Ordinance no. 54, of February 1st, 2016

THE PRESIDENT OF THE BRAZILIAN NATIONAL INSTITUTE OF METROLOGY, QUALITY, AND TECHNOLOGY – INMETRO, in the exercise of the powers vested by Article 4, paragraph 3, of Law no. 5,966, of December 11th, 1973; by Article 3, subsection I and IV, of Law 9,933, of December 20th, 1999; by Article 18, subsection V, of the Internal Structural Statute of the Autarky, approved by Decree no. 6,275, of November 28th, 2007;

Considering clause *f* of item 4.2 of the Term of Reference of the Brazilian Compliance Evaluation System (SBAC), approved by Conmetro Resolution no. 04, of December 2nd, 2002, which confers to Inmetro the competence to establish guidelines and criteria for the process of compliance evaluation;

Considering that Interministerial Ordinance MS/MDIC no. 692, of April 8th, 2009, which defines the operationalization of the actions Technical Cooperation and Quality Assurance of Medical Devices Safety subject to health surveillance control, as established by the Term of Technical Cooperation signed by the Ministry of Health (MS) and the Ministry of Development, Industry, and International Trade (MDIC);

Considering that Interministerial Ordinance MS/MDIC no. 16, of December 17th, 2010, which approves the Internal Rules of Steering Committee of Cooperation Term celebrated among the Ministry of Health (MS), through the Secretariat of Science, Technology and Strategic Inputs (SCTIE), Ministry of Development, Industry and Foreign Trade (MDIC), through the Brazilian National Institute of Metrology, Quality and Technology (Inmetro), Brazilian Health Surveillance Agency (ANVISA), and Oswaldo Cruz Foundation (Fiocruz), signed on April 8th, 2009;

Considering the Interministerial Ordinance MS/MDIC no. 206, of June 21st, 2013, which institutes the Technical Committee of Articulation with the Brazilian Health Surveillance Agency within the scope of Bigger Brazil Plan (CTVSPBM);

Considering the publication of the new edition of series of Technical Standards IEC 60601 and ISO/IEC 80601, including risk management, in internalized version by Brazilian National Standards Organization (ABNT) (ABNT NBR IEC 60601, and ABNT NBR ISO/IEC 80601);

Considering the publication of ANVISA Resolution RDC no. 27, June 21st, 2011, which makes provisions on the procedures to the mandatory certification of the equipment under Health Surveillance policy;

Considering the publication of ANVISA Normative Instruction no. 04, of September 10th, 2015, which approves the updated list of Technical Standards which shall be adopted to the certification of compliance within the scope of Brazilian Compliance Evaluation System (SBAC), of equipment under health surveillance policy;

Considering Inmetro Ordinance no. 118, of March 6th, 2015, which approves the improvement of General Requirements for Product Certification – RGCP -, published on the Brazilian Official Gazette on March 9th, 2015, section 01, pages 76 to 77;

Considering the need to improve the Requirements for the Compliance Evaluation of Electric Equipment under Health Surveillance Policy, established by Innmetro Ordinance no. 350, of September 6th, 2010, published on the Brazilian Official Gazette on September 9th, 2010, section 01, page 67, hereby resolves to lay down the following provisions:

Article 1. To approve the improvement of the Requirements for the Compliance Evaluation of Equipment under Health Surveillance Policy, available on the website www.inmetro.gov.br or on the following address:

> Instituto Nacional de Metrologia, Qualidade e Tecnologia – Inmetro
> Divisão de Regulamentação Técnica e Programas de Avaliação da Conformidade – Dipac Rua da Estrela n.º 67 - 3º andar – Rio Comprido
> 20.251-021 – Rio de Janeiro – RJ

Article 2. To ratify that the Public Consultation was published by Inmetro Ordinance no. 407, of August 26th, 2014, edited on Brazilian Official Gazette on August 28th, 2014, section 01, page 94, with the collaboration of technicians of the sector and society in general for the creation of the herein approved requirements.

Article 3. To ratify that shall be maintained, within the scope of the Brazilian Compliance Evaluation System (SBAC), the voluntary certification for Equipment under the Health Surveillance Policy, which shall be granted by a Product Certification Body – OCP, established in Brazil and accredited by Inmetro, according to the requirements for the compliance evaluation hereby established.

Paragraph 1. These Requirements shall be applied to equipment, including their parts and accessories for medical, dental, laboratorial or physiotherapeutic purposes, using direct or indirectly for diagnosis, treatment, rehabilitation, and monitoring in humans, and equipment with the purpose of beautification and aesthetics.

Paragraph 2. Shall be excluded from these Requirements the equipment that do not comply with Anvisa RDC no. 27/2011 and its substitutes.

Article 4. To ratify to manufacturers and importers that Anvisa may require mandatory certification of Equipment under Health Surveillance Policy through IN or RDC.

Article 5. To determine that the manufacturers and importers with certificates issued pursuant to Inmetro Ordinance no. 350/2010, which shall adapt to the herein approved requirements on the date of renewal or maintenance thereof, in compliance with the deadlines established by Anvisa Normative Instruction no. 04/2015, and its substitutes.

Article 6. To determine that, counted from the date of the publication of this Ordinance, the modifications made in designs after the certifications shall be informed to Inmetro and Anvisa in accordance with the herein approved requirements.

Article 7. To determine that the new certification processes initiated after the date of publication of this Ordinance on the Brazilian Official Gazette shall be in accordance with the herein approved requirements.

Article 8. To ratify that the electromedical equipment in accordance with the herein approved requirements shall not necessarily be considered safe, when examined and tested, if other characteristics are found that may interfere the safety enclosed by this Compliance

Evaluation Program or resulting in dangers arising from electromagnetic phenomena which may affect its operation or others equipment.

Article 9. To determine that six (6) months, counted from the date of the publication of this Ordinance, the Equipment under Health Surveillance Policy shall be certified be in accordance with the herein approved requirements, in compliance with the deadlines and conditions set forth in Anvisa Normative Instruction no. 04, of September 10th, 2015, and its substitutes.

Article 10. To revoke the Inmetro Ordinance no. 350/2010, on Dezember 31st, 2022.

Article 11. This Ordinance shall come into force on the date of its publication on the Brazilian Official Gazette.

LUIS FERNANDO PANELLI CESAR

REQUIREMENTS FOR COMPLIANCE ASSESSMENT OF EQUIPMENT UNDER HEALTH SURVEILLANCE POLICY

1. OBJECTIVE

To establish the criteria and compliance evaluation procedures for Equipment under Health Surveillance Policy, with emphasis on safety through the mechanism of certification in order to prevent accidents.

1.1. GROUPING FOR THE PURPOSE OF CERTIFICATION

The certification of Equipment under Health Surveillance Policy shall be performed by families, which is defined in accordance with the given criteria in Annex D of this RAC.

2. ACRONYMS

For the purposes of this RAC, the following acronyms shall be hereby adopted, as well as the acronyms contained in the complementary documents mentioned in Chapter 3 of this RAC.

AGR	Risk Management File
Anvisa	Brazilian Health Surveillance Agency
CBPFC	Good Manufacturing and Control Practices Certificate
CNPJ	Brazilian Registry of Legal Entities
EM	Electromedical
Nota:	Includes non-electric equipment under Health Surveillance Policy
GR	Risk Management
IN	Anvisa's Normative Instruction
MDP	Protection Means or Measures
MPO	Operator Protection Means or Measures
MPP	Patient Protection Means or Measures
PDS	Software Development Plan
RDC	Resolution of the Collegiate Board of Directors
RHProj	Design History Record
RHP	Product History Record
RMP	Product Master Record
SDPD	Software of Unknown Provenance
SGR	Risk Management Summary

3. COMPLEMENTARY DOCUMENTS

For the purposes of this RAC (Requirements for Compliance Evaluation), the following complementary documents shall be hereby adopted.

