It sets forth the period up to twelve (12) months from the date when this Ordinance is published, for products certified according to Inmetro Ordinance No. 86, of April 3, 2006, published in the Federal Official Gazette of April 6, 2006, Section I, page 44, to comply with requirements approved herein.

Revoke Inmetro Ordinance No. 86/2006, twelve months after this Ordinance is published.

This Ordinance shall enter into effect when published in the Federal Official Gazette.

ATTACHMENT TO INMETRO ORDINANCE No. 350/2010

REQUIREMENTS OF COMPLIANCE ASSESSMENT FOR ELECTRIC EQUIPMENT UNDER THE HEALTH SURVEILLANCE SYSTEM

1 PURPOSE

These Compliance Assessment Requirements (RACs) set forth the criteria for the Compliance Assessment Program (PAC) for Electric Equipment under the Health Surveillance System, complying with the requirements of standards listed in the Supplementary Documents, aiming at the user's safety.

2 SUPPLEMENTARY DOCUMENTS

ABNT NBR IEC 60601-1 Medical Electrical Equipment - Part 1 - General Provisions for Safety and their Amendments

ABNT NBR IEC 60601-2-X (The entire series) Medical Electrical Equipment - Part 2 - Private Prescriptions for Equipment Safety

ABNT NBR ISO 13485:2004 Health Products - Quality Management Systems - Requirements for Regulatory Purposes

Anvisa's Normative Ruling 08/2009 - It sets forth technical standards adopted for compliance certification purposes of Medical Electrical Equipment under the Health Surveillance System.

Law No. 9933, of December 20, 1999 - It deals with Conmetro and Inmetro competences, establishing the Metrology Services Rate and provides for other measures.

Law No. 8078 of September 11, 1990 - It deals with consumer protection and provides for other measures.

Law No. 6437 of August 20, 1977 – It regulates about violations to the federal health legislation, sets forth the corresponding sanctions and makes other provisions.

Inmetro Ordinance No. 179 of June 16, 2009 – It approves, to be thoroughly complied with, the Regulation for use of Trademarks, Accreditation Symbols, Compliance Acknowledgment of Principles of Good Laboratory Practices (GLP) and Inmetro's Identification Seals.

The Joint Ministerial Ordinance MS/MDIC No. 692 of April 8, 2009 - It sets forth the operation of technical cooperation activities for the Quality Assurance and Safety of Medical Devices subject to the health control

system, as set forth in the Technical Cooperation Terms between the Ministry of Health (MS) and the Ministry of Development, Industry and Foreign Trade (MDIC).

Anvisa Joint Board Resolution - RDC/ANVISA - No. 32 – It establishes the compulsory certification of Medical Electrical Equipment under the Health Surveillance System and provides for other measures.

Anvisa Joint Board Resolution Anvisa - RDC/ANVISA - No. 59, of June 27, 2000 - It provides for requirements of Good Manufacturing Practices and Control of Medical Products.

3 ACRONYMS

ABNT	Brazilian Association of Technical Standards
ANVISA	The Brazilian Agency for Health Surveillance
CNPJ	National Registry of Legal Entities
CONMETRO	National Board of Metrology, Standardization and Industrial Quality
CT	Technical Committee
DIPAC	Division of Compliance Assessment Programs (Inmetro)
DQUAL	Quality Board (Inmetro)
IEC	International Electrotechnical Commission
INMETRO	National Institute of Metrology, Standardization and Industrial Quality
IN	ANVISA Normative Ruling
ISO	International Organization for Standardization
MOU	Memorandum of Understanding
MDIC	Development, Industry and Foreign Trade Ministry
NBR	Registered Brazilian Standards
OCP	Product Certification Body Accredited by INMETRO
RAC	Requirements for Compliance Assessment
RDC	Joint Board Resolution
RMP	Product Master Record (RMP)
RTQ	Quality Technical Requirements
SBAC	Brazilian System of Compliance Assessment
SGQ	Quality Management System
VISA	Health Surveillance

4 DEFINITIONS

For the purposes of this RAC, the following definitions shall be used:

4.1. Compliance Certificate

Issue of a statement, based on a decision reached after careful review that compliance with specified requirements has been demonstrated

4.2. Original Characteristics

It comprises technical specifications, usage indication and purpose, physical characteristics, including a list of critical components and accessories, chemical characteristics (where applicable), the content of accompanying documents and markings on the equipment, which are the equipment design characteristics, when the product certification is granted. It shall also correspond to the equipment characteristics registered or to be registered with Anvisa.

4.3. Certification Committee

The OCP technical committee comprised by representatives of the applicants' class entities, users, and standardization bodies, all of which shall have an accredited training on the Medical Electrical Equipment under

the Health Surveillance rule. This committee has a permanent and advisory nature, the function of which is reviewing certification processes and assisting in the granting, maintenance, extension, reduction, warning, suspension or cancellation of certifications.

4.4. Authorized Company
An authorized company is the product manufacturer or importer.

4.5. Type Test
A test performed in one or more units, manufactured according to a particular design, in order to demonstrate that such design meets the specified conditions of ABNT standards adopted by this RAC.

4.6. Routine Test
A test, to which, each manufactured unit is submitted, during or after manufacturing, in order to verify whether it meets the conditions specified by this RAC.

4.7. Electrical Equipment under the Health Surveillance System
Electrical Equipment under the Health Surveillance System, including parts and accessories, are those energized by an electric or internal power supply with medical, dental, laboratory and physiotherapeutic purposes, directly or indirectly used for diagnosis, treatment and monitoring in humans, as well as for beautification and aesthetics purposes.

