Ordinance No. 350, of September 6, 2010

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

Inmetro Ordinance No. 86/2006 shall be revoked twelve months after this Ordinance is published. This Ordinance shall enter into effect on the date of its publication.

ATTACHMENT TO INMETRO ORDINANCE No. 350/2010

REQUIREMENTS FOR COMPLIANCE ASSESSMENT OF ELECTRICAL EQUIPMENT SUBJECT TO THE HEALTH SURVEILLANCE SYSTEM

1 PURPOSE

These Compliance Assessment Requirements (RACs) set forth the criteria for the Compliance Assessment Program (PAC) of Electrical Equipment subject to the Health Surveillance System, complying with the requirements of the standards listed in item “Complementary Documents” and focusing on the user’s safety.

2 COMPLEMENTARY DOCUMENTS

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

NBR IEC 60601-2-X (The entire series) Medical Electrical Equipment - Part 2 - Special Provisions for Equipment Safety

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

Anvisa’s Normative Instruction 08/2009 - sets forth the technical standards adopted for compliance certification of Electrical Equipment subject to the Health Surveillance System.

Law No. 9933, of December 20, 1999 – makes provisions on Conmetro’s and Inmetro’s competences, establishes the Metrology Services Fee and makes other provisions.

Law No. 8078, of September 11, 1990 – makes provision on the consumer’s protection and makes other provisions.

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

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

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

as laid down in the Technical Cooperation Agreements between the Ministry of Health (MS) and the Ministry of Development, Industry and Foreign Trade (MDIC).

Anvisa RDC - No. 32, of May 29, 2007 – establishes the compulsory certification of Medical Electrical Equipment subject to the Health Surveillance System and makes other provisions.

Anvisa RDC - No. 59, of June 27, 2000 – makes provisions on the requirements for Good Manufacturing and Control Practices of Medical Products.

3 ACRONYMS

ABNT	Brazilian Association of Technical Standards
ANVISA	Brazilian Health Surveillance Agency
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's Normative Instruction
ISO	International Organization for Standardization
MOU	Memorandum of Understanding
MDIC	Ministry of Development, Industry and Foreign Trade
NBR	Registered Brazilian Standards
OCP	Product Certification Body Accredited by INMETRO
RAC	Compliance Assessment Requirements
RDC	Collegiate Board of Directors' Resolution
RMP	Product Master Record
RTQ	Quality Technical Requirements
SBAC	Brazilian Compliance Assessment System
SGQ	Quality Management System
VISA	Local Health Surveillance Body

4 DEFINITIONS

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

4.1. Certificate of Compliance

Issuance of a statement, based on a decision reached after the critical analysis that the compliance with specified requirements has been demonstrated

4.2. Original Characteristics

It comprises technical specifications, indication for use, intended use, physical characteristics, including a list of critical components and accessories, chemical characteristics (if applicable), the content of the enclosed documents and markings on the equipment, which are all the equipment design characteristics in the moment the product certification is granted. They shall also correspond to the equipment's characteristics registered or to be registered at Anvisa.

4.3. Certification Committee

OCP's technical committee, composed by representatives of the applicants' class entities, users, and standardization bodies, all of which shall have an accredited training on Medical Electrical Equipment subject to the Health Surveillance System. 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

Manufacturer or importer of the product.

4.5. Type Test

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 herein adopted.

4.6. Routine Test
Test to which every manufactured unit is submitted during or after manufacturing in order to verify whether it meets the conditions herein specified.

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

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

4.9. Family
The characterization of a family is set forth in Annex D of this RAC.

4.10. Importer
Legal entity responsible for the entrance of international goods into the national territory, with the responsibility to ensure that routine tests are performed according to this RAC.

4.11. Testing Laboratory
Public, private or mixed entity, accredited by Inmetro according to the criteria set forth by this autarky, in order to perform tests based on the principles and policies adopted within the scope of the SBAC.

4.12. Master List of Quality Documents
Index or equivalent procedures in which all quality system documents are listed (procedures, work instructions, etc.) and the versions of these documents in force are indicated.

