.asp>. They are:

- a) *Document evidencing the conformity of the product to the requirements established in the RACs (Conformity Certificate);*
- b) *Articles of Association of the Supplier and qualified document evidencing that the petitioner is legally vested in powers to represent the supplier (Articles of Association, CNPJ Card, copy of CPF and ID of the Partners, Power of Attorney of the Legal Representative, when applicable);*
- c) *Conformity Evaluation Commitment Term signed by the Legal Representative in charge of marketing the product in the country (as per template available in <http://www.inmetro.gov.br/qualidade/regObjetos.asp>.)*

ATTENTION:

To request the Registration, the Conformity Certificate must have already been issued.

1.8 Some documents are written in other languages, may I use them ?

All documents required and attached to the Registration Process shall be written in Portuguese or have their Certified Sworn Translation attached thereto.

1.9 Does Inmetro certify products ?

No. The Product Certification is done exclusively by a Product Certification Office – OCP. Only offices qualified by Inmetro may Certify Products.

1.10 Who issues Conformity Certificates ?

The Conformity Certificate of products is issued exclusively by a Product Certification Office – OCP established in the country and qualified by Inmetro.

1.11 Where can I find a qualified OCP to certify my product ?

See the list of qualified OCPs in <http://www.inmetro.gov.br/organismos/index.asp> (the scope field shall be completed with the name of the regulated product).

1.12 What must be contained in the Conformity Certificate ?

The Conformity Certificate, issued by the Product Certification Office after the conclusion of the Certification Process, must contain, at least:-

- a)** Corporate name, National Registry of Legal entities (CNPJ), complete address and fantasy name of the supplier, when applicable;
- b)** Corporate name, CNPJ, complete address and fantasy name of the manufacturer, when applicable;
- c)** Name, address, signature of the person in charge and OCP identification number;
- d)** Issue date and validity of the Conformity Certificate;
- e)** Certification Scope;
- f)** Identification of the model(s) covered by the Conformity Certificate;
- g)** Identification of the models covered by the Conformity Certificate, in case of certification by family;
- h)** Identification of the manufacturing lot(s) (mandatory in case of Conformity Evaluation according to model 7);
- l)** Identification of the regulatory base, with the corresponding years of publication and reference to the Administrative Rule approving the RAC;
- j)** Business and Import identification numbers, if any, of the models provided under f) or g);
- k)** Number and date of the essay reports issued by the lab.

NOTE:

Any additional items required for the issue of the Conformity Certificate are shown in the specific RAC of the corresponding product.

ATTENTION:

The name given to the family shall contain the main characteristics defining its constitution (cannot be identified only by initials). The same goes for the model number.

Example: unsuitable name : “Family C”
Suitable name: “Electric Gasoline Fuel Pump family type C”

1.13 How can I know if the Certified Product Registration is done by family or model ?

The definition of the certification being “by family” or “by model” is contained in the Inmetro Administrative Rule publishing the Conformity Evaluation Requirements – RAC for the product.

The RAC also defines the concept of family or model, specific for each product, as per the following samples:-

1.2 GROUPING FOR CERTIFICATION AND REGISTRATION PURPOSES

1.2.1 For the Certification and Registration of the object of this RAC, the family concept applies.

1.2.2 The Certification and Registration of steel cables shall be done by family, which is constituted by a group of steel cable models, of one same manufacturer, same plant, same production process, having in common the same class, type of resistance and finish.

(Inmetro Administrative rule no. 181/2012 – Steel Cables RAC)

1.2 GROUPING BY TRADEMARK/MODEL OR FAMILY

1.2.1 For the Certification and Registration of the object of this RAC< the concept of trademark/model applies.

1.2.2 The Certification and Registration of children strollers shall be done for each stroller model, which constitutes template of the object, of one same trademark, made of the same material, sizes, brake mechanism, assembly/fitting system, accessories and product drawing, identified by one or more fantasy names, which may have different colors or patterns.

