

MEDICAL ELECTRICAL EQUIPMENT

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1 – PURPOSE

This Regulation settles the criteria of the Conformity Evaluation Program of Medical Electrical Equipment Certification, observing the requirements of the pertinent Rule or Regulation listed in complementary documents, aiming at the user security.

Note of TÜV Rheinland: This document presents the Inmetro Regulation (Regulation nº 86, of April 03th, 2006). The prescriptions of RDC 32, of May 29th, 2007 (ANVISA), concerning the certification's process must be considered too.

2 – RESPONSIBILITY

The Division of Conformity Evaluation Programs– Dqual / Dipac is responsible for this Regulation on Conformity Evaluation.

3 – COMPLEMENTARY DOCUMENTS

NIT-DICOR-021 Use of Laboratories by the OCP.

Rule of Ministry of Healthy nº 155, of February 27th, 1997.

Rule of Ministry of Healthy nº 1.104, of August 30th, 1999.

Resolution of CONMETRO nº 2, of December 11th, 1997, published on DOU of March 10th, 1998.

RDC 32 (ANVISA), of May 29th, 2007.

Normative Instruction nº08 (IN-08 ANVISA), of July 08th, 2009.

Normative Instruction nº13 (IN-13 ANVISA), de 22 de outubro de 2009.

Note of TÜV Rheinland: The Technical Standards indicated on the original text were not reproduced. Consider all the Technical Standards described in Normative Instruction nº 8 (ANVISA), of May 29th, 2007. The Resolution of ANVISA nº 444, of August 31th, 1999, was revoked and replaced by RDC 32 (ANVISA), of May 29th, 2007. The Inmetro Standard NIEDINQP-067 was included because of item 6.1.1.3.

4 – DEFINITIONS

In this Regulation, the definitions from 4.1 to 4.6 are used.

4.1 – Conformity Mark

Registered trademark, set or issued according to criteria settled by Inmetro, based on the principles and policies adopted in the scope of SBAC, which indicates the existence of a proper level of reliability that the medical electrical equipments comply with the respective technical specifications listed in this Regulation.

4.2 – License to use the Conformity Mark

A document, issued in accordance with the criteria established by Inmetro, based on the principles and policies adopted in the scope of SBAC, according to which an OCP grants to an authorized company, by means of a contract, the right to use the Conformity Mark in its products, according to this Regulation.

MEDICAL ELECTRICAL EQUIPMENT

4.3 – Medical Electrical equipment

Electrical equipment, provided with not more than one connection to a particular supply mains and intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient.

Note of TÜV Rheinland: According to RDC 32, the medical electrical equipment definition was modified to “electrical devices under the regulation of Brazilian Sanitary Vigilance, including their parts and accessories, are those which are energized by the supply mains or internally powered, with purpose of medical, odontological, laboratorial or physiotherapeutic applications, used directly or indirectly for diagnosis, treatment and monitoring of human beings, and for beauty and esthetic applications too”.

4.4 – Authorized Company

A legal representative, either a natural person or a legal entity, public or private, national or foreigner, that develops activities of production, mounting, designing, construction, transformation, importation, exportation, distribution or marketing of medical electrical equipment.

4.5 – Type Test

An test performed in one or more units manufactured according to a specific project, to demonstrate that the project meets certain specified conditions.

4.6 – Routine Test

Test which is submitted each unit manufactured, during or after manufacturing, to check if it meets certain specified conditions.