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

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

4.15. Product Certification Body (OCP)
Third-party public, private or mixed entity, accredited by Inmetro according to the criteria set forth by this autarky in order to perform product compliance assessments based on the principles and policies adopted within the scope of the Brazilian Compliance Assessment System (SBAC).

4.16. Product Master Record (RMP)

Compilation of records containing the product's complete drawings, its formulation and specifications, manufacturing and purchase procedures and specifications, quality system requirements, and the procedures related to finished products' packaging, labeling, technical assistance, maintenance, and installation.

4.17. Design History Record (RHP)
Compilation of records containing the complete history of the design of a finished product.

4.18. Compliance Assessment Requirement (RAC)
Document containing specific rules that establish a systemic treatment for the compliance assessment of products, processes, services, people or Quality Management Systems, in order to provide an adequate level of reliability with regard to the requirements set forth in the standard or RTQ.

4.19. Compliance Identification Mark
Graphic representation to identify objects with assessed compliance within the scope of the SBAC, according to Annex C.

4.20. Series
Name given by the applicant to unmistakably identify each unit produced.

4.21. Applicant
Public or private, domestic or foreign, physical or legal entity, legally established in the country, which performs one of the following activities: production, assembly, creation, construction, transformation, import, distribution, or marketing of Electrical Equipment subject to the Health Surveillance System, as covered by this RAC. It is responsible for applying for the product certification at the OCP and holds the permission for use of Compliance Identification Marks.

4.22. Pilot Unit
It corresponds to one product unit or a set of units manufactured according to the criteria for the manufacturing process established in the product design.

5 PROCEDURES FOR COMPLIANCE ASSESSMENT

5.1 The compliance assessment procedure used in Electrical Equipment subject to the Health Surveillance System set forth in this RAC is the voluntary certification, except for products for which the Regulatory Agency, Anvisa, requires compulsory certification by means of the IN/Anvisa in force.

5.2 This RAC sets forth the Model for an assessment of a Quality Management System of the product manufacturing process and product testing (type and routine tests). Verification tests related to the compliance maintenance may be performed at any time during the effectiveness of the certification.

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 Mark.

6.1 Model for an assessment of a Quality Management System of the Product Manufacturing Process and Product Testing

6.1.1 Initial Assessment

6.1.1.1. Request for beginning the process
The applicant shall submit a formal application to the OCP, featuring the name and characteristics of the product to be certified and attaching the product's 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, as well as the manufacturer's Quality Management System (QMS) documentation (quality manual and master list of quality documents), all of them at the latest version.

6.1.1.2 Application and Documentation Review
Before beginning with the certification, the OCP shall review the application and assess the forwarded documentation as to its compliance and compatibility with the herein requirements, including those inherent to the product manufacturing process. If the certification application is deemed impracticable, the OCP shall return all submitted documents and shall formally inform the applicant about the reason for the service infeasibility, by technically justifying it according to the scope of the application of the adopted technical standards and to the equipment's characteristics.

Note: The final decision of whether applying the compulsory certification to the product or not, under the herein terms, is at Anvisa's discretion, according to the IN in force.

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 (on the collected samples) according to the applicable technical standards listed in item 2 of this RAC, as stated in item 6.1.1.3.3.

6.1.1.3.1.2. The type test shall be fully performed on the pilot unit or on the sample taken from the production line of the equipment subject to the certification process.

6.1.1.3.1.3. In the initial assessment, reports of the type tests performed in Brazil or overseas shall be accepted

provided that the date of issue of such reports does not exceed 2 (two) years and that all changes made to the design are properly documented and the 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 subject to the certification process, whether domestic or foreign, shall send the document declaring that, after the tests reports have been issued, the product have not sufficiently changed to require the performance of new tests.

6.1.1.3.1.3.2. The OCP shall assess the submitted test report of the equipment initial design, for which the report was issued, and of 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

The OCP is responsible for selecting, under mutual agreement with the applicant, the laboratory to be hired for the performance of the type tests related to the product certification process, according to the provisions of item 12 of this RAC.

6.1.1.3.3. Definition of Sampling

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

6.1.1.3.3.1.1. The representative sample must be a pilot unit or one unit already within the production line.

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

6.1.1.3.3.2. For a product already within the production line, the collection performed by the OCP at the manufacturing site shall be a random selection of a product that has been inspected and released by the quality control in is a packaging ready to be commercialized. 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 may collect and send the sample to the laboratory or to the OCP itself, upon mutual agreement between the parties and under the 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 the OCP from validating the products after the production line has started to operate.