4.8. Manufacturer
The manufacturer is the legal entity in charge of a medical product design, manufacture, packaging and labeling, a system assembly or a product adaptation, before it is placed in the market or it starts operation, regardless of whether such operations are performed by such person or on its behalf by a third party.

4.9. Family
The family characterization is as set forth in Attachment D of this RAC.

4.10. Importer
It is the legal entity responsible for international goods entering in the domestic territory, with the responsibility to ensure that routine tests are performed according to this RAC.

4.11. Test Laboratory
A public, private or mixed entity, accredited by Inmetro, according to criteria it sets forth, in order to perform tests based on the principles and policies adopted as part of the SBAC.

4.12. Master List of Quality Documents
This list is the index or equivalent procedures where all quality system documents are listed (procedures, work instructions, etc.), where versions of documents in effect are indicated.

4.13. Production Batch
The amount of products produced in a manufacturing cycle, with homogeneity being the main characteristic.

4.14. Model or Type
A name given by the applicant to distinguish products.

4.15. Product Certification Body (OCP)
A third-party public, private or mixed entity accredited by Inmetro, according to criteria it sets forth, in order to perform services for product compliance assessment, based on principles and policies adopted as part of the Brazilian System of Compliance Assessment (SBAC).

4.16. Product Master Record (RMP)

The RMP is a compilation of records containing the product complete drawings, its formulation and specifications, manufacturing and purchasing procedures and specifications, quality system procedures and requirements and finished product procedures concerning packaging, labeling, technical assistance, maintenance and installation.

4.17. Design History Record (RHP)
The RHP is a record compilation containing the complete history of a design finished product.

4.18. Compliance Assessment Requirement (RAC)
A document containing specific rules, which sets forth a systemic handling for the compliance assessment of products, processes, services, people or Quality Assurance Systems, in order to provide an adequate reliability level in relation to requirements set forth in the standard or RTQ.

4.19. Compliance Identification Seal
A graphic representation to identify objects with assessed compliance within the SBAC, according to attachment C.

4.20. Series
A name given by the applicant to unequivocally identify each unit produced.

4.21. Applicant
A public or private, domestic or foreign, individual or legal entity, legally incorporated in the country, which performs the following activities: production, assembly, creation, construction, transformation, import, free or not free distribution, or marketing of Electric Equipment under the Health Surveillance System, as covered by this RAC. It is in charge of applying for the product certification with the OCP, which holds the concession of use of the Compliance Identification Seal.

4.22. Pilot Unit
The pilot unit corresponds to one product unit or a set of units produced following the criteria established in the production process criteria in the product design

5 PROCEDURES FOR COMPLIANCE ASSESSMENT

5.1 The compliance assessment procedure used in Electric Equipment under the Health Surveillance system set forth by this RAC is the voluntary certification, except for products for which the Regulation Agency, Anvisa, requires compulsory certification by means of the IN/Anvisa in effect.

5.2 This RAC sets forth the Model with a Quality Management System Assessment of the product manufacturing process and the product (type and routine) tests. At any time, verification tests related to compliance maintenance can be performed during the certification effectiveness.

5.3 Stages of the compliance assessment process, described under item 6, shall be performed by Product Certification Bodies (OCP).

6 STAGES OF THE COMPLIANCE ASSESSMENT PROCESS
This chapter sets forth the compliance assessment process for granting and maintaining the authorization to use the Compliance Identification Seal.

6.1 A Model with a Quality Management System Assessment of the Product Manufacturing Process and Product Tests

6.1.1 Initial Assessment

6.1.1.1. Process Initial Application

The applicant shall submit a formal application to OCP, featuring the name and characteristic of the product to be certified, by attaching the product technical documentation, including the user's manual and a descriptive memorial, containing clear instructions for use and the target audience to which the equipment is intended to, as well as the manufacturer's Quality Assurance System (SGQ) documentation (quality manual and master list of quality documents), all of them at the latest version.

6.1.1.2 Application and Documentation Review

OCP, before starting the certification service, shall review the application and assess the forwarded documentation concerning the compliance and compatibility with express requirements in this RAC, including the ones related to the product manufacturing process. If the certification application is deemed impracticable, OCP shall formally inform the applicant the reason for the service infeasibility, by technically justifying based on the application scope of technical rules adopted and the equipment characteristics, as well return all documents submitted.

Note: The final decision on applying the compulsory certification to the product, under the terms of this RAC, is Anvisa's, according with the IN in effect.

6.1.1.3. Initial Tests (Type Tests)

Tests shall be performed and recorded, taking into account the following stages:

6.1.1.3.1. Definition of Tests to Be Performed

6.1.1.3.1.1. Type tests shall be performed on the product according to applicable technical standards listed under item 2 of this RAC in the collected samples, as stated under item 6.1.1.3.3.

6.1.1.3.1.2. The type test shall be fully performed in the pilot unit or in the sample from the equipment production line, under the certification process.

6.1.1.3.1.3. In the initial assessment, reports of the equipment type tests tested in Brazil or abroad shall be accepted provided that the issue date of test reports does not exceed 2 (two) years and that all changes made to the design are properly documented and relevant tests have been performed and documented.

6.1.1.3.1.3.1. If no changes have been made to the design during that period, the manufacturer of the equipment undergoing the certification process, whether domestic or foreign, shall send the document stating that the product was not changed after the test report issue date, therefore, no new tests are to be performed.

6.1.1.3.1.3.2. OCP shall assess the submitted test report of the equipment initial design for which the report was issued, and the equipment current design, in order to verify the compliance of the test report with the equipment current design. This assessment shall be documented and included in the documentation of the equipment certification process.