Inmetro Ordinance no. 118, and its substitutes	03/06/2015	Improves the General Requirements of Product Certification (RGCP)

Inmetro Ordinance no. 248, and its substitutes	05/25/2015	Inmetro Vocabulary of Compliance Assessment with terms and definitions commonly used by the Compliance Assessment Inmetro Board
Inmetro Ordinance no. 96, and its substitutes	03/20/2008	Metrological Technical Regulation of digital electronic sphygmomanometers.
Inmetro Ordinance no. 89, and its substitutes	04/06/2006	Metrological Technical Regulation of digital clinical thermometers.
Law no. 6,437	08/20/1977	Regulates the violations to the Brazilian health surveillance legislation, sets forth their corresponding penalties, and makes other provisions.
Anvisa Normative Instruction no. 04, and its substitutes	09/10/2015	Approves the updated list of Technical Standards which shall be adopted to the certification of compliance within the scope of Brazilian Compliance Evaluation System (SBAC), of equipment under health surveillance policy, under the Anvisa Resolution RDC no. 27, of June 21st,2011.
Anvisa RDC no. 16	03/28/2013	Makes provisions on the requirements of Good Manufacturing Practices, and Medical Products, and In Vitro Diagnosis Products.
Anvisa RDC no. 23	04/04/2012	Makes provisions on the compulsory execution and notification of field actions by the registration holders for health products in Brazil.
Anvisa RDC no. 27	06/21/2011	Makes provisions on the procedures for the mandatory certification of equipment under the Health Surveillance Policy.
Anvisa RDC no. 67	12/21/2009	Makes provisions on technovigilance rules applicable to registration holders for health products in Brazil.
ABNT NBR ISO	17025:2005	General requirements for competence of testing and calibration laboratories.
ABNT NBR ISO	17025:2013	Compliance Assessment – Requirements for certification bodies of products, processes, and services
ABNT NBR IEC	60601	Electromedical Equipment, parts 1 and 2, general and specific requirements; internalized standards of the series IEC 60601 3rd edition including its amendments and corrigendum
ABNT NBR ISO	80601	Electromedical Equipment, specific requirements; internalized standards of the series ISO 80601 including its amendments and corrigendum.
ABNT NBR ISO	13485:2004	Medical devices – Quality Management Systems – Requirements for Regulatory Purposes
ABNT NBR ISO	14971:2009	Medical devices - Risk management application to medical devices

3.1 The general standard, collateral standard and specific standard shall be in equivalent versions for use.

4. DEFINITIONS

For the purposes of this RAC, the following definitions shall be adopted, as well as those contained in the complementary documents mentioned in item 3:

4.1. Technical Assistance

Technical Assistance: Maintenance or repair of a finished product in order to restore it to its specifications [Anvisa RDC no. 16, of 2013, item 1.2.1]

4.1.1 Technical Assistance – Extended definition [Inmetro]

This is the process that a professional, with knowledge of specific technical content, provides information and clarifications or perform actions to meet identified needs, including maintenance or repair of a finished product in order to restore it to its specifications;

4.1.1.1 Allows the information gathering relevant to the object in question for design improvement, quality improvement, effectiveness and efficiency of products, processes or services.

4.1.1.2 Contributes to the competitiveness of companies in the market, as well as strengthening its quality management systems.

4.1.1.3 Depends directly on the skills and abilities developed by its employees, through training as well as material resources provided for its execution.

4.1.1.4 Requires a higher priority in the quality management systems, proven through repeated employment of efforts with customers to solve problems.

4.1.1.5 a structure characterized by the following is recommended:

a) personnel who demonstrate knowledge and ability;

b) constant training evaluation of personnel when implementing the knowledge to attend the customers' need;

c) the use of "better acknowledged practices", and relevant standard-setting or regulatory documents as a response to specific problems; and

d) the use of various means of communication with the customer.

4.2 Original Characteristics

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 Critical Component

Component that directly affects the safety of the patient and/or user.

4.4 Usability Engineering

Application of knowledge about human behavior, abilities, limitations and other characteristics to the equipment design or electromedical system achieve proper usability. [IEC 62366:2007, definition 3.8]

4.5 Routine (or Production) Testing

Nondestructive testing, conducted by the manufacturer, which provides an evidence of compliance of a lot manufactured at a given time. The testing is performed in 100% of the units of a manufactured product or a product over the course of a production line in order to prove that the product assembly was performed according to the design requirements and conditions specified by this RAC.

4.6 Type (or qualification) Test

Test, destructive or not, which provides an evidence of compliance of an item at any given time, conducted in one or more units of a product to demonstrate that this product fulfill the requirements specified in the design, and it is according to evaluation requirements established based on Brazilian standards (ABNT), regional and international standards, and the conditions specified by this RAC.

4.7 Large-scale equipment for diagnosis or therapy:

Health Application Equipment used for diagnosis or therapy, it has a permanent installation in an environment specially built/adapted for its operation, with individualized and specific power supply system. This equipment requires the performance of maintenance actions on its installation site. A specialized team, usually requiring a formal commissioning for its approval, performs its installation.

NOTE: The following constitutes large-scale equipment, but not limited to these, equipment used for X-Ray, interventionists, nuclear medicine, computerized tomography, and MRI.

4.8 Manufacturer

Legal entity in charge of the design, manufacturing, assembling, transforming or processing a finished product or system, packaging and labeling of a medical product, 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 Contract Manufacturer

Third-party company, duly constituted as the legal person, which perform the industrialization of a medical product under the responsibility of a legal manufacturer through a legally established contract.

Note: "*Fabricante Contratado"* derives from the English term *"Contract Manufacturer"* (CM).

4.10 Legal 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.

4.11 Family

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

4.12 Risk Management

Systematic application of politics, procedures and management practices to the tasks of analysis, evaluation, control and risk management. [ABNT NBR ISO 14791: 2009, item 2.22]

4.13 Anvisa Normative Instruction – IN

It is a regulatory act from the Anvisa Collegiate Board of Directors which exceptionally establishes technical requirements to be fulfilled by an object.

4.14 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.

4.15 Protection Means

For any equipment or electromedical system connected by a structured cabling system, the manufacturer shall declare the protection means used to reduce the risk arising from electrical shock (MDP), which is divided into two classes: reduction means of risk of electrical shock to the patient (MPP); and reduction means of risk of electric shock to the equipment operator (MPO).

4.16 Serial or Lot Number

Distinct combination of letters or numbers, or both, by means of which the complete background of purchases, manufacture, packaging, labeling and distribution of finished products may be determined. [RDC no. 16, of March 28th, 2013, item 1.2.15]

4.17 Essential Production Process

This is a method, system or range of activities necessary for generating a product with a given critical purpose, implemented from the beginning to the final delivery of the product.

4.18 Design History Record (RHProj)

Compilation of records containing the complete history of the design of a finished product.

4.19 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.

4.20 Applicant

Legal entity, public or private, domestic or foreign, legally established in the country, with Brazilian Registry of Legal Entities (CNPJ), which performs at least one of the following activities: production, assembly, creation, construction, transformation, import, free distribution or not, or marketing of Equipment subject to the Health Surveillance Policy, as

covered by this RAC. It is responsible for applying for the product certification at the OCP, it has the responsibility to guarantee the execution of routine testing set forth in this RAC. It holds the permission for use of Compliance Identification Marks, being accountable for requesting record and registration in Anvisa.

4.21 Risk Management Summary

Risk Management Summary (SGR) is the fundamental document in the prioritization of risk management, in accordance with analysis and evaluation, to the definition of acceptability, treatment and control that shall be given to each one of the risks or dangerous situations identified for a product or EM system. This serves to give traceability to the implementation of the itens of ABNT NBR ISO 14971 (clause 3.5 of ABNT NBR ISO 14971) and supports the prioritization of corrective actions, besides containing the record of any change in the design. SGR shall also correlate, at least, all the requirements of the standards applicable to the product that was established by Normative Instruction, and its risk management process (analysis, evaluation, control and monitoring) in accordance with ABNT NBR ISO 14971. This shall include dangerous situations that have not been set forth in standards applicable to the product, though which have been identified as relevant in the risk analysis.

4.22 Pilot or Production Unit

Pilot or Production Unit corresponds to one product unit or a set of units manufactured according to the criteria for the manufacturing process established in the product design. The pilot unit uses the material which will be used in the production of the product, and the process and exclusive tooling required for its fabrication, being built after a complete risk management analysis by the manufacturer, through evaluation and testing prior to certification.

5. MECHANISM OF COMPLIANCE EVALUATION

The mechanism of compliance evaluation used in this document is the Certification, applicable to Equipment under the Health Surveillance Policy set forth in this RAC.

6. STAGES OF THE COMPLIANCE EVALUATION

The compliance evaluation process consists of several stages, and each stage follows a sequence of process. This chapter sets forth the compliance assessment process, which shall follow the requirements of RGCP, complemented by this RAC.