5 – ACRONYMS

ANVISA	Agência Nacional de Vigilância Sanitária (Health Surveillance Brazilian Agency)
CBAC	Comitê Brasileiro de Avaliação da Conformidade (Brazilian Committee on Conformity Assessment)
CNPJ	Cadastro Nacional da Pessoa Jurídica (Corporate Taxpayers' Roll)
Conmetro	Conselho Nacional de Metrologia, Normalização e Qualidade Industrial (Brazilian Board of Metrology, Normalization and Industrial Quality)
CT	Comissão Técnica (Technical Commission)
DOU	Diário Oficial da União (Brazilian Official Gazette)
DQUAL	Diretoria da Qualidade (Quality Administrative Board)
IEC	International Electrotechnical Commission
INMETRO	Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (Brazilian Institute of Metrology, Normalization and Industrial Quality)
NBR	Normas Brasileiras (Brazilian Standards)
OAC	Organismo Acreditado (Certified Body)
OCP	Organismo de Certificação de Produto acreditado pelo INMETRO (Body of Product Certification accredited by Inmetro)
RBLE	Rede Brasileira de Laboratórios de Ensaios (Brazilian Test Laboratories Net)
SBAC	Sistema Brasileiro de Avaliação da Conformidade (Brazilian Conformity Assessment System)
UO	Unidade Organizacional (Organizational Unit).

MEDICAL ELECTRICAL EQUIPMENT

6 – CONFORMITY IDENTIFICATION

The purpose of the conformity identification in the scope of SBAC is to indicate that the product, process or service complies with the criteria defined on RAC, as well as to assure its traceability. This conformity identification can be performed by marking the product (mark, mark on the package or any other means) or by the issuance of a conformity or registration certificate.

6.1 – Conformity Mark

The procedure for the permission to use the Conformity Mark includes the following steps:

- a) analysis, by OCP, of the licensed company petition to obtain a license to use the Conformity Mark;
- b) analysis of the licensed company documentation;
- c) audit in the licensed company, as per Annex B;
- d) routine tests, as per Annex A;
- e) appreciation of the process in the Certification Commission;
- f) signature of the contract that is object of the license;
- g) date of issue and validity of the license to use the Conformity Mark;
- h) model of the conformity assessment mark to be applied, it is in annex C;
- i) supervision and control of the licensing;
- j) type tests every 5 years;
- l) evaluation of the need of new tests in case of product changes.

6.1.1 – Controls and Checks Performed by OCP

6.1.1.1 – After the granting of the license to use the Conformity Mark, its control is performed only by OCP, which plans the audits and tests as per this Regulation, to check if the technical-organizational conditions which originated the initial license are kept, with the possibility of other audits with no previous notice, when there is a resolution by OCP's Certification Commission based on evidences that justify them.

6.1.1.2 – OCP must settle a procedure to collect the sample in the market or in the factory, to make the tests and checks set in the technical specifications listed in this Regulation. The authorized company is in charge of the costs and the product replacement due to this sampling.

6.1.1.3 – Once the sample collection is performed, it must be sent to the laboratory, for carrying out the tests. To hire the testing laboratory, OCP should observe the Regulation of Inmetro NIEDINQP-067.

6.1.1.4 – OCP must apply the same criteria used in this Regulation to define the tests and those used in this Regulation to accept or reprove the tests.

6.1.2 – Controls performed by the licensed company

6.1.3 – The control of the certified medical electrical equipment is executed by the licensed company, under its sole and unique responsibility.

6.1.4 – The control must aim at checking and assuring the conformity of the medical electrical equipment to the applicable technical standards related in this Regulation.

MEDICAL ELECTRICAL EQUIPMENT

6.1.5 – The manufacturer must exercise all of the controls that meet the technical-organizational requirements of quality control defined in Annex B.

6.1.6 – The manufacturer must perform routine tests, according to Annex A of this Regulation, and exercise all controls relating to these tests and evaluations, to be used as evidences during audits.

6.1.7 – The controls' result must be available for OCP.

6.2 – Conformity Certificate

6.3 – Registration Certificate

7. LICENSE TO USE THE CONFORMITY MARK

7.1 – The license to use the Conformity Mark issued by the OAC, aims at formally establish the rights to use the mark of compliance by the company.

7.2 – The license to use the Conformity Mark must include the following information:

- a) corporate name, assumed name (if available), full address CNPJ of the OAC and the licensed company;
- b) identification (number) of the license to use the Conformity Mark;
- c) date of issue and validity of the license;
- d) identification of the models covered by the license, mentioning the applied technical standard;
- e) certification identification, mentioning the applied technical standard;
- f) name, registration number and signature of the OAC;
- g) description of the product including brand, type and model, when applicable;
- h) identification of the batch, which is mandatory in case of conformity evaluation of batch;
- i) corporate name and full address of the manufacturing unit.