6.1.1.4. Initial Audit

After evidencing compliance with item 6.1.1.2 of this RAC, the OCP shall plan the audit of the manufacturer's Quality Management System (QMS) upon mutual agreement with the applicant.

6.1.1.4.1. In order to perform the initial audit seeking to assess the factory's QMS, one must:

a) Verify compliance with the requirements detailed in Annex B herein;
b) Confirm that routine tests, as described in Annex A, are performed by the manufacturer in 100% of the manufactured units;
c) Monitor the manufacturing of the product models included within the scope of this certification;
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 applicable, a copy of the audit/inspection reports about its QMS, respectively issued by an OCP or a health surveillance authority in Brazil (ANVISA, VISAs etc.), and records of corrective actions that have been implemented when these were found.

6.1.1.4.3. If the manufacturer maintains a certification of its QMS within the scope of the SBAC, according to ABNT NBR ISO 13485:2004 standard, or has the Certificate of Good Manufacturing and Control Practices issued by ANVISA , according to RDC/ANVISA No. 59/00, the certification may be accepted as a replacement of the inspections required in Annex B, provided that the OCP may evidence in the last audit report of such certifications that the requirements set forth in Annex B have been verified and are met. In both cases, the certificate shall be valid.

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

6.1.1.5. Issuance of the Certificate of Compliance
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 met.

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

6.1.1.5.2. Once the product is compliant, the OCP shall formalize the granting of authorization to use the Compliance Identification Mark for a period of five (5) years, as provided in Chapter 9, in the products that meet the criteria set forth in this RAC.

6.1.1.5.3. The OCP shall submit the entire certification process to the Certification Committee, without any exception, when all requirements of this RAC have been met, and shall only decide to grant the certification after such Committee issues their opinion about the process.

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

6.1.1.5.5. The certificate shall contain at least the following information:
a) Company name, its National Registry of Legal Entities (CNPJ), and its commercial name, if 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's complete information (name, accreditation number and signature);
e) Data about the certified product specifying its commercial name and certified models;
f) Identification of the testing laboratory(ies) and test report(s), along with their date of issue;
g) Original date of issue (first certificate), revision date, and expiration date;
h) Identification of the technical standards applicable to the certification;
i) List of accessories and parts tested along with the product;
j) Version of the user's manual of the design of the product assessed for the certification;
k) Version of the evaluated software, for equipment with embedded or accompanying software.

6.1.1.5.5.1. In cases in which the audited site consists of a manufacturer hired by the real product manufacturer to perform manufacturing under its own responsibility, the hired manufacturer's address, company name, and CNPJ (if applicable) shall be included in the issued certificate.

6.1.1.5.5.2. The certificate may be composed by multiple pages and shall not contain any attachments. Pages shall be numbered and each page shall contain the certificate number and its date of issue. 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 the conditions the resulted in the initial authorization to use the Compliance Identification Mark still remain. Performing maintenance compliance assessments is under the OCP's sole responsibility.

6.1.2.1. Maintenance Assessment Planning

6.1.2.1.1. The certification maintenance process consists of an annual assessment of the requirements set forth in Annexes A, B and C herein. Inmetro or Anvisa may request the type tests to be performed at any time in order to check for compliance maintenance of the certified products.

6.1.2.1.2. Provided that there is justifiable evidence, the OCP is authorized to perform additional audits.

6.1.2.2. Maintenance Tests
This item establishes the required tests to prove that the product subject to the compliance assessment, after the certificate of compliance is issued in the initial assessment, remains compliant with the herein regulatory requirements. 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. The OCP shall yearly select a representative sample of the certified product, according to item 6.1.1.3.3.2, in order to monitor the performance of routine tests, Annex A, and to ensure their compliance. These

tests may be performed at the manufacturer's facilities. If the product to be certified is manufactured upon requests, the OCP must be prepared to monitor the performance of routine tests, Annex A, and to check for this product's compliance.