6.1 Definition of Certification Model used

This RAC sets forth the Certification Model 5 – Type tests, evaluation and approval of the Quality Management System (QMS) of the manufacturing process, followed by audits carried out *in loco* and in importers holding record and registration, certification applicants, and by tests performed in samples collected from the market and from the manufacturer, subjected to evaluation and approval of Risk Management of the manufacturing process.

6.2 Initial Evaluation

The criteria for Certification Initial Evaluation shall follow the requirements of RGCP.

6.2.1 Certification Request

The Certification Request shall begin with a budget request for the certification, and the criteria for the Certification Request shall follow the requirements of RGCP, in accordance with

the standards and deadlines established by Anvisa Normative Instruction no. 04/2015 and its substitutes, complemented by this RAC.

6.2.1.1 The 6.2.1.1 requirement of RGCP shall be fully applied.

6.2.1.2 The 6.2.1.2 requirement of RGCP shall be applied:

6.2.1.2.1 The items 'a', 'd', 'g', 'l', 'm', 'p' and Notes 1, 2, 3 and 4 shall be fully applied;

6.2.1.2.2 The item 'b' shall be applied with the following wording.

"Relation of model(s) which compose the certification object family, according to rules on family formation as set out in Annex III of this RAC. When the certification has been made by family, this shall refer to its technical description(s) and include the list of all commercial brands;"

6.2.1.2.3 The item 'c' shall be fully excluded.

6.2.1.2.4 The item 'e' shall be fully applied and complemented with:

"The following items shall be part of "Descriptive Memorial": list of technical standards with justification, defined by the manufacturer as applicable to the product; the identification, with justification, should a product be part or not of a family; the identification, with justification, should a product be part or not of an electromedical system; and the description of products which are parts of the system, if applicable."

6.2.1.2.5 The item 'f' shall be fully applied and complemented with the following wording:

"The product's user manual, draft or final version in accordance with ABNT NBR IEC 62366/2010, item 6 and clause 5.1. The user manual shall specify the medical device application in the usability-engineering record. This specification shall always include, if applicable:

a) Significant performance characteristics:

i) Medical indication for;

ii) the intended population of patients informing at least their age, weight, health and patient's condition;

iii) part of the body or tissue type in which is applied or with which it is interacts;

iv) intended user profile, with a wording in an understanding level consistent with the intended user profile; and

v) intended use conditions informing at least the environment for use, including hygiene requirements; frequency of use; location and mobility.

b) A summary of the product application specification or "intended declaration of use";

c) Principle of operation; and

d) Significant constructive physical characteristics."

6.2.1.2.6 The item 'h' shall be fully applied; Model 5 is the unique certification model.

6.2.1.2.7 The item 'I' and 'j' shall be fully applied replacing the term "Applicant Supplier" for "Applicant" as set forth in the definition 4.20 of this RAC;

6.2.1.2.8 The item 'k' shall be fully applied replacing the term "Manufacturer" for "Manufacturer, Contract Manufacturer, and/or Legal Manufacturer, if applicable," as set forth in the definitions 4.8, 4.9, and 4.10 of this RAC.

6.2.1.2.9 The item 'n' shall be applied replaced with the following wording;

"Documents related to the Quality Management System of the manufacturing process, applicable to the object to be certified set forth in Annex B, for they shall be audited by OCP, as set forth in the herein document." The latest audit report of the requirements set forth in Annex B may be provided to companies with valid certificates issued by OAC accredited by Inmetro or a MLA member of IAF in accordance with ABNT NBR ISO 13585:2004, as an evidence of requirements set forth in Annex B of this RAC of ABNT NBR ISO 13485:2004 standard.

6.2.1.2.10 The compliance with the requirement of item 'o' is optional;

6.2.1.2.11 The item 'q' shall be excluded.

6.2.1.2.12 The item 'r' shall be fully applied and complemented with the following wording:

"Other documents shall be requested by OCP, for the implementation of item 6.2.4 (Definition of Test planning)"

6.2.1.2.13 In addition to the documentation provided in RGCP, the manufacturer shall provide a descriptive summary of Risk Management in accordance with ABNT NBR ISO 14971, general requirements for Risk Management, item 3 including:

a) Senior management responsibilities, item 3.2.

b) Personnel Qualification, item 3.3.

c) Risk Management Plan, item 3.4.

d) Risk Management Summary, item 3.5.

6.2.2 Analysis of requests and compliance of the documentation

The criteria for analysis of requests and documentation shall follow the requirements of RGCP.

6.2.2.1 The 6.2.2.1 requirement of RGCP shall be fully applied.

6.2.2.2 The 6.2.2.2 requirement of RGCP shall be fully applied.

6.2.2.3 The 6.2.2.3 requirement of RGCP shall be fully applied.

6.2.2.4 Analysis of Risk Management File

In this stage, the applicant shall send the Risk Management File of the manufacturing process to OCP. The AGR will be analysed by OCP:

6.2.2.4.1 To prepare the manufacturer's audit; and

6.2.2.4.2 To elaborate the Test planning, which shall establish the test required for the product's Compliance Evaluation. The AGR shall be minimally accompanied, among other documents, if applicable, of:

a) product's technical specification;

b) product's electrical schematics;

c) identification of the function of equipment or EM system which are essential performances:

d) list of critical components;

e) Selection criteria of high integrity components;

f) list of certified components and their certificates;

g) flammability classification for insulation materials;

h) isolation diagram including MDP – MPP and MPO;

i) comparative indexes of tracking solid insulation materials (CTI);

j) degree of pollution;

k) specification of wires;

l) insulation class of transformers, motors, electrical keys, lamp sockets, etc.;

m) overvoltage category of the equipment;

o) usability-engineering record;

p) policy of determining the acceptable risk and the acceptability of residual risks;

q) project calculations of tensioning safety factor for equipment which have unsprung masses;

r) documentation of Development Life Cycle for Programmable Electro Medical Systems (SEMP), with the identification of dangers, risk control, requirements specification, architecture, project implementation, verification, validation, modification and SEMP connection to other equipment; and

s) risk management summary.

6.2.3 Initial Audit of Quality Management System and Evaluation of Production Process

6.2.3.1 The 6.2.3 requirement of RGCP shall be fully excluded.

6.2.3.2 Initial Audits of Risk Management Systems (SGR), Quality Management Systems (QMS), and Evaluation of Production Process

The Initial Audits of Risk Management Systems, Quality Management Systems, and Evaluation of Production Process shall be performed regardless of whether the manufacturer or applicant has SGR and SGQ certified, based on the current edition of ABNT NBR ISO 14971, ABTN NBR IEC 60601-1, and ABNT NBR ISO 13485 standards, respectively, if applicable. The OCP shall assess the documents and records of SGR and SGR, and perform audit in the premises of the

manufacturing unit, in order to verify the compliance of the production process, including the design, essential production process, product manufacturing, facilities, and staff training. The audit shall pursue the objective evidence that the production process is effectively systemized and monitored, providing evidences of compliance with the quality management requirements and product risk management set forth in the RAC.

6.2.3.2.1 The compliance records for the compliance with these requirements shall be obtained consistently. The visit date for the audit shall be scheduled in agreement with the certification applicant.

6.2.3.2.2 The initial audit shall be conducted in essential(s) production(s) process(es) in order to cover all the stages of product's design and manufacturing, facilities, and training of personnel objected to certification. This shall include audit to importers, record and registration holders, certification applicants.

6.2.3.2.3 The evaluation of SGR and SGQ shall be performed by OCP based on the scope of the certification process and in compliance with the requirements of the current edition of ABNT NBR ISO 14971, ABNT NBR IEC 60601-1, and ABNT NBR ISO 13485 standards.

6.2.3.2.4 The Brazilian OCP shall proceed to the initial audit of GR and SGQ in the manufacturing unit during the initial evaluation stage or request the audit to be conducted by OAC accredited by MLA member body of IAF, with which the OCP has MoU, through an Audit Plan developed by the Brazilian OCP. This audit shall necessarily consider all requirements of Annexes A and B of this RAC, in order to verify the compliance of the production process and GR. The results of these audits shall be treated and evaluated by the Brazilian OCP.

6.2.3.2.5 The certificates issued by a foreign OCP shall be accompanied by a sworn translation in Portuguese, when these have been issued in a different language other than English or Spanish. The other documents regarding the Management System, which are in a different language other than English or Spanish, shall be translated to Portuguese.