6.1.1.3.2. Definition of Laboratory

OCP is responsible for selecting the laboratory to be hired to perform tests on the test type, related to the product certification process, under a common agreement with the applicant, complying with the provisions of Section 12 of this RAC.

6.1.1.3.3. Definition of Sampling

6.1.1.3.3.1. OCP shall use a representative sample of the product to be certified, in the compliance assessment process.

6.1.1.3.3.1.1. A representative sample must be a pilot unit or which is already in the production line.

6.1.1.3.3.1.2. In cases of equipment family certification, a family representative sample must be selected by the most critical configuration model.

6.1.1.3.3.2. For a product already in the production line, collection performed at the production plant shall mean that OCP shall randomly select a product that has been inspected and released by the plant quality control, in a package ready for marketing. If other samples are required, the same procedure shall be used for selection.

6.1.1.3.3.3. In case of pilot units, the manufacturer can collect and send the sample to the laboratory or OCP itself, upon mutual agreement between the parties and under OCP's responsibility. If other samples are required, the same procedure shall be used for selection.

6.1.1.3.3.3.1. The approval of the pilot unit in initial tests does not exempt OCP from validating products, after the production line operation is started.

6.1.1.4. Initial Audit

After evidencing compliance in relation to items 6.1.1.2 of this RAC, OCP shall plan the audit of the manufacturer's Quality Assurance System (SGQ), upon mutual agreement with the applicant.

6.1.1.4.1. In order to perform the initial audit aiming at assessing the plant SGQ, it is necessary:

a) Verify compliance with requirements detailed in Attachment B to this RAC;
b) Confirm that routine tests, as described in Attachment A, are performed by the manufacturer in 100% of the units produced;
c) Monitor manufacturing of product models included in the certification scope;
d) Assess the RHP and RMP of the product to be certified.

6.1.1.4.2. During the audit, the manufacturer shall submit, if any, a copy of the audit/inspection reports of its Quality Assurance System (SGQ), respectively issued by an OCP or a health authority in Brazil (ANVISA, VISAs etc.) as well as records of corrective actions implemented, when found.

6.1.1.4.3. If the manufacturer maintains a certification of its Quality Assurance System (SGQ) within the SBAC, according to ABNT NBR ISO 13485:2004 standard or the Certificate of Good Manufacturing and Control Practices issued by ANVISA , according to RDC/ANVISA No. 59/00, the certification may be accepted instead of the required inspections set forth in Attachment B, provided that OCP is able to demonstrate in the latest audit report of such certifications that requirements set forth in Attachment B have been verified and are compliant. In both cases, the certificate shall be valid.

6.1.1.4.3.1. In case the ABNT NBR ISO 13485:2004 or RDC/ANVISA No. 59/00 standard is used, audits performed by OCP shall only assess sub-items "b", "c" and "d" of Item 6.1.1.4.1.

6.1.1.5. Compliance Certificate Issue

This stage shall be performed when all requirements of items 6.1.1.1, 6.1.1.2, 6.1.1.3 and 6.1.1.4 of this RAC are complied with.

6.1.1.5.1. The certificate shall only be granted to an applicant that has all non-compliances removed from its process.

6.1.1.5.2. Once the product is compliant, OCP shall formalize the authorization concession to use the Compliance Identification Seal for a period of five (5) years, as provided for in Chapter 9, for the product(s) meeting criteria set forth in this RAC.

6.1.1.5.3. OCP shall submit the entire certification process to the Certification Committee, without any exception, when all requirements of this RAC are complied with. OCP shall only decide to grant certification after the Certification Committee issues its opinion about the process.

6.1.1.5.4. The decision reached by the Certification Committee does not exempt OCP from its responsibility in granting certifications.

6.1.1.5.5. The certificate shall contain, at least the following information:
a) Corporate name and the Corporate Taxpayer Registry Number (CNPJ) as well as the trade name, where applicable, of the authorized company and the manufacturer;
b) Full address of the authorized company and the manufacturer;
c) The certificate identification (number);
d) The OCP full data (name, accreditation number and signature);
e) Data about the certified product specifying its trade name and certified models;
f) Identification of test laboratory(ies) and testing report(s), with their issue date(s);
g) Original issue date (first certificate concession), revision date and validity date;
h) Identification of technical standards applied for certification;
i) List of accessories and parts tested jointly with the product;
j) Version of the user's manual of the product design, assessed to be granted the certification;
k) Version of the software evaluated, for equipment with embedded or accompanying software.

6.1.1.5.5.1. In cases in which the audited site consists of a manufacturer contracted by the product manufacturer to perform manufacturing under its responsibility, the contracted manufacturer's address, company name and Corporate Taxpayer Registry Number (CNPJ) (where applicable) shall be included in the issued certificate.

6.1.1.5.5.2. The certificate may be comprised by multiple pages and shall not contain any attachments. Pages shall be numbered and each page shall contain the certificate number and its issue date. The first page shall indicate the number of pages comprising the entire certificate.

6.1.2. Maintenance Assessment
Certification maintenance is performed to verify, by means of assessments, that conditions leading to the initial concession authorization for using the Compliance Identification Seal are maintained. Performing maintenance compliance assessment services is under OCP's sole responsibility.

6.1.2.1. Maintenance Assessment Planning

6.1.2.1.1. The certification maintenance process is contained in the annual assessment of requirements set forth in Attachments A, B and C to this RAC. At any time, Inmetro or Anvisa may request that type tests are performed to check for compliance maintenance of certified products.