6.1.2.2.1.2. The OCP shall evaluate the Product Master Record (RMP) and the Design History Record (RHP) (e.g., a comparison between the lists of components submitted during granting and maintenance, found in the production line, and a verification by physical means, such as external and internal pictures of the product and/or technical drawings of the production line, among other findings) in order to evidence that the product has not changed if compared to the original characteristics previously assessed for the certification granting.

6.1.2.2.1.3. If the design has changed or if there have been updates in parts, pieces, components, or software versions, the impact of such changes on the product certification shall be verified. If required, new type tests shall be performed on a representative sample of the product, according to the applicable standards listed in item 2 of this RAC.

6.1.2.2.1.4. Should new tests not be performed regardless of the changes found, the OCP shall prepare a report justifying each change made, based on technical and scientific knowledge, explaining why the product had not been sent for new type tests. A copy of this report shall be owned by the authorized company.

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

6.1.2.2.1.5. At anytime and during the effectiveness of the certificate, Anvisa or Inmetro may request for the performance of the type tests established in item 6.1.1.3 in order to check for the compliance maintenance of the equipment.

6.1.2.2.2. Definition of Laboratory

The OCP is responsible for selecting, upon mutual agreement with the applicant, the laboratory to be hired for the performance of the tests on the certification maintenance process of the product, according to the provisions of item 12 of this RAC.

6.1.2.3. Maintenance Audit

6.1.2.3.1. In order to perform maintenance audits to assess the manufacturer's Quality Management System (QMS), it is required to:

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

6.1.1.4.4. If the manufacturer maintains a certification of its QMS within the scope of the SBAC, according to ABNT NBR ISO 13485:2004, or has the Certificate of Good Manufacturing and Control Practices issued by ANVISA, according to RDC/ANVISA No. 59/00, the certification may be accepted as a replacement of the inspections required in Annex B, provided that the OCP may evidence in the last audit report of such certifications that the requirements set forth in Annex B have been verified and are met. In both cases, the certificate shall be valid.

6.1.2.3.1.1. In case ABNT NBR ISO 13485:2004 or RDC/ANVISA No. 59/00 is used, audits performed by the 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 met.

6.1.1.5.6. The certificate shall only be granted to an applicant that has all non-conformities removed from its manufacturing process.

6.1.1.5.7. Once the product is compliant with the criteria established herein, the OCP shall formalize the maintenance of the authorization to use the Compliance Identification, as provided in Chapter 9.

6.1.2.4.1. The OCP shall submit the entire certification maintenance process to the Certification Committee, without any exception, after all maintenance requirements of this RAC have been met. The OCP shall only decide to maintain the certification after the Certification Committee issues their opinion about the process.

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

6.1.3. Treatment of Deviations in the Compliance Assessment Process

If any activity performed by the OCP identifies any non-conformity, the OCP shall issue a non-conformity report by sending it to the authorized company/applicant so the required actions may be taken in order to treat such the non-conformities.

6.1.3.1. Treatment of Non-Conformities 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 the implementation evidence before new tests are performed. If non-conformities are found in the manufacturer's Quality Management System (QMS), the required corrective actions shall be implemented to adjust the quality system. Implementation evidence shall be submitted to the OCP.

6.1.3.1.1. The OCP shall assess whether it is required to conduct a new audit to verify the implementation of corrective actions and whether non-conformities have been properly treated.

6.1.3.2. Treatment of Non-Conformities in the Maintenance Process

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

6.1.3.2.1. This decision shall be duly grounded to ensure that non-conforming products or products with threatened safety will not be commercialized. Records of the authorized company and the manufacturer shall be provided to the OCP so that the extensions of these rejections may be analyzed. The certification and, as a result, the authorization to use the Compliance Identification Mark on the rejected model shall be suspended until all corrective actions are implemented by the company.

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

6.1.3.3. Treatment of Non-Conforming Products in the Market

If non-conforming products are distributed or commercialized, the OCP shall monitor the process of replacing or repairing these products, being the authorized company held responsible for this action.

6.1.3.3.1. The impact of the non-conformities on the risks associated with product use shall be taken into account, as well as the need to withdraw from the market these non-conforming products in case repair/correction is not possible. This decision shall be documented by the OCP and included in the documentation of the product certification process.