6.2.3.2.6 During the audit, the certification applicant manufacturer shall provide to OCP all documents corresponding to the certification of SGR and SGQ, and submit the records of the production process which shall be clearly stated the identification of the object of certification. The OCP shall analyze the relevant documentation to ensure that the requirements described in Annexes A and B of this RAC have been met. To the audit of importers, record and registration holders, certification applicants, the OCP shall analyze the relevant documentation to ensure that the requirements described in Annex B of this RAC have been met.

6.2.3.2.7 During the audit, the manufacturer shall submit, if available, copies of the reports to evaluation of the items of ABNT NBR ISO 14971 and ABNT NBR IEC 60601-1 of Annex A, and ABNT NBR ISO13485:2004, of Annex B, of any other evaluation of the system, audits/inspections of SGR and SQR, and the records of corrective actions which have been implemented when identified and applicable.

6.2.3.2.8 Should be needed the inclusion of new products and/or accessories within the already certified family of products, after the initial audit, the OCP shall verify whether or not a special audit is necessary, if the initial audit has not covered all stages of manufacturing required for the new products.

6.2.3.2.9 The OCP, after the audit, shall issue a report, recording the result of the same, in accordance with this RAC.

6.2.3.2.10 The audit report shall be signed by at least the audit team, and a copy shall be available to the certification applicant.

6.2.3.2.11 Any change in the manufacturing process shall be informed to the OCP and may require another audit, if it affects the compliance of the product.

6.2.3.2.12 In case of certification based on "pilot unit", the OCP, during the audit, shall ensure that the product manufactured in scale corresponds to a tested "pilot unit".

6.2.3.3.13 Evaluation of SGQ of the manufacturer

The SGQ of the manufacturer shall be evaluated:

a) In accordance with ABNT NBR ISO 13485:2004, and hereby verifies the requirements set forth in Annex B of this RAC; or
b) Through analysis of the last audit report, of requirements set forth in Annex B, provided that such audit report has covered the production line of the product object to certification to companies with valid certificates issued by OAC accredited by Inmetro in accordance with ABNT NBR ISO 13585:2004; or
c) Through analysis of compliance of the last audit report of requirements of Annex B set forth in Anvisa RDC no. 16/2013 "Good Manufacturing and Control Practices Certification," to companies with valid certificates issued by Anvisa. The analysis shall comply with the evaluation criteria of activities of the table 10 of Annex B – Criteria for the Compliance Evaluation of the Activities in accordance with Anvisa RDC no. 16/2013.

6.2.3.3.14 The audit of AGR shall:

a) Confirm the compliance with the requirements described in Annex A; and

b) Evaluate the procedures that the legal manufacturer have in force to RMP and RHProj.

6.2.4 Definition of Test Planning

The 6.2.4 requirement of RGCP shall be fully applied.

6.2.4.1 Definition of Tests to be performed

The 6.2.4.1 requirement of RGCP shall be applied with the following wording:

The Test Planning shall be initially defined by the manufacturer and the OCP, in compliance with the current applicable standards of Anvisa Normative Instruction; and subsequently it shall pass through critical analysis of the laboratory for the budget execution, meeting the following requirements:

6.2.4.1.1 In this stage, the OCP shall analyze the consistency of documentation submitted by the applicant in item 6.2.3 for the development of the product Test Planning defined by the risk management chart.

6.2.4.1.2 The Test Planning shall be established between the OCP and the Laboratory before the beginning of the tests, in accordance with the following requirements:

a) The laboratory shall interact with the OCP, in the case of questions about the conduction of the tests, in the stage of definition of tests to be performed.

b) An interaction shall exist between the OCP and the laboratory in order to enable and facilitate the conduction of tests or should a modification on the Initial Test Planning is required.

6.2.4.1.3 The laboratory shall confirm and list all the documentation received in the test report required for testing, listed in the item 6.2.1, and it shall indicate its versions whenever practicable.

6.2.4.1.4 During the testing, the laboratory may question and request the review of the test planning and the submitted documentation.

6.2.4.1.5 The type test shall be entirely performed in the pilot unit or in a sample of the production line of the equipment in certification process.

6.2.4.1.6 The issuance of reports shall not exceed two (2) years from the acceptance date of hiring the OCP for the certification of the product.

6.2.4.1.7 The issuance of reports shall not exceed four (4) years from the acceptance date of hiring the OCP for the certification of large-scale equipment set forth in item 4.7.

6.2.4.1.8 The test reports, which meet at least the requirements of item 6 of this RAC, may be accepted, provided that:

a) Any changes made to the design are duly documented, and the relevant tests performed are likewise documented;

b) Should there have not been significant changes in the product, in accordance with the item A1 of Annex A of this RAC, since the reports issuance, the applicant shall submit document stating that the product has not been modified after the issue date of the test report; and

c) The evaluation of the performed tests, the equipment initial design and risk management of the product for which the report has been issued, the updated design of the equipment and the statement of item 6.2.4.1.8.b shall integrate the documentation of the certification process of the equipment.

6.2.4.1.9 The planning of type tests on samples taken from the product shall be conducted by the OCP after the evaluation of the documents listed in item 6.2.3. The analysis of test reports previously performed, submitted by the applicant, which shall be in accordance with the applicable technical standards listed in item 3 of this RAC and current Anvisa Normative Instruction and the requirements of RGCP complemented by this RAC

6.2.4.1.10 The type tests shall be repeated through the evaluation of OCP of the impact of modifications in the mechanical or electrical-electronic project, or changes to the critical components, items 4.8 and 4.9 of ABNT NBR IEC 60601-1 standard of the list of materials of the originally certified product made by the manufacturer, when such evaluation concludes that the revisions or modifications impact the compliance previously evaluated. The type tests shall also be repeated by the determination of Anvisa or at the time of recertification of the product and design, with technical justification for such action.

6.2.4.2 Definition of Sampling

The 6.2.4.2 requirement of RGCP shall be applied with the following wording:

“To perform the initial tests of evaluation of the product, the sample shall be collected by the OCP or, by an agreement between the parties, forwarded to the OCP by the

manufacturer. The sample shall be composed of one (1) unit of the production line already inspected, authorized, and packed for sale, or one (1) pilot unit. The OCP or the manufacturer, respectively, shall formulate a report of the sample, detailing the following information: sample submission date, place of manufacture, storage conditions, sample identification (model/brand, manufacturing batch and date of manufacture).";

6.2.4.2.1 To perform the tests of recertification of the product, the sample shall be collected by the OCP or, by an agreement between the parties, forwarded to the laboratory under the supervision of OCP by the manufacturer. The sample shall be composed of one (1) unit of the production line already inspected, authorized, and packed for sale. The OCP shall formulate a report of the sample, detailing the following information: date, place of manufacture, storage conditions, sample identification (model, brand, manufacturing batch, software version if applicable, and date of manufacture).";

6.2.4.2.2 The manufacturer, when agreed with the OCP, shall control all characteristics of the sample before sending it to the laboratory;

6.2.4.2.3 The OCP shall control all characteristics of the sample to be sent to the laboratory for the recertification or when identifying non-compliance during the maintenance audit;

6.2.4.2.5 Should the OCP deems necessary the evaluation of more than one (1) sample, the number of samples, acceptance/rejection criteria and exceptional cases shall be negotiated with the manufacturer for a number greater than or equal to three (3) samples;

6.2.4.2.6 The Note 1 shall be applied in the initial evaluation of the product;

6.2.4.2.7 The Note 2 shall be fully applied; and

6.2.4.2.8 The Note 3 shall be fully excluded.

6.2.4.2.9 Should the OCP or the manufacturer deems necessary, by an agreement between the parties, the evaluation of more than one (1) sample, the number of samples, acceptance/rejection criteria and exceptional cases shall envisage a number greater than or equal to or a multiple of three (3) samples, with all the samples being taken from the same manufacturing batch. In this case, the following requirements of RGCP shall be fully applied:

a) the Table 4; and

b) the item 6.2.4.2.1.

6.2.4.2.10 The 6.2.4.2.2 requirement of RGCP shall be fully excluded.

6.2.4.2.11 The 6.2.4.2.3 and 6.2.4.2.4 requirements of RGCP shall be applied replacing the term "Prototype" for "Pilot or Production Unit, as set forth in the requirement 4.22 of this RAC.

6.2.4.2.12 The OCP shall verify the compliance and evaluation of all applicable normative requirements through the manufacturer or the testing laboratory;

6.2.4.2.13 The manufacturer shall evidence to the OCP, through photos, diagrams and other means to assure unequivocally, that the sample meets the characteristics defined by the OCP.