(Inmetro Administrative Rule no. 351/2012 – RAC on Children Strollers)

In the link <http://www.inmetro.gov.br/qualidade/regObjetos.asp>. may be found in the table regarding all RAC published by Inmetro which have compulsory registration, with the identification of whether the Certification is by model or by family.

1.14 Who may request the Registration ?

The Registration is requested by the Supplier. The Supplier is an “Individual or Legal Entity”, public or private, local or foreign, legally established in the country, developing activities of production, assembly, creation, construction, conversion, import, export, recovery, repair, distribution of marketing of the product or provision of services”.

1.15 May the OCP request the Registration on my behalf ?

The Registration of object lies within the direct interest of the Supplier, which shall not delegate to third parties the responsibility for an activity directly affecting the permission to manufacture and market its product.

1.16 I am importing a Product; what do I have to do first: the Consent or the Registration ?

For products subject to compulsory certification, after obtaining the certification, the first step is to request the registration with the Orchestra System through the link <http://inmetro.gov.br/quality/regObjetos.asp>. Only with the registration number granted, which authorizes the marketing of the product(s) in the country, the company will be able to proceed to the import, observing the provisions of the Inmetro Administrative Rule no. 548/2012 (available in <http://www.inmetro.gov.br/qualidade/anuencia/asp>).

In the case of model 7 of Certification, for imported products, the consent shall be requested prior to the Certification, being the registration made afterwards.

ATTENTION:

The Product Registration shall always be done first. After the grant of the Registration, the Import License(s) – LI(s) are approved.

ATTENTION:

For the purpose of importing only the product samples, necessary to make the essays provided for the certification, the Registration is not necessary.

1.17 If I manufacture or import several models of one Product, how many Registrations shall I request ?

It depends on what is established in the Conformity Evaluation Requirements – RAC covering the regulations for the product. This is why it is essential to have it on hand and study it.

Should the Certification be done “by model”, the Registration must be requested for each model manufactured. That is, there shall be opened as many Registration procedures with the System as the manufactured models.

Should the Certification be done “by family”, the Registration must be requested for each family manufactured. That is, there shall be opened as many Registration procedures with the System as the families manufactured (the procedures shall inform all models pertaining to the family).

The RAC defines how a family is constituted. In general, the family is characterized by a set of models manufactured in the same manufacturing unit, same production process and which have in common the same project and the same constructive characteristics.

Its Certificate of Conformity (the Certificate) shall contain the models or families evaluated, according to the RAC.

ATTENTION:

In order to import only product samples, necessary to make the essays provided by the Certification, the Registration is not necessary.

2. HOW TO OBTAIN AND MAINTAIN THE REGISTRATION ?

5 HOW TO OBTAIN AND MAINTAIN

THE REGISTRATION

2.1 Where do I request the Registration ?

The Registration is requested exclusively at the Inmetro Internet page – <http://www.inmetro.gov.br/quality/regObjetos.asp>.

After the completion of the supplier records in the System (called Orchestra System – Orchestra System Manual for the Registration of Object, available in <http://www.inmetro.gov.br/quality/regObjetos.asp>), the Payment slip to the Federal Government is generated [Guia de Recolhimento à União – GRU], in respect of the Registration grant fee, in the amount of Forty-seven Reais and thirty-nine cents (R\$ 47,39) payable within 30 days.

As of such moment, the process receives an automatic number in the System, by means of which the process may/shall be followed-up.

Only after the automatic identification of the GRU payment the Registration process starts to run in the System, for analysis by Inmetro.

ATTENTION:

We do not issue a second copy of the GRU slip. If the GRU is not paid within the period granted, the process will be cancelled, the amount paid shall not be reimbursed, and the supplier shall start a new process from scratch.

2.2 May I pay GRU if it is overdue ?

No. Should the payment period of the GRU become past due, the Supplier shall start a new Registration Request with the Orchestra System to issue a new GRU. Should a past due GRU be paid, the amount shall not be reimbursed to the party requesting the Registration.