6.1.3.3.2. If the product cannot be repaired, the non-conforming products shall be recalled and destroyed under OCP's monitoring. If there is the possibility of repairing them, they must be submitted after repair to all tests required for the release of a finished product and that evaluate if the non-conformity was duly treated.

6.1.3.3.3. Tests referred to in item 6.1.3.3.2 may be performed by the manufacturer in its facilities; their results shall be duly recorded, ensuring their compliance with the traceability criteria required for the QMS of medical products, as established in RDC/ANVISA No. 59/00 and ABNT NBR ISO 13485:2004.

7 TREATMENT OF COMPLAINTS

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

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

a) Values and effectively deals with complaints submitted by customers;
b) Is aware and agrees to comply with and to be subject to the penalties provided by laws (Law No. 8078/1990, Law No. 9933/1999, or others.);
c) Encourages and analyzes results, as well as takes appropriate actions, according to the statistics of the received complaints;
d) Sets responsibilities as to the treatment of complaints;
e) Compromises to respond to Inmetro about any complaint it has received, within the established deadline.

7.2 A formally assigned individual or team, properly trained and free to appropriately treat complaints;

7.4 A Complaint Treatment Procedure, which shall include a simple form to record customers' complaints and to trace, investigate, answer, conclude and close the complaint case.

7.5 Adequate records of each submitted and treated complaint.

7.6 An annual critical analysis of the statistics related to the received complaints and evidence of implementation of their corresponding corrective actions and opportunities of improvement.

8. COMPLIANCE IDENTIFICATION MARK

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

8.2 Specification

8.2.1 The Compliance Identification Mark is defined in Annex C herein.

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

8.3 Traceability

The authorized company shall implement a traceability control of the products that have the Compliance Identification Mark, which shall be made available to Inmetro for a period of time equivalent to the product's expected life cycle, but never less than five (5) years from the date of its commercial shipment. The 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 MARK

9.1 The authorization to use the Compliance Identification Mark has its validity associated with the validity of the certification.

9.2 Authorization Granting

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

9.2.2 The authorization to use the Compliance Identification Mark shall be granted by the issuance of the formal instrument, the certificate, which shall contain at least the data referred to in item 6.1.1.5.5.

9.3 Authorization Maintenance

9.3.1 The maintenance of the authorization to use the Compliance Identification Mark depends on the non-existence

of any non-conformity during the maintenance assessment process, as set forth in sub-item 6.1.2 and 6.1.3.2 of this RAC.

9.4 Authorization Suspension, Cancellation or Renewal

The cancellation, suspension or renewal of the authorization to use the Compliance Identification Mark shall occur when any of the herein requirements has not been met.

9.4.1 In case of certificate suspension or cancellation due to the non-compliance with any requirement set forth in this RAC, the authorization to use the Compliance Identification Mark shall be deemed as under the same condition. In such cases, the company holding the authorization shall stop using the Mark and every piece of advertising related to it.

9.4.2 The partial or full interruption of this suspension is subject to the proof that the authorized company has treated the non-conformities that had caused such suspension.

9.4.3 The applicant that holds the authorization to use the canceled Compliance Identification Mark shall go through 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 issuance of the test report;
b) Change in the revision of any technical standard used in the original test;
c) Change in the equipment structure that implies product changes if compared to the previously assessed compliance;
d) Upon Anvisa's determination.

Note: in item 9.4.4.a, in case of specific equipment, the regulatory body (Anvisa) may establish their own deadlines by a normative instruction.