6.2.4.2.14 The collection of samples, by family, shall be performed in accordance with the Annex D of this RAC, by selecting the most critical configuration model.

6.2.4.2.15 The approval of the pilot unit in the initial tests does not exempt the OCP to validate the products after the start of operation of the production line.

6.2.4.2.16 The tests shall be performed with the collected sample(s).

6.2.4.2.17 In the case of the failure of the sample in tests, the non-compliance shall be reported to the applicant. Should the applicant does not technically refute the non-compliance, this stage shall be suspended, and the applicant shall submit a plan of adjustment and elimination of non-compliance(s) noticed to restart the tests defined as required by the OCP, based on the analysis of the corrective action of the manufacturer. The date for the restart of initial tests shall be agreed between the applicant, the OCP and the laboratory.

6.4.2.2.18 In case of the failure of the tests, and depending on the evaluation of the OCP, the sample shall be considered disapproved and a new sample shall be forwarded to the laboratory by the manufacturer. The OCP shall control all characteristics of the new sample.

6.2.4.3 Definition of laboratory

For the purposes of the herein RAC, the criteria of Definition of Laboratory shall follow the requirements of RGCP, as set forth or modified in this RAC:

6.2.4.3.1 The 6.2.4.3.1 requirement of RGCP shall be fully applied.

6.2.4.3.2 The 6.2.4.3.2 requirement of RGCP with the following modifications:

a) The item 'a' and the Notes 1, 2, 3 and 4 shall be fully applied;

b) The item 'b' shall be fully excluded and it shall be replaced with the following wording:

"When the laboratory(ies) fully accredited by Inmetro/GCRE or signatory of mutual recognition agreements ILAC or IAAC, in the specific scope does(do) not meet, a maximum of, four (4) months the deadline for the beginning of the tests set forth in this RAC from the signature of the contract in an exceptional and temporary manner, the OCP may use laboratories in accordance with the 6.2.4.3.1 requirement of RGCP." This deadline is extended to a maximum of six (6) months to large-scale equipment in accordance with the definition 4.7.

d) The item 'c' shall be fully excluded; and
e) The third-party accredited laboratory has the prerogative to perform tests on external sites regarding the physical location of the laboratory, provided that it is clearly described in the scope of accreditation to its status as accredited to perform tests on external facilities to the laboratory.

6.2.4.3.3 The 6.2.4.3.3 requirement of RGCP shall be fully applied.

6.2.4.3.4 The 6.2.4.3.4 requirement of RGCP shall be applied with the following wording:

"In any of the cases of full or partial use of the first-party laboratory accredited in the scope of the specific test, the OCP shall witness, record the performance of all tests, including the monitoring of the stage of selection and preparation of the samples and the collection of results."

6.2.4.3.5 The 6.2.4.3.5 requirement of RGCP shall be applied with the following wording:

“In any of the cases of use of first or third-party laboratory accredited for another test scope, the OCP shall record the performance of all tests, including the monitoring of the stage of selection and preparation of samples and the collection of results, after acknowledging and recording the training and infrastructure (including equipment) of the laboratory.”

6.2.4.3.6 The 6.2.4.3.6 requirement of RGCP shall be fully applied adding the following wording:

“To meet the requirement of formal verification of experience, the professional of the OCP shall have a record of participation in, at least, three (3) audits in the last three consecutive years, in the ABNT NBR ISO/IEC 17025:2005 standard and evidences of knowledge, training and experience in the test to be evaluated and the product to be tested. The final formal audit training in ABNT NBR ISO/IEC 17025:2005 standard shall be administered by an organization independent from the OCP.”

6.2.4.3.7 The 6.2.4.3.7 requirement of RGCP shall be fully applied.

6.2.4.3.8 Should a single laboratory is not able to perform all required tests, more than one laboratory may be used, in compliance with the requirements for the selection of laboratory of RGCP complemented by this RAC.

6.2.5 Treatment of non-compliances in the stage of Initial Evaluation”

The 6.2.5 requirement and items of “Treatment of non-compliances in the stage of initial evaluation” of RGCP shall be fully applied.

6.2.6 Issuance of the Certificate of Compliance

The issuance of the Certificate of Compliance shall follow the requirements described in the RGCP and it shall be performed by family of equipment under the Health Surveillance policy, as set forth in Annex D of this RAC.

6.2.6.1 Critical Analysis and Decision of Certification

The 6.2.6.1 requirement and items of “Critical Analysis and Decision of Certification” of RGCP shall be fully applied and complemented with the following requirements:

6.2.6.1.1 In the case of certification of digital sphygmomanometers and digital clinical thermometers which shall meet metrological regulation, the certification of compliance shall only be granted to the applicant after obtaining the Ordinance of Approval of the Model published by Inmetro.

6.2.6.1.2 Reports of product tests for meeting metrological requirements may be used in the certification process of this RAC should duplicate any specific requirement of compliance evaluation.

6.2.6.1.3 The Certification of Compliance shall be valid for five (5) years from the issuance.

6.2.6.2 Issuance of the Certificate

The 6.2.6.2 requirement “Issuance of the Certificate” of RGCP shall be fully applied:

6.2.6.2.1 The 6.2.6.2.1 and 6.2.6.2.2 requirements of RGCP shall be fully applied.

6.2.6.3 Certificate of Compliance

The 6.2.6.3 requirement “Certificate of Compliance” of RGCP shall be fully applied:

6.2.6.3.1 The 6.2.6.3.1 requirement of RGCP shall be fully applied in accordance with the following items:

a) The items ‘a’, ‘d’, ‘e’, ‘g’, ‘l’, and ‘n’ and the Notes 1 and 2 (specific for digital sphygmomanometers and thermometers) shall be fully applied

a) the item ‘b’ shall be fully applied replacing the term “applicant supplier” for “applicant” as set forth in the definition 4.20 of this RAC;

b) the item ‘c’ shall be fully applied replacing the term “Manufacturer” for “Manufacturer, Contract Manufacturer, and/or Legal Manufacturer, if applicable,” as set forth in the definitions 4.8, 4.9, and 4.10 of this RAC;

c) the item ‘f’ shall be fully applied indicating “Model 5”;

d) the item ‘h’ shall be fully applied supplementing with information on the original characteristics of the product;

e) the items ‘i’ and ‘j’ shall be fully excluded;

f) the item ‘k’ shall be fully applied along with the identification of technical standards applied in the certification;

g) the item ‘m’ shall be fully applied along with the information of date(s) of issue of the test(s) report(s);

h) provide the date of acceptance of the proposal when the date of issue of the test report is greater than two years or four years for large-scale equipment, as set forth in the definition of item 4.7, in the date of issue of the certificate;

i) provide the list of accessories and parts tested with the product;

j) provide the version of user manual and the design of the evaluated product to grant the certification; and

k) provide the version of the evaluated software, for equipment with embedded or accompanying software.

6.3 Evaluation of the Maintenance

The Evaluation of the Maintenance shall be performed by the OCP, in accordance with the conditions laid down in RGCP, in Annexes A and B of this RAC. The notes 1, 2 and 3 of the 6.3 requirement of RGCP shall be excluded in this RAC.

6.3.1 Maintenance Audit of Quality Management System, Risk Management and Productive Process of the Manufacturer.

The maintenance audit shall be performed by the OCP, in accordance with the conditions laid down in RGCP and in Annexes A and B of this RAC, with the following modifications:

6.3.1.1 The 6.3.1.1 requirement of RGCP shall be applied replaced by:

6.3.1.1.1 The OCP shall schedule the performance of periodical maintenance audit in the productive process of the manufacturer or service provider covering, at least, the following stages:

a) verification of the original documentation mentioned in item 6.2.1, in particular regarding the availability, organization and retrieval;

b) analysis of records, especially those associated to the compliance with the fulfillment of the requirements to perform the audits listed in Annexes A and B of this RAC; and

c) the OCP shall evaluate, during the audit of companies with productive process considered essential to the manufacture of the product object of this certification, should these companies adopt a Quality Management System certified in accordance with the ABNT NBR ISO 13485:2004 standard or Anvisa RDC nº 16/2013 "Good Manufacturing and Control Practices Certificate":

i) the last audit report of the product object of this certification covers and complies the requirements set forth in Annex B.

ii) in both cases the certificate is valid; and

iii) the general items of verification of Annex A of this RAC have been met.