6.1.2.1.2. Provided that there are justifiable evidences, OCP is authorized to perform additional audits.

6.1.2.2. Maintenance Tests
This item sets forth the required tests to prove that the product subject to the compliance assessment, after the initial assessment compliance certificate is issued, remains compliant with regulatory requirements set forth in this RAC. Maintenance tests shall be performed and recorded, taking into account the following stages:

6.1.2.2.1. Definition of Tests to Be Performed

6.1.2.2.1.1. Every year, OCP shall select a sample representing the certified product, according to item 6.1.1.3.3.2, to monitor the implementation of routine tests, Attachment A, and ensure compliance. These tests can be performed at the manufacturer's facilities. If the product to be certified is made to order, OCP must be prepared to monitor the implementation of routine tests, Attachment A, and check compliance with the product compliance.

6.1.2.2.1.2. OCP shall demonstrate that the product is unchanged if compared to the original characteristics assessed in the certification concession, by assessing the Product Master Record (RMP) and the Design History

Record (RHP) (e.g., a comparison between the lists of components submitted during concession and maintenance, found at the production line and verify by physical means, such as external and internal pictures of the product and/or technical drawings of the production line, among other findings).

6.1.2.2.1.3. If design changes or upgrade of parts, pieces, components or software versions are seen, the impact of such changes in the product certification shall be verified. If new type tests are required for a product representative sample, they shall be performed according to the applicable rules listed under item 2 of this RAC.

6.1.2.2.1.4. When the product is not sent for further testing, despite the changes found, OCP shall prepare a report justifying each change made, based on technical and scientific knowledge, explaining why the product was not sent for new new type tests to be performed. A copy of this report shall be retained by the authorized company.

6.1.2.2.1.4.1. This report shall be part of the maintenance process to be verified by the Certification Committee, according to item 6.1.2.4.3.

6.1.2.2.1.5. At anytime, Anvisa or Inmetro may request type tests to be performed, set forth according to items 6.1.1.3 during the certificate effectiveness, in order to check the equipment compliance maintenance.

6.1.2.2.2. Definition of Laboratory

OCP is responsible for selecting the laboratory to be hired to perform tests on the product certification maintenance process, under a common agreement with the applicant, complying with the provisions of Section 12 of this RAC.

6.1.2.3. Maintenance Audit

6.1.2.3.1. For a maintenance audit aiming at assessing the manufacturer's Quality Assurance System (SGQ), it is necessary to:

a) Verify compliance with requirements detailed in Attachment B to this RAC;
b) Confirm that routine tests, as described in Attachment A, are performed by the manufacturer in 100% of the units produced;
c) Monitor manufacturing of product models included in the certification scope;
d) Assess the RHP and RMP changes of the certified product.

6.1.2.3.2. If the manufacturer maintains certification for its Quality Assurance System (SGQ) within the SBAC, according to ABNT NBR ISO 13485:2004 standard or a Certificate of Good Manufacturing and Control Practices issued by ANVISA, according to RDC/ANVISA No. 59/00, this certification may be accepted instead of the required verifications provided for in Attachment B, provided that OCP may prove, in the last audit report of such certifications, that the requirements provided for in Attachment B have been verified and are compliant. In both cases, the certificate shall be valid.

6.1.2.3.2.1. In case the ABNT NBR ISO 13485:2004 or RDC/ANVISA No. 59/00 standard is used, audits performed by OCP shall only assess sub-items "b", "c" and "d" of Item 6.1.2.3.1.

6.1.2.4. Compliance Maintenance Formalization

This stage shall be performed when all requirements of this RAC are complied with.

6.1.2.4.1. Certification shall only be maintained for an authorized company that has all non-compliances removed from its process.

6.1.2.4.2. If the product complies with the criteria set forth in this RAC, OCP shall formalize the authorization maintenance to use the Compliance Identification Seal, as set forth in Chapter 9.

6.1.2.4.3. OCP shall submit the entire certification maintenance process to the Certification Committee, without any exception, after all maintenance requirements of this RAC are complied with. OCP shall only decide to maintain the certification after the Certification Committee issues its opinion about the process.

6.1.2.4.4. The decision of not granting the certification maintenance results in immediate certificate suspension and therefore, the disempowerment to use the Compliance Identification Seal for the rejected product. Other actions may also occur, such as the product withdrawal from the market (recall).

6.1.3. Handling Deviations in the Compliance Assessment Process

If any activity performed by OCP identifies non-compliance, OCP shall issue a non-compliance report by sending it to the authorized company/applicant, so the required actions are taken, in order to remedy the non-compliance.

6.1.3.1. Handling Non-Compliances in the Initial Assessment Process

In case of product rejection in the type test, the manufacturer shall implement corrective actions in its process and submit implementation evidences before new tests are performed. If non-compliances are found in the manufacturer's Quality Assurance System (SGQ), it shall implement the required corrective actions to its system adequacy, and implementation evidences shall be submitted to OCP.

6.1.3.1.1. OCP shall assess whether it is necessary to conduct a new audit to verify the implementation of corrective actions and whether non-compliances have been properly dealt with.

6.1.3.2. Handling Non-Compliances in the Maintenance Process

Rejected products, in possession of the authorized company, shall be destroyed while monitored by OCP, unless it is possible to reprocess them.

6.1.3.2.1. This decision shall be properly grounded to ensure that non-compliant products or products with threatened safety are not marketed. Records of the authorized company and the manufacturer shall be provided to OCP, so that a review of such rejections is performed. Certification and, as a result, the authorization to use the Compliance Identification Seal on the rejected model shall be suspended until all the corrective actions are implemented by the company.

6.1.3.2.2. If non-conformities are found during the maintenance testing performed in the certified product, OCP shall evaluate the need for new type tests, according to item 6.1.1.3 in a laboratory chosen according to item 12 of this RAC, in a representative sample of the product. This decision shall be documented and included in the documentation of the product certification process.