7.3 – If there is a revision of the specific technical standards and/or of this Regulation, on which the granting of the license to use the Conformity Mark was based, Inmetro, with the help of the Health Equipment CT, will set a new term for the adjustment to the new requirements.

8 – CONFORMITY ASSESSMENT

8.1 – License Permission

The procedure for granting the license to use the Conformity Mark includes the following steps:

- a) analysis by OCP of the licensed company petition to obtain a license to use the Conformity Mark;
- b) analysis of the licensed company documentation;
- c) audit in the licensed company, as per Annex B;
- d) routine tests, as per Annex A;
- e) appreciation of the process in the Certification Commission;

MEDICAL ELECTRICAL EQUIPMENT

- f) signature of the contract that is object of the license;
- g) date of issue of the license to use the Conformity Mark;
- h) supervision and control of the licensing;
- i) type tests every 5 years;
- j) evaluation of the need of new tests in case of product changes.

Note: The authorized company that completely ceases the manufacturing and/or importation and the commercialization of medical electrical equipments in which it holds the license to use the Conformity Mark, must immediately communicate this situation to the OCP and return it the original license. The OCP, in turn, notifies this situation to Inmetro.

8.2 – Audit and Test

8.2.1 – Type tests are those established in NBR IEC 60601-1 and in the applied particular technical standards listed in this Regulation.

8.2.2 – Type tests must be carried out in third party laboratories that are accredited by Inmetro, chosen with common agreement with the licensed company. If it is not possible, or if it is technically impossible, OCP must follow Inmetro Rule NIT-DICOR-021.

8.2.3 – At the request of the licensed company, an initial conformity evaluation can be performed.

8.2.4 – To the applied technical standards by means of tests in prototypes.

8.2.5 – When the tests are performed in a prototype which is approved, the initial results must be confirmed in the quality control evaluation of the factory, provided that the product has not undergone technical modifications.

8.3 – Authorized company evaluation

8.3.1 – For the initial evaluation of the quality control of the factory, the requirements prescribed in the Annex B of this Regulation must be checked.

8.3.2 – In the initial evaluation of the quality control of the factory, the requirements listed in the Annex A of this Regulation must be checked.

8.3.3 – Type tests are those prescribed in NBR IEC 60601-1/94 and in the technical standards.

8.3.4 – Particular applicable listed in this Regulation.

8.3.5 – Type tests must be carried out in third party laboratories that are accredited by Inmetro, chosen with common agreement with the licensed company. If it is not possible, or if it is technically impossible, OCP must follow Inmetro Rule NIE-DINQ-067.

8.3.6 – Routine tests are those listed in Annex A of this Regulation.

8.4 – Product Change

Any product change must be reported to the OCP to verify the necessity of further tests for granting the license.

MEDICAL ELECTRICAL EQUIPMENT

8.5 – License Extension

When the licensed company wishes to extend the license for additional models of the same product, complying with the same technical standards, it can ask for its extension to the OCP. The petition must be made for a determined model and for a determined factory.

Note: OCP's Certification Commission must define if the extension petition is pertinent, deciding on carrying out of further tests in the additional models of the same product.

8.6 – License Maintenance

8.6.1 – Periodic Evaluation

a) In the periodic evaluation of the quality control of the factory, the requirements prescribed in the Annexes A and B of this Regulation must be checked.

b) This periodic evaluation must be performed every 12 (twelve) months and a second one can also be performed if the parties agree on that.

c) If the manufacturer holds a quality system certification, in the scope of SBAC, according to ISO 9000 series, the OCP, in this periodic evaluation, can accept or not such certification, provided that the Annex A is observed.

8.6.2 – Tests

8.6.2.1 – Type tests

They will be carried out in one unit of a representative sample of the product, every 5 years.

8.6.2.2 – Routine Tests

They must be performed by the manufacturer in 100% of the manufactured units. Routine tests are those listed in the Annex A of this Regulation.