6.3.1.2 The 6.3.1.2 requirement of RGCP shall be applied replacing the term "Inmetro/Dconf" for "Anvisa":

6.3.1.3 The OCP shall witness the performance of routine testing on the production line if applicable.

6.3.1.3.1 The audit shall be conducted in an agreement between the OCP and the manufacturer. The OCP shall schedule the factory audit for the period in which the production line is producing.

6.3.1.3.2 The OCP shall witness the operation of the production line and the performance of the functional and routine tests, if applicable, as scheduled, recording the serial number and the product model evaluated in witness tests.

6.3.1.4 Should it not be possible for the OCP to witness the operation of the assembly line until the maintenance audit, the OCP shall schedule an additional audit to be performed in the week of the resumption of the assembly line production.

6.3.1.5 Provided that there is justifiable evidence or by instruction of Anvisa the OCP may perform additional maintenance audits and type tests to verify the maintenance of the compliance of certified products.

6.3.1.6 The frequency of maintenance audits shall not be greater than fifteen (15) months from the date of issue;

6.3.2 Maintenance Test Planning

The 6.3.2 requirement of RGCP shall be applied, complemented and modified as the following. The establishment of the Maintenance Test Planning may occur by the determination of the OCP, based on the audit in accordance with the Annex A, due to changes in the design or standards that require new tests, or by the determination of Anvisa. Under these conditions, the Maintenance Test Planning shall follow the requirements of RGCP complemented by this RAC.

Note 1: The Maintenance Test Planning shall not be applied to factory routine testing, previously agreed between the OCP and the manufacturer, in accordance with the AGR and Annexes A and B of this RAC, if applicable.

6.3.2.1 Definition of Tests to be performed

The maintenance tests shall be performed in accordance with the requirements of the item 6.4.2.1 of RGCP, observing the current Anvisa Normative Instruction complemented by this RAC.

6.3.2.2 Definition of Maintenance of the Sampling

The criteria of the Definition of Maintenance of the Sampling in the evaluation of the maintenance shall follow, along with the requirements of RGCP, the following requirements:

6.3.2.2.1 The collection of samples, by family, in accordance with the Annex D of this RAC, shall include the most critical configuration model.

6.3.2.2.2 At least one (1) sample shall be collected form the production line, by random selection performed by the OCP, of products already inspected, authorized and packed for sale.

6.3.2.3 Definition of Laboratory

The criteria of the Definition of Laboratory, should modifications in the product are identified during the certification maintenance audit, shall follow, along with the requirements of RGCP, the same requirements of item 6.2.4.3 of this RAC.

6.3.3 Treatment of non-compliances in the stage of Maintenance

The criteria for the treatment of non-compliances in the stage of maintenance shall follow the requirements of RGCP, complemented by the instructions of this RAC.

6.3.3.1 Should occur failure during the performance of the tests of item 6.3.2.1, the Certification of Compliance shall be suspended until the applicant evidences, in a new audit, when a new collection of samples and the performance of new tests shall be conducted, the elimination of the non-compliance. A new audit shall occur within a period not exceeding fifteen (15) days.

6.3.3.2 Should occur failure of the sample during the testing, the non-compliance shall be notified to the applicant and the Certificate of Compliance shall be suspended. Should the applicant has not technically contested the non-compliance within 15 days, the applicant shall submit a plan of adjustment and elimination of the non-compliance(s) observed for the resumption of the tests defined as required by the OCP, based on the analysis of the corrective action of the manufacturer. A new sample shall be collected in accordance with the 6.3.2.2 requirement of this RAC and new tests shall be performed.

6.3.3.3 The failed products in the possession of the applicant shall be destroyed by the manufacturer while being monitored by the OCP, unless it is possible for them to be reprocessed.

6.3.3.3.1 This decision shall be duly grounded to ensure that non-complying products or products with threatened safety will not be sold.

6.3.3.4 Should non-compliances found during the maintenance testing have been corrected, the OCP shall evaluate the need for new testing in accordance with the item 6.2.5 of this RAC.

6.3.3.5 the OCP shall inform to Anvisa, through the email certifica.eletromedicos@anvisa.gov.br about the non-compliances identified in the process of the certification maintenance, which requires a field action or recall, whenever there are enough evidence or proof that a medical device does not meet the essential requirements of applicable safety and efficacy. The following information about the product and the identified problem shall be included in the e-mail:

a) description of the problem;

b) trade name and model of the product;

c) batches/series at risk;

d) registration number at Anvisa;

e) name of the applicant holder of the certificate;

f) risk related to the use of the product; and

g) corrective actions related to the product/problem.

6.3.3.6 Nonconforming products that cannot be repaired shall be collected and destroyed while being monitored by the OCP. In case of a possibility of repairing them, they shall be submitted after repair to all tests required for the release of a finished product and that evaluate if the non-compliance was duly corrected.

6.3.4 Confirmation of the Maintenance

The criteria for the confirmation of the maintenance of the certification shall follow the requirements of RGCP, complemented by the instructions of this RAC.

6.3.4.1 The OCP shall inform about the cancellation or suspension of the certificate to Anvisa through the email certifica.eletromedicos@anvisa.gov.br containing the following information:

a) Certificate number and number of OCP;

b) applicant's name;

c) brand and model of the product;

d) registration number at Anvisa;

e) a report of the reason for the cancellation or suspension, with the report number if applicable.

6.4 Evaluation of the Recertification

At the end of the five (5) years term after the issuance of the Certificate of Compliance, the criteria for the evaluation of the recertification shall follow the requirements of RGCP, complemented by the instructions applied in the items 6.2.3 "Analysis of Risk Management File,"

6.2.5 “Initial Test Planning,” 6.2.4.2 “Definition of the Sampling,” and 6.2.4.3 “Definition of laboratory” of this RAC.

6.4.1 Complete type tests shall be repeated in accordance with the following situations:

a) Test reports may be accepted up to two (2) years from the date of acceptance of the recertification, when the conditions laid down in items (b), (c) or (d) do not occur. To large-scale equipment in accordance with the item 4.7, the term for the date of issue of the test report is extended to four (4) years. The terms shall be applied in the date of acceptance of the contract of the OCP for the recertification of the product;

b) Change in the revision of any technical standard of the current Normative Instruction used in the initial test affecting the results of the tests previously performed;

c) Change in the equipment structure which implies product changes if compared to the previously evaluated compliance; and

d) Upon determination of Anvisa.

6.4.2 The OCP shall inform to Anvisa, through the email certifica.eletromedicos@anvisa.gov.br about the non-compliances identified in the recertification, which require a field action or recall, whenever there have enough evidence or proof that a medical device does not meet the essential requirements of applicable safety and efficacy. Use the requirements of the item 6.3.3.5.

7 TREATMENT OF COMPLAINTS

The criteria for the treatment of complaints shall follow the requirements of RGCP complemented by this RAC.

7.1 The 7 requirement, “Treatment of Complaints”, shall be fully applied and complemented with:

7.2. The OCP shall perform audits with a maximum interval of 15 months, in the applicant, done to evaluate the compliance with the 7 requirement of RGCP; and

7.3 The applicant shall ensure forwarding the complaints to the manufacturer, and their responses by the manufacturer to the customer;

7.4 The applicant shall have a treatment of complaints covering the 7 requirement of RGCP, expressed as Complaint Treatment Policy signed by the chief executive.

8 ACTIVITIES PERFORMED BY THE OCP ACCREDITED BY A MLA MEMBER OF IAF

The criteria “Activities Performed by the OCP Accredited by a MLA Member of IAF” shall follow the requirements of RGCP.

8.1 The 8 requirement “Activities Performed by the OCP Accredited by a MLA Member of IAF”of RGCP shall be fully applied

9 TRANSFER OF CERTIFICATE

The criteria “Transfer of Certificate” shall follow the requirements of RGCP.

9.1 The 9 requirement, “Transfer of Certificate”, of RGCP shall be fully applied and complemented by the mutual understanding of the liability limits of the issuer OCP and the receiver OCP of the activity.

10 TERMINATION OF THE CERTIFICATION

The criteria for the Termination of the Certification shall follow the requirements of RGCP, complemented by the instructions of this RAC.

10.1 The 10.1 requirement of RGCP shall be fully applied.

10.2 The 10.2 requirement of RGCP shall be fully applied and complemented with:

10.2.1 The collection of samples and the performance of tests for closing the process may be performed in accordance with the Annex A of this RAC at the criterion of OCP.

10.2.2 The collection of samples and closing tests will not be required for large-scale EM equipment and EM systems. The OCP shall evaluate the most recent records of monitoring tests performed by the responsible manufacturer of the chain of production.