6.1.3.3. Handling Non-Compliant Products in the Market

In the event non-compliant products are distributed or sold, OCP shall monitor the process of replacing or repairing the products sold/marketed, with the authorized company being held responsible for this action.

6.1.3.3.1. The non-compliance impact of risks associated with the use of the product shall be taken into account and the need for the non-compliant products to be withdrawn from the market or not, in case repair/correction is not possible. This decision shall be documented by OCP and integrate the documents of the product certification process.

6.1.3.3.2. If it is not a repairable product, non-compliant products shall be collected and destroyed while monitored by OCP. If there is the possibility of repairing the product, it must be submitted, after the repair, to all tests necessary for the release of a finished product, which evaluate if the non-conformity was duly repaired.

6.1.3.3.3. Tests referred to under item 6.1.3.3.2 can be performed by the manufacturer in its facilities, and their results shall be duly recorded, ensuring the traceability criteria required for the Quality Assurance System (SGQ) for medical products, RDC/ANVISA No. 59/00 and ABNT NBR ISO 13485:2004 standard.

7 HANDLING COMPLAINTS

The authorized company shall keep records of all complaints or failures brought to its attention, concerning the certified product, as well as take appropriate actions to meet the certification requirements, making them available to OCP, when requested.

7.1 A Complaint Handling Policy, signed by its chief executive, demonstrating that the company:

a) Values and effectively deals with complaints submitted by its customers;

b) Is aware and agrees to comply with and be subject to penalties provided by laws (Law No. 8078/1990, Law No. 9933/1999, or others.);

c) Encourages and reviews results, as well as takes appropriate actions, according to the complaint statistics received;

d) Sets responsibilities concerning how to handle complaints;

e) Compromises to answer to Inmetro about any complaint it has received, within the deadline set forth.

7.2 An individual or team, formally assigned, properly trained and free to handle complaints appropriately;

7.4 A Complaint Handling Procedure, which shall include a plain form to record customers' complaint, as well as track, investigate, answer, deal with and finalize the complaint.

7.5 Adequate records of each submitted and handled complaint.

7.6 An annual review of complaint statistics and implementation evidences of the corresponding corrective actions, as well as improvement opportunities.

8. COMPLIANCE IDENTIFICATION SEAL

The compliance identification within the SBAC indicates that the products covered by this Ordinance are aligned with the provisions of Inmetro Ordinance No. 179/2009 and according to the requirements and the compliance assessment procedures set forth in this RAC.

8.2 Specification

8.2.1 The Compliance Identification Seal is set forth in Attachment C to this RAC.

8.2.2 The Compliance Identification Seal shall meet the requirements of this RAC and shall be under the authorized company's responsibility. Inmetro may, at any time and hour, request samples of the manufactured seal, in order to verify their compliance.

8.3 Traceability

The authorized company shall implement a traceability control of the products bearing the Compliance Identification Seal, which shall be available for Inmetro, for a period of time equivalent to the product expected life cycle, but in no case it shall be less than five (5) years from the commercial distribution date by the manufacturer. OCP shall verify the implementation of this control, as well as the traceability effectiveness of such certified products.

9 AUTHORIZATION TO USE THE COMPLIANCE IDENTIFICATION SEAL

9.1 Authorization to use the Compliance Identification Seal has its validity associated with the validity set forth in the certification.

9.2 Authorization Concession

9.2.1 The authorization concession to use the Compliance Identification Seal is performed when the product complies with the criteria set forth in this RAC.

9.2.2 The authorization concession to use the Compliance Identification Seal shall be granted by submitting a formal instrument, the certificate, which shall contain at least the data referred to under item 6.1.1.5.5.

9.3 Authorization Maintenance

9.3.1 The authorization maintenance to use the Compliance Identification Seal is conditioned to the non-existence of any non-compliance during the maintenance assessment process, as set forth under sub-item 6.1.2 and 6.1.3.2 of this RAC.

9.4 Authorization Suspension, Cancellation or Renewal

The authorization cancellation, suspension or renewal, to use the Compliance Identification Seal shall occur when any of this RAC requirement is not complied with.

9.4.1 In case of certificate suspension or cancellation, as a result of non-compliance with any requirement set forth by this RAC, the authorization to use the Compliance Identification Seal shall be granted under the same condition. In such cases, the company holding the authorization shall stop using the Compliance Identification Seal, as well as any and all advertising it has in relation to it.

9.4.2 The interruption of this partial or full suspension is subject to verification by the authorized company of remedying the non-compliances, which caused the suspension.

9.4.3 The applicant bearing the authorization to use the canceled Compliance Identification Seal shall perform a new and complete certification process.

9.4.4 Upon the certification renewal, type tests shall only be repeated in the following situations:

a) After five (5) years from the test report issuance;
b) Changed revision of any technical standard used in the original test;
c) Changed equipment structure, which implies in product changes in relation to the previously assessed compliance;
d) Upon Anvisa's determination.

Note: under item 9.4.4.a, dealing with particular equipment, the regulatory body (Anvisa) may establish its own deadlines through a normative ruling.