8.7 – Acceptance and Refusal

8.7.1 – In the evaluation of the medical electrical equipment, for approval, the tests previously described must be sent to the OCP's Certification Commission, which will decide on their acceptance or refusal.

8.7.2 – In the tests to evaluate medical electrical equipments, if there is any non-conformity, these must be repeated in two new samples, and non-conformities will not be admitted.

The failure of the assessment tests brings about the immediate suspension of the license to use the Conformity Mark.

9 – USE OF LABORATORIES

10 – ACCEPTANCE OF THE CONFORMITY ASSESSMENT ACTIVITIES

For acknowledging and accepting the certification activities established in this RAC which are implemented by a Certification Body that operates abroad the OCP must observe the following:

- Any agreement on the acknowledgement of the necessary activities for compulsory certification, in the scope of SBAC, such as results of tests or inspection reports, with certification bodies operating abroad, will only be accepted if such activities, besides being reciprocally acknowledged, are

MEDICAL ELECTRICAL EQUIPMENT

performed by bodies which observe the same international rules for accreditation adopted by the Accreditation Body (Inmetro);

- In any situation, the OCC who integrates SBAC is responsible for the compulsory certification, in the scope of the System.

11 – REVISIONS STATUS

Correction of terms in the entire text.

Item 1 – Note of TÜV Rheinland included.

Item 3 – Correction of complementary documents and note of TÜV Rheinland included.

Item 4.3 – Note of TÜV Rheinland included.

Item 5 – Note of TÜV Rheinland included.

Item 9 – Inclusion of the item.

Annex B – Note of TÜV Rheinland included.

Annex C – Replacement of the labels.

ANNEX A

ROUTINE TESTS

Routine tests are those indicated in the subclause 4.1 of item A.2 of Annex A of NBR 60601-1/1994, specifically:

- a) Equipment operation;
- b) Grounding (clause 18);
- c) Leakage current (clause 19);
- d) Dielectric strength (clause 20).

MEDICAL ELECTRICAL EQUIPMENT

**ANNEX B
REQUIREMENTS FOR THE EVALUATION OF QUALITY CONTROL IN THE FACTORY**

In the evaluation of the manufacturer's quality management system, the compliance with at least the following NBR ISO 9001:2000 items has to be checked:

- 4.2.3 Control of documents
- 4.2.4 Control of records
- 7.1 Planning of product realization
- 7.4.3 Verification of purchased product
- 7.5.1 Control of production and service provision
- 7.5.3 Identification and traceability
- 7.5.5 Preservation of product
- 7.6 Control of monitoring and measuring equipment
- 8.2.3 Monitoring and measurement of processes
- 8.2.4 Monitoring and measurement of product
- 8.3 Control of nonconforming product

Note of TÜV Rheinland: Replace, when applicable, the evaluated items by the correspondent items of the new version of NBR ISO 9001:2008.

MEDICAL ELECTRICAL EQUIPMENT

**ANNEX C
CERTIFICATION IDENTIFICATION IN THE SCOPE OF SBAC**

The OCP should make sure that the apposition of the Conformity Mark is made in an indelible, permanent and clear way, and that it is possible for the medical electrical equipment to be tracked by sequential numbering or other means determined by OCP in common agreement with the licensed company.

Fonts
Univers
Univers-Black
Maximum Reduction 50 mm

Logo to be used in packaging



Logo to be used in the product



Logo UC: to be used only for customers who still use it in its products and packings.

The medical electrical equipment manufacturer and importer must follow the guidance below to use the identification conformity mark:

- a) In the package, the mark can be printed or a label can be used, displaying indelible and permanent features, provided that the minimum dimensions defined in the Conformity Evaluation Regulation, approved by this Rule, are observed;
- b) In the product, when the conformity identification which is stamped, printed or inserted by means of the mark does not fit in the frontal part of the medical electrical equipment, it can be placed in other regions;
- c) Black and white version may only be used in the package if the package color and the color of the colored mark are alike;
- d) In the product, although the colored mark is preferential, the use of the black and white version is allowed.