5.4 Is there a Second Copy or Term Extension for the GRU ?

No. Should the GRU payment term expire, the Supplier shall start a new Registration Request with the Orchestra System, to issue a new GRU.

2.4 What are the main steps of the Registration ?

The main steps of the Registration procedure, which occur within the Orchestra System are:-

STEP	PERFORMED BY
Registration Request	Supplier
Analysis of Request	Inmetro

Registration Grant	Inmetro
Request for Registration Maintenance	Supplier
Analysis of Registration Maintenance	Inmetro
Confirmation of Registration Maintenance	Inmetro
Request for Registration Renewal	Supplier
Analysis of Registration Renewal	Inmetro
Grant of Registration Renewal	Inmetro

ATTENTION:

The full registration system occurs in the Orchestra System. Therefore, it is the Supplier's responsibility to access the Orchestra System to follow up the full course of the process, to know all terms (continuity and renewal), irrespectively of the receipt of the automatic warnings in the recorded e-mail.

ATTENTION:

Make sure that the e-mail of the Orchestra System is not blocked by your computers' anti-spam.

2.6 How long does Inmetro take to grant the Registration ?

After the acknowledgement of the GRU payment, the Inmetro analysis to grant the Registration occurs within maximum 15 days.

2.6 How to follow up my Registration ?

All steps of the Registration process occur within the Orchestra System. The Supplier shall regularly access the System to follow-up the progress of the process in his working area (each step of the process "runs" through the opening of "Tasks" in the working area). All Registration procedures of a given Supplier are in his working area of the System. Additionally, the System is programmed to "Communicate" with the Supplier, by sending automatic e-mail to the e-mail address fed into the System in the initial records of the Supplier. The Supplier shall pay attention to the tasks awaiting performance, observing their expiry periods.

ATTENTION:

It is the Supplier's responsibility to access the Orchestra System to follow-up the full course of the process, to become aware of all terms (continuity and renewal), irrespectively of receiving the automatic warnings through the recorded e-mail.

In "My procedures in course" you may see the course of all such procedures and progress stages.

The automatic e-mails of the Orchestra System shall not be answered.

Make sure that the e-mail of the Orchestra System is not blocked by your computer's anti-spam.

2.7 How may I request the Registration ?

The Registration request is made by the Supplier, by inserting its records in the System, attaching the documents and description of the family and/or of the product model(s). After the conclusion of the task by the System, a process number is generated and will remain the same indefinitely. Likewise, the GRU is generated for payment of the Registration Fee, payable within 30 days (counted as of the date of request).

2.8 How is the Registration Request Analyzed ?

The Request Analysis in the System, made by Inmetro, consists of the analysis of the documents and information provided by the Supplier, to check whether all requirements were complied with. Should the documents or information provided have no non-conformities, the Registration is granted. Should non-

conformities be determined in the documents or information provided, the Supplier receives, in the e-mail recorded with the System, the task notice to make the necessary adjustments so as to correct the non-conformities.

ATTENTION:

The Request Analysis only starts after the automatic acknowledgement of the GRU, by the Payment System. The system identifies the payment in up to 48 hours.

ATTENTION:

See in the table below, the main documentation problems. Avoiding them shall cause your process to run faster.

MAIN NON-CONFORMITIES FOUND IN THE REQUEST ANALYSIS STAGE:

NON-CONFORMITY	CORRECTION
Supplier's information inserted in the System records (CNPJ, address, etc.) do not match the articles of association attached to the System.	Correct the data recorded in the initial screen of the Orchestra according to the Articles of Association.
Certificate issued by the OCP with conflicting information with the Supplier's Records in the System or with the Articles of Association.	Contact OCP and request the correction of the data informed in the Certificate of Conformity according to the Articles of Association.
Certificate issued by OCP with insufficient information.	Contact OCP and request the addition of the missing information to the Certificate of Conformity, according to the specific regulations.
Family or Model(s) shown in the Certificate issued by the OCP in disagreement with what the OCP has informed in the Prodcert	Contact OCP and request the adjustment of the Family/Model(s) shown in the Certificate of Conformity, so as to reflect what was informed in the Prodcert.
The Commitment Term is outdated or lacks information.	Access the page http://www.inmetro.gov.br/quality/regobjetos.asp , download the updated Commitment Term (for-dconf-176-rev.01 – Apr.Sept/13 – page 01/01). The Term must be duly completed and executed by the legal representative of the Company with updated date.

2.9 How is the Registration Granted ?

When the Registration is granted by the System, the Supplier receives, in the e-mail recorded with the System, the information of the Registration number in the format 000000/0000 (six digit number/YEAR with 4 digits). The Registration number shall be the same for all versions of one same model or for all models of one same family.

ATTENTION:

The Product Registration Number never changes, except of the Registration is cancelled by Inmetro or upon request of the Supplier, when a new Registration process shall be started.

ATTENTION:

The grant of the Registration is published in the Federal Official Gazette – DOU, but the use, by the Supplier, of the Conformity Identification Stamp with the Registration number is already authorized straight after its grant by the System (an automatic e-mail is sent informing the conclusion of the task of analysis).

2.10 How is the Registration Continuity Request done ?

After the grant, the Continuity of the Registration occurs with the frequency determined by the Inmetro Administrative Rule publishing the Conformity Evaluation Requirements – RAC for the product. The term for the first Continuity, in case of Certification, counts as of the date of the grant of the Certificate by OCP, as can be seen in the following example for a RAC defining annual frequency of Continuity and Certificate validity of 36 months:

Example:-

Date of issue of the Certificate	07/10/2013
Date of grant of the Registration by Inmetro	12/15/2013
Date of 1 st Continuity	07/10/2014
Date of 2 nd Continuity	07/10/2015

65 days in advance of the date provided for Continuity, the System opens for the Supplier to insert the necessary documents and information. The system sends automatic e-mail to the Supplier notifying that the Continuity process shall be performed.

ATTENTION:

Should the Continuity process period be lost, the Supplier may have its Registration suspended by Inmetro.

2.11 How does the Analysis of the Registration Continuity Request occur ?

Inmetro analyzes the documents and information provided by the Supplier so as to check whether all requirements were complied with. Should no non-conformities be found in the documents, the Registration Continuity is granted. Should non-conformities be found in the documents or information provided, the Supplier receives, through the e-mail recorded with the System, the task notice to make the adjustments required so as to remedy the Continuity non-conformities.

2.12 How is the Registration Continuity Confirmed ?

When the Continuity is granted by the System, the Supplier receives, through the e-mail recorded with the System, the information of the confirmation of the Registration Continuity (there is no publication in the Federal Official Gazette).

2.13 When and How the Registration renewal is done ?

All Registrations have a validity period, therefore shall be renewed from time to time. The term to renew of the Registration, in case of Certification, counts as of the date of grant of the Certificate by the OCP. The Renewal shall be done before the expiry of the Certificate validity (Defined in the Product RAC), as can be seen in the following example, for a RAC defining annual Continuity frequency and Certificate validity of 36 months:-

Example:-

Date of issue of the Certificate	07/10/2013
Date of grant of the Registration by Inmetro	12/15/2013
Date of 1 st Continuity	07/10/2014
Date of 2 nd Continuity	07/10/2015
Renewal date	07/10/2016

95 days in advance of the date provided for Renewal, the System opens for the Supplier to insert the necessary information. The System sends automatic e-mail to the Supplier warning that the Renewal shall be done.

Once the information and documents required for the Renewal are inserted, after the conclusion of the System's task, a GRU is generated to pay the Registration Fee, due within 30 days.

ATTENTION:

Should the Renewal term be lost, the Supplier may have its Registration suspended by Inmetro.