10 RESPONSIBILITIES AND DUTIES

10.1 For the authorized company:

a. Maintain technical and organizational conditions, which were the basis for obtaining the authorization to use the Compliance Identification Seal.
b. Comply with all conditions set forth in this RAC, in legal provisions and contractual provisions concerning the certification, regardless of their transcription.
c. Notify any product changes to OCP with the assessed compliance, as well as to submit any performed changes to OCP's review and approval, before marketing the modified product.
d. Directly shoulder the technical, civil and criminal responsibilities regarding the product it sells, as well as all documents related to the compliance assessment, with no possibility of transferring such responsibility.
e. Accept relevant decisions reached by OCP, concerning certification, appealing to OCP in first instance and in second instance, with Inmetro's ombudsman services, in cases of complaints and appeals.
f. Accept all conditions set forth in the technical standards related to item 2 of this RAC, legal provisions and contractual provisions, related to the authorization, regardless of their transcription.
g. Make possible to OCP or its contractor, by proving such condition, the audit and monitoring works, as well as other testing and certification activities according to this RAC.
h. Apply the Compliance Identification Seal on every certified equipment, according to criteria set forth in this RAC.

i. Ensure that a certified product does not hold the same coding of a non-certified product (as per code and model).
j. Perform routine tests, according to Attachment A, in 100% of the manufactured units.
k. Perform type tests, according to item 6.1.1.3, by Anvisa's or Inmetro's resolution, for evidencing the compliance maintenance of certified products.
l. Ensure that RHP and RMP are continuously updated, at any certification time, under penalty of certification suspension or cancellation.
m. Immediately report to Inmetro if the product manufacture, import or marketing is stopped.
n. Inform OCP when the equipment manufacture, marketing and/or import is definitely stopped, for which it holds the authorization to use the Compliance Seal.
o. Comply with other legal requirements of the product manufacture, import and marketing, under penalty of suspending or canceling the certificate.
p. Use the compliance identification in advertisements, after due authorization by the Quality Board (Dqual), http://www.inmetro.gov.br/qualidade/autSelo.asp, provided it makes it clear which products actually had their compliance assessed, besides presentating the advertising materials to be disclosed, as per Inmetro Ordinance No. 179/2009.

10.2 For OCP

a) Implement the compliance assessment program, as provided for in this RAC, according to requirements set forth herein, mandatorily settling all questions before Inmetro.
b) Use the database system provided by Inmetro, in order to keep information about certified products updated.
c) Immediately notify Inmetro and Anvisa regarding the certification suspension, extension, reduction and cancellation.
d) Submit Memoranda of Understanding to Inmetro for review and approval, within the scope of this RAC, set forth with other certification bodies.
e) Accept any penalties imposed by the product regulatory bodies.
f) Transfer to the authorized company the requirements set forth by Inmetro, which has an impact on it.
g) Take responsibility for selecting and contracting third parties, such as a laboratory, a product and plant assessment body.
h) For tests performed by foreign laboratories, upon the consent of the regulatory body, the test method equivalence, voltage and supply frequency of the tested equipment, as well as sampling methodology used shall be complied with. Additionally, these laboratories shall be accredited by Inmetro or by an Accreditation Body, which has entered into one of the following mutual acknowledgment agreements, of which Inmetro is participant.
i) Keep in its e-mail address, a clear and easy-to-reach list of all certificates issued with an electronic copy, enabling to fully read texts and information regarding such certificates, or by means of queries to reports extracted from a database, containing all the information included in the certificates issued.
j) Monitor the publication of adverse event notices at the website of the regulatory body (Anvisa), associated with certified products. OCP shall assess whether the published adverse event impacts such certification; if so, it shall take appropriate measures with the authorized company to monitor corrective actions taken to remedy the problem that caused the adverse event. This action shall be documented and be part of the product certification process documentation.
k) Monitor and implement determinations of the regulatory body (Anvisa), regarding the need for type tests in a certified product.
l) Issue consolidated reports and other documents when required by the regulatory body (Anvisa).

11 PENALTIES

11.1 The authorized company or applicant misusing and/or making abusive use of the Compliance Identification Seal shall be subject to penalties, according to Inmetro Ordinance No. 179 of June 16, 2009.

11.2 The authorized company failing to meet the requirements of this RAC is subject to penalties of certification suspension and cancellation, set forth and operationalized, according to the OCP and Inmetro certification systems.

11.3 Within the SBAC's scope, the following shall be considered as violations subject to penalties, among others:

a) provide products with quality standards not complying with the Compliance Identification Seal set forth in this RAC;
b) use the Compliance Identification Seal on non-authorized products;
c) not to inform, or provide false information regarding certified products;
d) prevent the auditors' access to the system documents and records;
e) not to accept the verification and collection within deadlines set forth in this RAC.

11.4 For products subject to registration with Anvisa, failure to comply with this RAC, in the reasonable items, is subject to the penalties set forth in Law No. 6437/77 and Art. 273 of the Brazilian Criminal Code - Law No. 2848/40.

12 TESTING LABORATORY USE

12.1 Type tests planned to assess the compliance of this RAC shall be performed by a third-party laboratory accredited by Inmetro, for the scope provided for in this RAC.

Note: If a single laboratory is not able to perform all required tests, more than one laboratory can be used, according to the criteria set forth under item 12 of this RAC.

12.2 Under an exceptional and precarious nature, since it depends on the assessment by OCP, a non-accredited laboratory can be used for that particular scope, if one of the cases set forth below occur:

a) When there is not a laboratory accredited by Inmetro for part of the product Compliance Assessment Program scope.
b) When the laboratory(ies) accredited by Inmetro does(do) not answer within six (6) months at most, the deadline to start the tests described in the RACs, from the day when the agreement is signed.

12.2.1 An assessment performed by OCP in the laboratory not accredited by Inmetro shall be performed by an OCP's professional, who has records of at least 3 audits in the past three successive years, according to the ABNT NBR ISO/IEC 17025:2005 standard.

12.2.2 OCP shall obtain objective evidences that the laboratory not accredited by Inmetro is able to perform all tests required by the regulations set forth in this RAC.