10 RESPONSIBILITIES AND DUTIES

10.1 Authorized company:

a. Maintain the technical and organizational conditions that were the basis for obtaining the authorization to use the Compliance Identification Mark.
b. Comply with all conditions set forth in this RAC, in legal and contractual provisions related to the certification, regardless of their transcription.
c. Notify any product change to the OCP along with the assessed compliance, as well as to submit any performed changes to the OCP's analysis and approval before marketing the modified product.
d. Take direct technical, civil and criminal responsibilities with regard to the commercialized product and to all documents related to the compliance assessment, with no possibility of transferring such responsibility.
e. Accept relevant decisions reached by the OCP as to the certification, appealing to the OCP in the first instance and to Inmetro's ombudsman services in the second in cases of complaints and appeals.
f. Accept all conditions set forth in the technical standards listed in item 2 of this RAC, in legal and contractual provisions with regard to the authorization, regardless of their transcription.
g. Ease the conduction of audits and monitoring activities to the OCP or its contractor, as well as the performance of other tests and certification activities according to this RAC.
h. Apply the Compliance Identification Mark on every certified equipment, according to the criteria set forth in this RAC.
i. Ensure that a certified product does not have the same coding of a non-certified product (code and model).
j. Perform routine tests, according to Annex A, in 100% of the manufactured units.
k. Perform type tests, according to item 6.1.1.3 and to Anvisa's or Inmetro's determination, in order to prove 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 manufacturing, import or commercialization is interrupted.
n. Inform the OCP when the manufacturing, commercialization and/or import of the equipment that has the authorization to use the Compliance Mark is interrupted for good.
o. Comply with other legal requirements as to product manufacturing, import and commercialization, under penalty of having the certificate suspended or cancelled.
p. Use the identification of the compliance in advertisements, after due authorization granted by the Quality Board (Dqual), http://www.inmetro.gov.br/qualidade/autSelo.asp, provided that it is clear which products actually had their compliance assessed, besides submitting the materials to be advertised, according to Inmetro Ordinance No. 179/2009.

10.2 OCP

a) Implement the compliance assessment program provided in this RAC, according to the requirements set forth herein, mandatorily settling all questions with Inmetro.

b) Use the database system provided by Inmetro in order to keep information about certified products updated.

c) Immediately notify Inmetro and Anvisa as to certification suspensions, extensions, reductions and cancellations.

d) Submit to Inmetro, for analysis and approval, the Memoranda of Understanding within the scope of this RAC and established with other certification bodies.

e) Accept any penalties imposed by the product regulatory bodies.

f) Make the authorized company acknowledge the requirements set forth by Inmetro and that may impact on it.

g) Take responsibility for selecting and hiring third parties, such as laboratories and product and factory assessment bodies.

h) As for tests performed by foreign laboratories, provided that the regulatory body has consented, the test method equivalence, voltage and supply frequency of the tested equipment and the used sampling methodology shall be observed. Additionally, these laboratories shall be accredited by Inmetro or by an Accreditation Body that is the undersigned of a mutual acknowledgment agreement, of which Inmetro is a party.

i) Keep in its email 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 consulting reports extracted from a database, containing all the information included in the issued certificates.

j) Monitor on the website of the regulatory body (Anvisa) the publication of adverse event notices associated with certified products. The OCP shall assess whether the published adverse event impacts on the certification; if so, appropriate measures shall be taken with the authorized company in order to follow up the corrective actions implemented to solve the problem that caused the adverse event. These actions shall be documented and be part of the product certification process documentation.

k) Follow up and implement determinations of the regulatory body (Anvisa), regarding the need for the performance of 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 the applicant that misuses and/or makes abusive use of the Compliance Identification Mark shall be subject to penalties, according to Inmetro Ordinance No. 179 of June 16, 2009.

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

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

a) provide products with the Compliance Identification Mark that does not meet the quality standards established in this RAC;

b) use the Compliance Identification Mark on non-authorized products;

c) not to inform, or provide false information, about certified products;

d) prevent auditors from accessing quality documents and records;

e) not to accept the verification and sample collection within the deadlines set forth in this RAC.

11.4 As for products subject to *registro* at Anvisa, failure to comply with this RAC, regarding the applicable items, is subject to the penalties set forth in Law No. 6437/77 and in Art. 273 of the Brazilian Criminal Code - Law No. 2848/40.

12 USE OF TESTING LABORATORY

12.1 Type tests intended to assess the compliance with this RAC shall be performed by a third-party laboratory accredited by Inmetro as to the scope herein.

Note: If no laboratory is able to perform all required tests, more than one laboratory may be used, according to the criteria set forth in item 12 of this RAC.

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

a) When there is no laboratory accredited by Inmetro for part of the scope of the Product Compliance Assessment Program.

b) When the laboratory(ies) accredited by Inmetro does(do) not comply within the maximum deadline of six (6) months to start the tests described in RACs, counted from the day the contract is signed.