10.3 The requirement 10.3 of RGCP shall be fully applied.

10.4 The requirement 10.4 of RGCP shall be fully applied.

10.5 The requirement 10.5 of RGCP shall be fully applied.

10.6 The requirement 10.6 of RGCP shall be fully applied and complemented with:

10.6.1 The OCP shall notify the termination of the certification to Anvisa through the email certifica.eletromedicos@anvisa.gov.br with the following information:

a) certificate number and number of OCP;

b) applicant’s name;

c) brand and model of the product; and

d) registration number at Anvisa

e) attach the reason for the termination.

10.7 The requirement 10.7 of RGCP shall be fully applied and complemented with:

10.7.1 The results of the audit, tests and termination records shall be documented to integrate the documentation of the certification process and shall be kept by the OCP in electronic means or other at least 5 years from the termination of the certification.

11 COMPLIANCE IDENTIFICATION MARK

The criterion “Compliance Identification Mark” shall follow the requirements of RGCP, complemented by the instructions of this RAC:

11.1 The requirement 11.1 of RGCP shall be fully applied.

11.2 The requirement 11.2 of RGCP shall be applied and replaced with the following wording:

“The Compliance Identification Mark may be printed in the Certificate of Compliance, and shall be marked or affixed to the product and/or printed or affixed to the packaging, in compliance with the instructions of Annex C, Compliance Identification Mark, of this RAC.”

11.3 The requirement 11.3 of RGCP shall be applied and replaced with the following wording:

“In the case of imported products, the Compliance Identification Mark shall be marked or affixed to the product and/or printed or affixed to the packaging, in compliance with the instructions of Annex C, Compliance Identification Mark, of this RAC, before entering the country.”

11.4 Specification

The specification of the Compliance Identification Mark is defined in the Annex C of this RAC.

11.5 Traceability

The applicant shall implement a traceability control of the products that have the Compliance Identification Mark, which shall be made available to Inmetro and Anvisa for a period of time equivalent to the product’s expected life cycle, though 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.

12 AUTHORZATION TO USE THE COMPLIANCE IDENTIFICATION MARK

Item “Authorization to Use the Compliance Identification Mark” shall follow the requirements of RGCP.

12.1 The 12 requirement, “Authorization to Use the Compliance Identification Mark,” of RGCP shall be fully applied.

13 RESPONSIBILITIES AND DUTIES

Item “Responsibilities and Duties” shall follow the requirements of RGCP, replacing the term “in the specific RAC of the object” for “in this RAC”; replacing the term “the specific RAC of the object” for “this RAC"; and complementing the requirement with the following wording:

13.1 Duties of the Applicant Holder of the Certificate. The applicant shall:

13.1.1 only produce, import and market the products object of the certification, which comply with this RAC and as evidenced by the Certification of Compliance.

13.1.2 The 13.1.2, 13.1.3, 13.1.4, 13.1.5, 13.1.6, 13.1.7, 13.1.8, 13.1.9, 13.1.10, 13.1.17, 13.1.18, 13.1.19 and 13.1.20 requirements of RGCP shall be fully applied.

13.1.3 The 13.1.11 and 13.1.15 requirement of RGCP shall be fully excluded.

13.1.4 The 13.1.12 requirement of RGCP shall be applied with the following wording:

“When announcing the field action or recall of certified products with non-compliances, this shall be in accordance with the Anvisa Resolution RDC no. 23/2012 or its substitutes.”

13.1.5 The requirement 13.1.13 of RGCP shall be replaced with the following wording:

"**13.1.13.1** Report to Anvisa, regarding the deadlines in compliance with the Anvisa Resolution RDC no. 67, of December 21st, 2009, or its substitutes, when identifying the certificated object distributed on the marked is presenting non-compliances, which put the health or the safety of the consumer at risk, after the following occurrences verified in national territory and associated to the health product registered in Anvisa under its name:

a) death, serious threat to public health and forgery
b) severe adverse event, with no associated death; and non-severe adverse event whose recurrence has the potential to cause a severe adverse event in a patient, user or other person.

13.1.13.2 Report to Anvisa, regarding the deadlines in compliance with the Anvisa Resolution RDC no. 67, of December 21st, 2009, or its substitutes, after technical complaint verified in national territory and associated to the health product registered in Anvisa under its name, which can lead to a severe adverse event in a patient, user, or other person, provided that at least one of the conditions below are verified:

a) the possibility of technical complaints recurrence is not remote;

b) an occurrence of the same type has already caused or contributed to death or serious harm to health in the last two years;

c) the registration holder for the product needs or would need to perform an action to prevent a health hazard;

d) there is a possibility of misuse induced by precarious design, labeling, or instructions.

13.1.13.3 Report to Anvisa, regarding the deadlines in compliance with the Anvisa Resolution RDC no. 23, of April 4th, 2012, or its substitutes, for notification of the performance of field action involving medical device of its responsibility, in accordance with the following conditions:

I – in case of the need to use wide circulation media vehicle to disseminate the alert message;

II – in case of several threat to public health;

III - when identified risk of occurrence of serious adverse event and the situation does not fit in Article 9, subsections I or II of Anvisa RDC no. 23/2012."

13.1.6 The 13.1.14 and 13.1.16 requirements shall be fully applied replacing the term "Inmetro" for "Inmetro and Anvisa".

13.1.7 In addition to the compliance of the requirements of RGCP, the applicant shall:

13.1.7.1 Ensure the performance of routine testing on products, in accordance with the Annex A, in 100% of manufactured units.

13.1.7.2 Perform tests in accordance with item 6.2.4, upon determination of Anvisa or Inmetro, to prove the maintenance of the compliance of certified products.

13.1.7.3 Ensure that RMP and RHProj are continuously updated at any certification time, under penalty of certification suspension or cancellation in case of non-compliance of this requirement.

13.1.7.4 Ensure, in case of digital sphygmomanometers or digital clinical thermometers, the maintenance of the same conditions of the Ordinance of model approval, when such product is subjected to certification/maintenance/recertification. In case of changes in the product to meet the herein approved requirement, the product shall be subjected to new technical verification model of Legal Metrology Board of Directors – Dimel, through the email dicol@inmetro.gov.br, regardless of the impact analysis, which needed to be performed in the pilot unit to the compliance with the requirements of this RAC.

13.1.7.5 Meet the other legal requirements for manufacture, import and marketing of the product, under penalty of certification suspension or cancellation.

13.2 Duties of the OCP. The OCP shall:

13.2.2 The 13.2.1, 13.2.2, 13.2.3, 13.2.4, 13.2.5, 13.2.6, 13.2.8, 13.2.9, 13.2.12, 13.2.13, 13.2.14, 13.2.16 and 13.2.17 requirement of RGCP shall be fully applied.

13.2.3 The 13.2.7 requirement of RGCP shall be applied replacing for the following wording "Collect samples to perform tests defined in this RAC, if applicable upon determination of Anvisa, before duly substantiated suspicions or complaints, bearing the costs related to the collection and testing, observing the provisions of item 14 of this RAC."

13.2.4 The 13.2.10 requirement of RGCP shall be fully applied replacing the term "Inmetro" for "Inmetro and to Anvisa".

13.2.5 The 13.2.11 requirement of RGCP shall be fully applied replacing the term "Inmetro/Cgcre" for "Anvisa"; and the term "ABNT NBR ISO 9001 or ISO 9001" for "ABNT NBR ISO 13485:2004 or Anvisa RDC no. 16/2013 Good Manufacturing Practices".

13.2.6 The 13.2.15 requirements of RGCP shall be fully applied replacing the term "Inmetro/Dconf" for "Inmetro/Dconf and to Anvisa.";

13.2.7 In addition to RGCP, the OCP shall:

13.2.7.1 Request to the applicant to subject the product to a new technical verification model of Legal Metrology Board of Directors – Dimel, through the email dicol@inmetro.gov.br, regardless of the impact analysis, which needed to be performed in the pilot unit to the compliance with the requirements of this RAC, in case of digital sphygmomanometers or digital clinical thermometers when such product undergoes any change under the conditions mentioned in the Ordinance of model approval.

13.2.7.2 Accept eventual penalties imposed by the regulatory bodies of the product.

13.2.7.3 Inform the applicant about the requirements set forth by Inmetro and Anvisa that may impact on it.

13.2.7.4 Keep updated, on the website of Inmetro, the list of all certificates issued, 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.