Note: If a single laboratory is not able to perform all required tests, more than one laboratory can be used, according to the criteria set forth under item 12 of this RAC.

12.3 Shall any of the cases above apply, OCP must follow the priority order below, when selecting a laboratory not accredited by Inmetro, provided that it is qualified for that particular scope:

a) A third-party laboratory accredited to another test scope(s);
b) A first-party accredited laboratory;
c) A third-party non-accredited laboratory;
d) A first-party non-accredited laboratory;

12.4 Taking into account the possibilities described in sub-items 12.2 and 12.3, OCP shall record, using evidential documents, the reasons to select such laboratory.

12.5 For tests performed by foreign laboratories, the testing method and the sampling methodology equivalence shall be complied with in this RAC. Additionally, these laboratories shall be accredited by Inmetro or by an Accreditation Agency, which has entered into one of the following mutual acknowledgment agreements, in which Inmetro is participant:

a) Interamerican Accreditation Cooperation – IAAC
b) European Cooperation for Accreditation – EA
c) International Laboratory Accreditation Cooperation – ILAC

Notes:
1) The list of accredited laboratories can be obtained by accessing Inmetro website at www.inmetro.gov.br, for cooperations and agencies which have entered into such agreements;
2) The laboratory accreditation scope shall include the testing method applied under the scope of this RAC;
3) Testing reports issued by the laboratory shall contain clear and unambiguous identification of its status as an accredited laboratory.

13 ACTIVITIES PERFORMED BY FOREIGN OCPs

13.1 Compliance assessment activities performed by a foreign body can be accepted, provided that all of the following conditions are met:
a) The Product Certification Body (OCP) in Brazil, accredited by Inmetro, shall have a Memorandum of Agreement (MOU) with the foreign body;
b) The foreign body shall be accredited by the same international rules adopted by Inmetro for the same or equivalent scope;
c) Activities performed abroad shall be equivalent to those regulated by Inmetro;
d) The body accredited by Inmetro shall issue the authorization to use the Compliance Identification Seal according to the Brazilian regulation and shall bear all responsibilities for activities performed abroad and resulting from this issuance, as if it had performed all activities itself;
e) The Brazilian OCP, accredited by Inmetro, shall be in charge of judging and granting permits, maintenance and renewal of authorizations for using the Compliance Identification Seal, and
f) Inmetro shall approve the MOU.

13.2 In case the assessment is performed by a foreign OCP and does not include all requirements set forth in this RAC, OCP shall complement the assessment by performing the requirements not complied with.

14. CERTIFICATION PROCESS CLOSURE

14.1 OCP shall schedule a special audit to verify and record the following requirements:
· The number of items and the manufacture date of the last production batch;
· The material available in stock for new productions;
· The quantity of finished products in stock and authorized company's forecast for this batch to be consumed;
· If the requirements set forth in this regulation have been met since the latest monitoring audit;
· Sample collection for the process final tests, according to Attachment A to this RAC.

14.2 OCP shall also schedule the process closure tests. These tests are those that would be performed at the posterior maintenance assessment.

14.3 If the result of such tests presents any non-compliance, OCP, before considering the process as canceled, shall request from the authorized company the corresponding handling, as set forth under item 6.1.3 of this RAC.

14.4 Results of this audit and of the closure tests shall be documented and comprise the documentation of the product certification process.

14.5 After completing the stages above, OCP shall notify this cancellation to its Certification Committee, Inmetro and Anvisa.

ATTACHMENT A - ROUTINE TESTS

A.1 Routine tests shall be conducted according to the requirements set forth in clauses 18, 19 and 20 of ABNT NBR IEC 60601 - 1:1994 and amendment 1:1997, in addition to checking product operation, which is the subject matter of the certification, specifically:

a) Equipment operation (items to be checked will be the subject matter according to OCP and the manufacturer, in order to ensure the safety of the product, which is the certification subject matter, according to its purpose).
b) Grounding (clause 18);
c) Leakage current (clause 19);
d) Dielectric strength (clause 20).

A.2 Routine tests for dielectric strength shall be conducted according to the requirements set forth in clause 20 of ABNT NBR IEC 60601 - 1:1994 and amendment 1:1997. The time specified in this clause may be reduced, according to the manufacturer's preference, provided that such application is duly justified by the manufacturer and agreed with the OCP.

ATTACHMENT B - TECHNICAL REQUIREMENTS FOR QUALITY SYSTEM ASSESSMENT, ACCORDING TO ABNT NBR ISO 13485:2004

B-1 At the initial assessment and maintenance stages of the manufacture Quality Assurance System (SGQ) using the ABNT NBR ISO 13485:2004 standard for the product(s) subject to the certification, it is necessary to verify the compliance with the requirements listed below:

4.2.3 Document Control
4.2.4 Registration Control
7.1 Product Implementation Planning
7.2.3 Communication with the Client *(ref. Handling Customers' Complaints 7.2.3. c)*
7.3.6 Design Validation and Development
7.3.7 Control of Design Changes and Development
7.4.3 Verification of Purchased Product
7.5.1 Control of Production and Service Providing
7.5.2 Validation of Production Processes and Service Providing
7.5.3 Identification and Traceability
7.5.5 Product Preservation
7.6 Control of Measuring and Monitoring Devices
8.2.3 Process Measuring and Monitoring
8.2.4 Product Measuring and Monitoring
8.3 Non-Compliant Product Control
8.5.2 Corrective Action

ATTACHMENT C - CERTIFICATION IDENTIFICATION UNDER THE SCOPE OF SBAC

C.1 The identification of the certified product, according to this RAC, must contain the information set forth in this Attachment and according to the scope, either compulsory or voluntary.