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

12.2.2 The OCP shall obtain objective evidence that the laboratory not accredited by Inmetro is able to perform all tests required by the regulations set forth in this RAC.
Note: If no laboratory is able to perform all required tests, more than one laboratory may be used, according to the criteria set forth in item 12 of this RAC.

12.3 Should any of the cases above apply, the OCP must follow the priority order below, when selecting a laboratory not accredited by Inmetro, but qualified for that particular scope:
a) A third-party laboratory accredited for 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, the OCP shall record the reasons for selecting the laboratory by using evidential documents.

12.5 For tests performed by foreign laboratories, the equivalence of the testing method and the sampling methodology shall comply with in this RAC. Additionally, these laboratories shall be accredited by Inmetro or by an Accreditation Body that is the undersigned of one of the following mutual acknowledgment agreements, in which Inmetro is a party:
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 the website of Inmetro www.inmetro.gov.br and of the cooperations and bodies that are the undersigned in such agreements;
2) The scope of the laboratory accreditation shall include the testing method applied within the scope of this RAC;
3) Test 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 may 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 Understanding (MOU) with the foreign body;
b) The foreign body shall be accredited according to the same international rules adopted by Inmetro and for the same or equivalent scope;
c) The activities performed overseas shall be equivalent to those regulated by Inmetro;
d) The body accredited by Inmetro shall issue the authorization to use the Compliance Identification Mark according to the Brazilian regulation and shall take full responsibility for the activities performed overseas and that may result 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 to use the Compliance Identification Mark; 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, the OCP shall complement the assessment by meeting the requirements not complied before.

14. CERTIFICATION PROCESS CLOSURE

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

14.2 The OCP shall also schedule the process closure tests. These tests would be performed upon next maintenance assessment.

14.3 If the result of these tests presents any non-conformity, the OCP shall request for the authorized company to correctly treat them according to item 6.1.3 of this RAC, before considering the process cancelled.

14.4 The results of the closing audit and tests shall be documented and be included in the documentation of the product certification process.

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

ANNEX 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, besides checking the operation of the product subject to the certification, specifically:

a) Equipment operation (items to be checked will be object of an agreement between the OCP and the manufacturer in order to ensure the safety of the product subject to the certification according to its indented use).
b) Earth 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, at the manufacturer's discretion, provided that such application is duly justified by the manufacturer and agreed with the OCP.

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

B-1 At the initial and maintenance assessments of the manufacturer's QMS based on ABNT NBR ISO 13485:2004 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 Record Control
7.1 Product Implementation Planning
7.2.3 Communication with customers *(ref. Treatment of 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 Products
7.5.1 Control of Production and Service Provision
7.5.2 Validation of Manufacturing Processes and Service Provision
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-Conforming Product Control
8.5.2 Corrective Actions

ANNEX C - CERTIFICATION IDENTIFICATION WITHIN THE SCOPE OF THE SBAC

C.1 The identification of the certified product, according to this RAC, shall contain the information established in this Annex and comply with the field of application, either compulsory or voluntary.

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

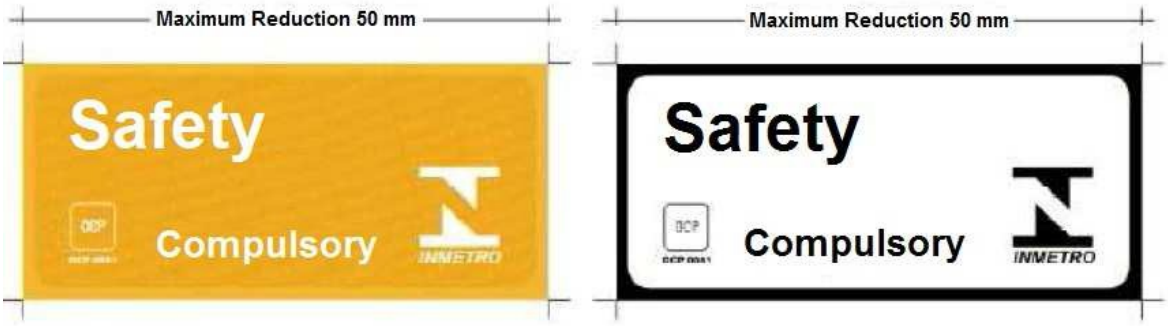
a) The mark, according to Figure 1a, may only be used on products listed in the existing IN/Anvisa, which sets forth the technical standards adopted for compliance certification of Medical Electrical Equipment subject to the Health Surveillance System;
b) The mark may be printed or may be used as a label, provided that it meets the minimal dimensions defined in Figure 1a and 1b of this RAC and as long as it is indelible and permanent;
c) When the Compliance Identification Mark is stamped, printed or inserted onto the product by means of a label defined in Figure 1a and 1b of this RAC and does not fit in the frontal portion of the Medical Electrical Equipment, it may be affixed to other parts;
d) The black and white version may be used on the packaging only if its color is similar to the colored mark.