2.14 How does the Analysis of the Registration Renewal Request occur ?

Inmetro analyzes the documents and information provided by the Supplier, so as to check whether all requirements were duly complied with. Should no non-conformities be found in the documents, the Renewal is granted. Should non-conformities be found in the documents or information provided, the Supplier receives, through the e-mail recorded with the System, the Task Notice to make the necessary adjustments to remedy the Renewal non-conformities.

ATTENTION:

The analysis of the documents shall only start after the automatic acknowledgement by the System that the GRU has been paid. The System identifies the payment in up to 48 hours.

2.15 How is the Registration Renewal Granted ?

When the Renewal is granted in the System, the Supplier receives, through the e-mail recorded with the System, the information of the conclusion of the Renewal analysis task. The Registration number remains the same for all versions of one same model or for all models of a same family.

ATTENTION:-

The Product Registration number does not change after the Registration Renewal. The Orchestra process number does not change after the Registration Renewal.

The Registration Renewal is published in the Federal Official Gazette – DOU, but the use, by the Supplier, of the Conformity Identification Stamp with the renewed Registration number is already authorized straight after its grant in the System (an automatic e-mail is sent informing the conclusion of the Renewal analysis task).

2.16 Which Registration steps apply to model 7 of Certification (Certification by Lot) ?

When the RAC establishes the possibility of the Supplier choosing model 7, the Certification is done only for a certain Certification lot. The Certificate issued by OCP is only valid for the certified lot, therefore it shall be valid for as long as the lot is available to the trade.

In case of Model 7, only the following steps apply:-

Registration Request	Supplier
Analysis of the Documents	Inmetro
Grant of the Registration	Inmetro

**6 TERMS, VALIDITY AND PUBLICITY
OF THE REGISTRATION**

3. TERMS, VALIDITY AND PUBLICITY OF THE REGISTRATION

3.1 How can I obtain the Evidence of Registration ?

Inmetro publishes in the Federal Official Gazette the Administrative Rule disclosing the registrations granted. To access the Grant Administrative rules, Registration cancellations and renewals, it is enough to access <http://www.inmetro.gov.br/registrosobjetos>.

3.2 Will my Registration number change ?

After the grant the Inmetro Registration number does not change, except in case of cancellation. In such case, once the irregularities giving cause to the cancellation are remedied, a new registration process shall be requested by the Supplier, which will give cause, in case of approval, to a new Registration number.

3.3 What is the validity of my Registration ?

The validity of the Registration is the same as the validity of the Certificate issued by OCP. After the grant, the Registration Renewal occurs conditionally to validity of the Certificate issued by OCP.

In case of Certification through model 7 (certification per lot) the validity of the Certificate (and, consequently, the Registration) is undefined (is conditional to the duration, in the trade, of the certified lot).

3.4 Do I have terms to be met ?

After the grant of the Registration, the Supplier (manufacturer/importer) shall pay attention to the terms for Continuity Process and Registration Renewal.

The terms for Continuity and Renewal are notified by the Orchestra System, automatically, through the e-mail recorded with the System. Losing the terms for Continuity or Renewal may cause the temporary suspension or cancellation of the Registration.

The frequency of Continuity Procedures and Registration Renewal are determined by the Inmetro Administrative Rule publishing the Conformity Evaluation Requirements – RAC for the product. The Term for Continuity or Registration Renewal, in case of Certification, counts as of the date of grant of the certificate by OCP, as can be seen in the following example, for a RAC defining annual frequency for Continuity Procedures and the validity term of the Certificate of 36 months:

Example:-

Date of issue of the Certificate	07/10/2013
Date of grant of the Registration by Inmetro	12/15/2013
Date of 1 st Continuity	07/10/2014
Date of 2 nd Continuity	07/10/2015
Registration Renewal date	07/10/2016

ATTENTION:

The Supplier must pay attention to the terms to be complied with. There are automatic notices by e-mail, however the responsibility of accessing the Orchestra System to maintain and renew the Registration, lies with the Supplier.