C.2 The authorized company shall comply with the following guidelines in order to use the Compliance Identification Seal:

a) The seal, according to Figure 1a, can only be used on products listed in the existing IN/Anvisa, which sets forth technical standards adopted for compliance certification of Medical Electrical Equipment, under the Health Surveillance System;
b) The seal can be printed on the package or a label can be used, with indelibility and permanence characteristics, provided that it meets the minimum dimension required, as set forth in Figure 1a and 1b of this RAC;
c) When the Compliance Identification Seal is stamped, printed or inserted on the product by means of a label, according to Figure 1a and 1b of this RAC, and does not fit the Medical Electrical Equipment front part, it may be affixed on other parts;
d) The black and white version can be used on the package, only if its color is similar to the colored seal.

C.3 OCP shall ensure that the Compliance Identification Seal placement is performed in an indelible, permanent and visible manner, as well as the possibility of Medical Electrical Equipment under the Health Surveillance System to be tracked by sequential numbering, or otherwise, as set forth by OCP upon mutual agreement with the authorized company.

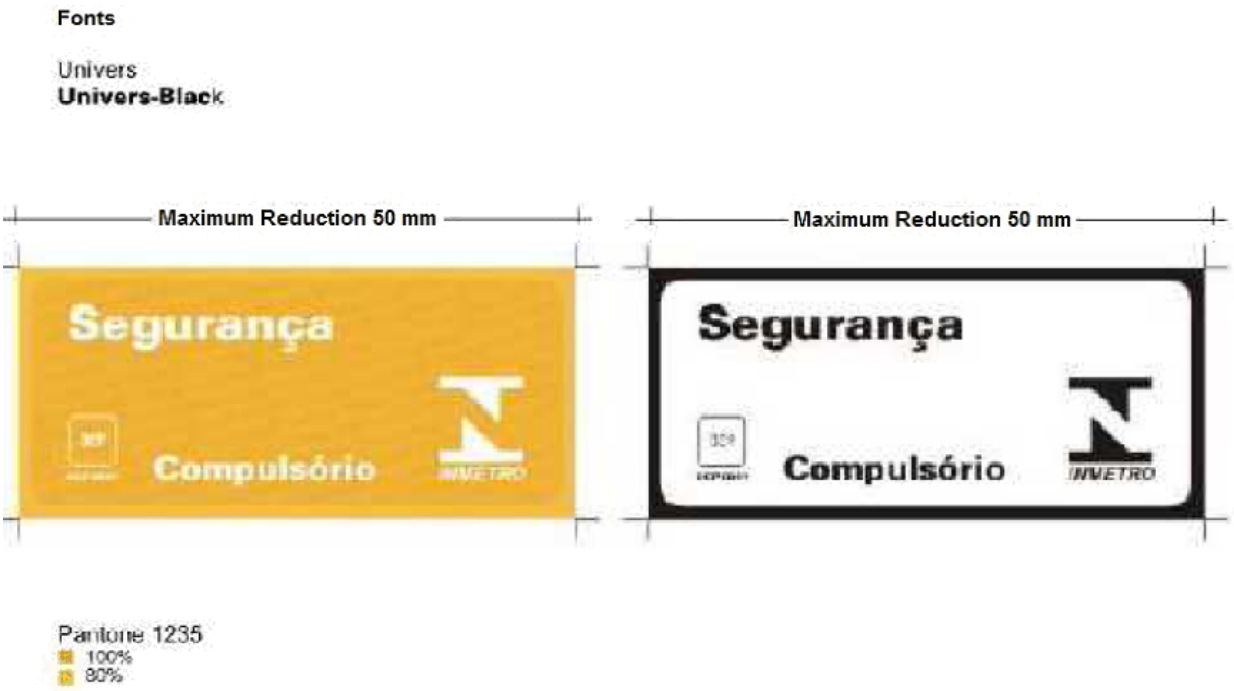
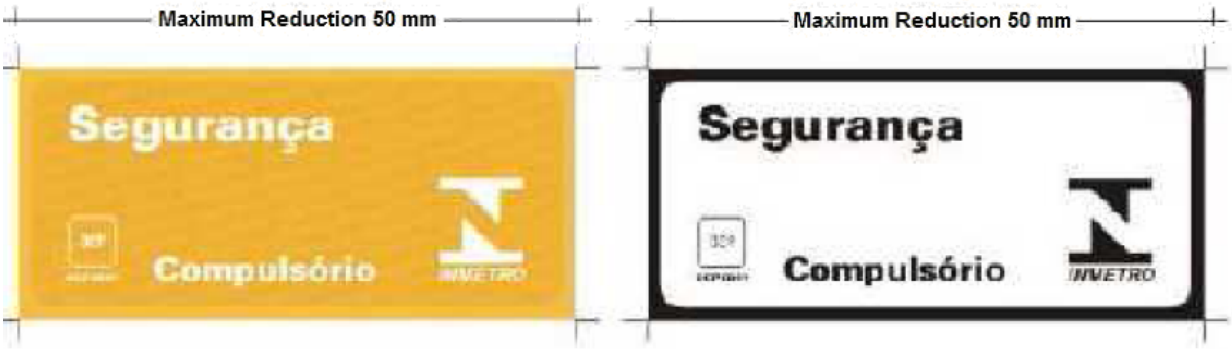


Figure 1a - For compulsory

Fonts

Univers
Univers-Black



Pantone 1235
100%
80%

Figure 1b - For voluntary

Figure 2: Compact seal

ATTACHMENT D - FAMILY DESCRIPTION