C.3 The OCP shall ensure that the Compliance Identification Mark affixation is performed in an indelible, permanent and visible manner, as well as the possibility of Medical Electrical Equipment subject to the Health Surveillance System being traced by sequential numbers, or otherwise established by the OCP upon mutual agreement with the authorized company.

Figure 1a - For compulsory certification

Fonts

Univers
Univers-Black



Pantone 1235
100%
80%

Figure 1b - For voluntary certification

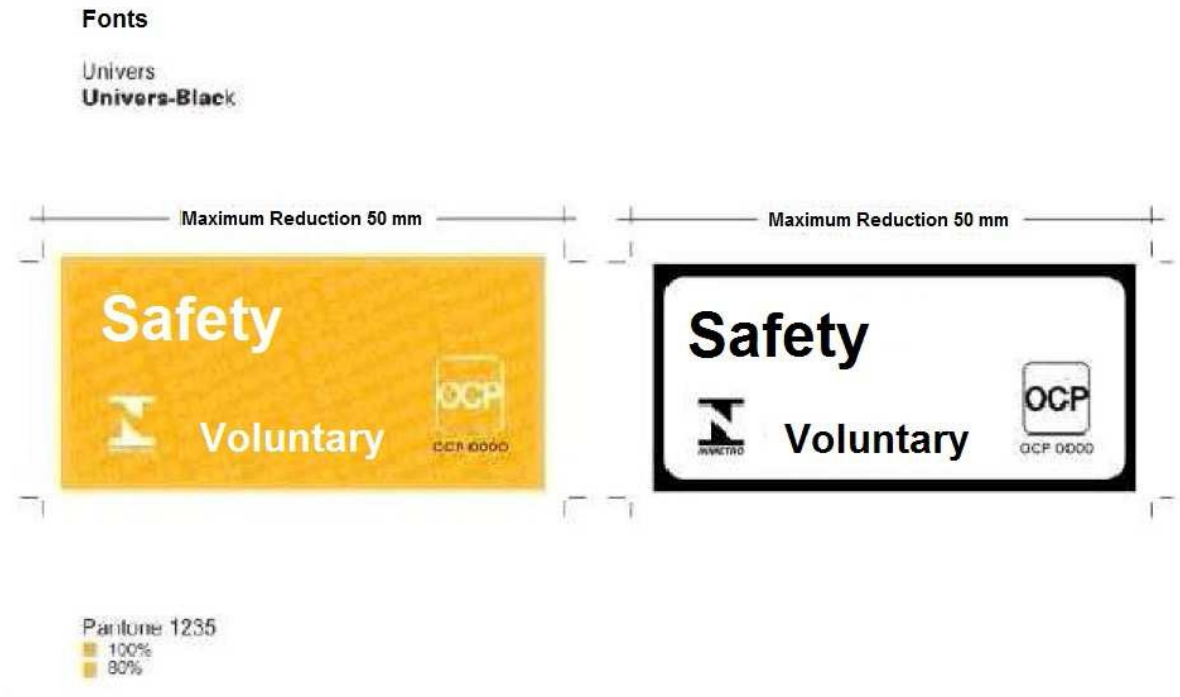


Figure 2: Compact Mark

ANNEX D – CHARACTERIZATION OF THE FAMILY