ATTENTION:

The Continuity Process and Renewal in the System open 60 to 95 days in advance so that the processing is finished up to the date provided.

3.5 After obtaining the Registration, what do I have to do to maintain it ?

The Supplier shall pay attention to the Continuity and Renewal procedures of the Registration. Delays in the holding of audits and essays may cause loss of the deadlines for Continuity or Renewal, causing the suspension of the Registration.

ATTENTION:

Make sure that the conditions provided by the Contract of the Product Certification Body – OCP assure the due compliance with the terms for the Registration Continuity and Renewal.

3.6 Where can people obtain information on the products registered ?

Inmetro maintains the Bank of Registration of Objects in the link <http://www.inmetro.gov.br/registrosobjetos/Default.aspx?pag=1>. Searches may be conducted in the Bank through the Registration number, by product, by the CNPJ of the Supplier, by the Certificate number, among other. Likewise, the status of the Registration may be seen: “Active”, “Suspended” or “Cancelled”.

7 AMENDMENTS TO THE REGISTRATION

8 AMENDMENTS TO THE REGISTRATION

4.1 I already have the Registration, however I developed new products; do I have to make a new Registration?

There are 2 (two) possibilities:

Certification “per model”: when the Certification is “per model”, it is necessary to make the Registration of the new model, starting a new Registration process.

Certification “per family”: when the Certification is “by family”, it is possible to include a new model in the family already registered. For such purpose, after the grant, the Orchestra System opens for requests of inclusion of models (by means of opening the task “Scope Change”). It is possible to include new models in the family up to 45 days prior to the date provided for the Continuity of the Registration.

ATTENTION:

Upon the expiry of the 45 days term prior to the Continuity Process, the System closes the task “Scope Change” and the new model shall only be included in the Registration Continuity Process. After the conclusion of the Continuity, the System opens once again for inclusion of new models in the family registered and remains open for up to 45 days prior to the next Continuity request period.

4.2 How do I request an amendment (inclusion or exclusion) of model(s) of a family already Registered ?

It is possible to include or exclude model(s) from the family anytime after the grant of the Registration, by means of the task “Scope Change”(which is immediately opened by the System after the grant), or in the Registration Continuity Task.

4.3 I changed address, however the CNPJ continues to be the same; Do I have to request a new Registration?

Should the address change of the company holding the Registration refer to the manufacturing plan, then yes, a new Registration must be requested. Otherwise, it will not be necessary to request a new Registration, but only to request change of address through the task “Scope Change” or “Registration Continuity Process”, attaching, the new articles of association to the Orchestra System, evidencing the address change.

ATTENTION:

Attention: should the change of address be of the manufacturing plant, a new registration process must be started.

4.4 My CNPJ changed; Do I have to request a new Registration ?

Yes, the change of CNPJ implies a new Registration process, with the cancellation of the Registration(s) granted previously.

9 REGISTRATION SUSPENSION AND CANCELLATION

5. REGISTRATION SUSPENSION AND CANCELLATION

5.1 Under which situations is my Registration suspended ? What happens if my registration is suspended ?

The Registration is suspended for 15 days when:

- The Registration Continuity or Renewal was untimely requested;
- The Registration Continuity or Renewal was timely requested, however the non-conformity(ies) identified during the stage were not remedied by the Supplier within 15 days;
- Denunciation or audit procedure identify irregularities in the product.

During the suspension of the Registration, the Supplier is prevented from manufacturing and marketing the product.

5.2 Under which situations is my registration cancelled ? What happens if my registration is cancelled ?

The registration is cancelled when the Supplier, submitted to suspension, fails to remedy the non-conformities within 15 days.

Should the Registration be cancelled, the Supplier is prevented from manufacturing and marketing the product as of the cancellation date. Only with the grant of a new Registration shall the product be manufactured and marketed once again.

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