13.2.7.5 Monitor on the website of the regulatory body (Anvisa) the publication of alerts associated with certified products. The OCP shall evaluate whether the published alert affects the certification; if so, appropriate measures shall be taken with the applicant in order to follow up the corrective actions implemented to solve the problem that caused the alert. These actions shall be documented and be part of the product certification process documentation.

13.2.7.6 Follow up and implement determinations of the regulatory body (Anvisa), regarding the need for the performance of tests in a certified product.

13.2.7.7 Issue consolidated reports and other documents determined by the regulatory body (Anvisa), when requested.

14 MARKET SURVEILLANCE

The criteria for market surveillance are under the responsibility of Anvisa, being established by regulations of this Agency for Equipment under Health Surveillance.

14.1 Metrological equipment, digital electronic sphygmomanometers (Inmetro Ordinance no. 96/2008 and its substitutes), and digital clinical thermometers (Inmetro Ordinance no. 89/2006 and its substitutes) are the responsibility of Anvisa and Inmetro/Dimel.

15 PENALTIES

The criteria for application of penalties shall follow the requirements of RGCP, complemented by this RAC.

15.1 The applicant 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.

15.2 To products subject to record and registration at Anvisa, the applicant that fails to meet the requirements of this RAC, regarding the applicaple items, is subject to the penalties set forth in Law no. 6437/77 and in Article 273 of the Brazilian Criminal Code - Law no. 2848/40, and shall be considered as violations subject to penalties, among others:

15.2.1 Provide products with the Compliance Identification Mark that does not meet the quality standards established in this RAC;

15.2.2 Use the Compliance Identification Mark on non-authorized products;

15.2.3 Not to inform, or provide false information, about certified products;

15.2.4 Prevent auditors from accessing documents and records of their system; and

15.2.5 Not to accept the verification and sample collection within the deadlines set forth in this RAC.

15.3 The non-compliance of the applicable requirements of this RAC, by the applicant company whose products are subject to record and registration at Anvisa, constitutes health infringement, under the Law no. 6,437, of August 20th, 1977, and Article 273 of the Brazilian Criminal Code – Law no. 2848/40, without prejudice to the civil, administrative and criminal liabilities, including those established by Law no. 8078, of September 11th, 1990.

16 COMPLAINT

The requirement 16 "Complaint" of RGCP shall be fully applied.

ANNEX A – AUDIT

A.1 The factory audits shall be performed in accordance with the requirements of Table 1.

1. The risk management file shall be used as a basis for the evaluation. The AGR shall prove that there has not been changes with significant impact to the product safety not met by control measures. The requirements of the Tables 2, 3, 4, 5, 6 and 7 shall be audited and may be used electronic means and tools of the documental compliance evaluation.

A.2 The documents, which shall be used in the production, shall be inspected in the initial certification audit.

1. Statistical data of production for manufacturers in Brazil, or foreign manufacturers initiating the production of the object of certification shall only be available during the first maintenance audit or should occur a special audit prior to this one.

2. Statistical data of production for foreign manufacturers that already produce the object of this certification shall be verified in the Factory Initial Audit.

TABLE 1 – General Requirements of Compliance Evaluation

Application of risk management to medical devices Compliance Evaluation Requirements in Audit
1 General Requirements of Compliance Evaluation in Audit The Brazilian OCP shall proceed to the initial audit of GR and SGQ in the manufacturing unit or request the audit to be conducted by OAC accredited by MLA member body of IAF, with which the OCP has MoU, through an Audit Plan developed by the Brazilian OCP. This audit shall necessarily consider all requirements of Annexes A and B of this RAC, in order to verify the compliance of the production process and GR. The results of these audits shall be treated and evaluated by the Brazilian OCP.
2 The OCP shall evaluate the Risk Management File (AGR) and in compliance with the requirements of this RAC and the following standards:
2.1 ABNT NBR ISO 14971/2009, Medical devices, application of risk management to Medical Devices (Table 2)
2.2 ABNT NBR IEC 60601-1/2010, Electromedical Equipment, Part 1, General Requirements for basic safety and essential performance, clause 14, Programmable Electromedical Systems, 2013 corrected version (Table 3)
2.3 ABNT NBR IEC 60601-1-6/2011, Electromedical Equipment, Part 1-6, General Requirements for basic safety and essential performance, Collateral standard, Usability, 2013 corrected version (Table 4).
2.4 ABNT NBR IEC 62366, Medical Devices, Application of Usability Engineering on medical devices (Table 5)
2.5 Items of Verification of ABNT NBR IEC 60601-1-9/2010 Standard or Risk Management

2.6 IEC 62304/2006, Electromedical Equipment, software and life cycle of healthcare software process (Table 7).
3 The OCP shall verify through the analysis of AGR the requirements of the tables 2, 3, 4, 5, 6 and 7 of this RAC, in order to identify if that no change has occurred in the product nor in technical standard which may affect the product safety and has not been validated by laboratory testing.
3.1 The OCP shall verify any changes in RHProj and RMP which result in the need of performance of new type tests, in accordance with item 6.2.4 of this RAC.
4 The OCP shall witness the complete manufacturing on the production line, and verify the RHP, of a product, in order to ensure there are no processes or changes in processes that have not been documented in AGR. Should the certification be for family, the selected model shall be the most critical configuration of the certified product.
4.1 The OCP shall witness the performance of routine tests in the production line, provided by the manufacturer, in accordance with the AGR of the product, registering the model and serial number of the product tested in the audit report. The selection of sample for testing shall follow the instructions of item 6.2.6 of this RAC.
5 The inspection of the documentation of the factory shall prove that the routine tests are applied to 100% of the manufactured units to confirm the correct operation (essential performance) of the product and electrical safety, if applicable. The requirements, which shall be verified, are object of agreement between the OCP and the manufacturer in order to ensure the safety of the certified product.
6 The routine tests of electrical safety shall prove that the product meets the following clauses 8.6, 8.7 and 8.8 of ABNT NBR IEC 60601-1:2010 2013 corrected version: a) grounding (clause 8.6); b) measurement of leakage current (clause 8.7); c) dielectric strength test (clause 8.8, non-destructive); and d) the functional tests are specified by the manufactured and agreed with the OCP.
6.1 The use of verification, prescribed in IEC TR 62354:2014, is recommended for routine testing, General procedures for testing electromedical equipment, Routine testing in the production line item K.
7 The OCP shall analyze the AGR by applying all requirements of ABNT NBR ISO 14971 (Table 2 of this RAC). Should any change to technical standard or to the design that affects the safety be identified, the OCP shall confirm in the AGR if the product has been tested again for the analyzed requirement(s) or if control measures have been established.
8 Among the changes documented in the AGR on the object of analysis, the modifications in the mechanical design, electrical design, software, product assembly, materials and electronic components that may affect or change the functional safety, and the safety of product electromagnetic (EMC) and electric compatibility shall be listed.
9 The product samples, which require to be collected for testing during a factory audit, shall meet the item 6.2.4.2 of this RAC.
10 The OCP shall evaluate the Quality Management System of the manufacturer and audit the importers, holders of record and registration, certification applicants, in accordance with the requirements of Annex B of this RAC. The certification in compliance with the ABNT NBR ISO 13485/2004 is optional. In case of external certification, the certificate shall be valid and the certifiers' audit report shall ensure the accordance with the items of Annex B of this RAC. The manufacturer shall also evidence the compliance with the requirements of Anvisa RDC no. 16/2013 Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices.

Table 2 – Requirements for Evaluation of ABNT NBR ISO 14971 standard

Application of risk management to medical devices Compliance Evaluation Requirement in Audit	
Requirement Description	**Standard Requirement**
General Requirements for Risk Management	3
Management responsibilities	3.2
Qualification of personnel	3.3
Risk Management Plan	3.4
Risk Management File	3.5
Risk Analysis	4
Risk analysis process	4.1
Intended use and identification of characteristics related to the safety of the medical device	4.2
Idenfitication of Hazards	4.3
Estimation of the risk(s) for each hazardous situation	4.4
Risk evaluation	5
Risk control	6
Risk control option analysis	6.2
Implementation of risk control measure(s)	6.3
Residual risk evaluation	6.4
Risk/benefit analysis	6.5
Risks arising from risk control measures	6.6
Completeness of risk control	6.7
Evaluation of overall residual risk acceptability	7
Risk management report	8
Production and Post-Production information	9

Table 3 - Items of Verification of ABNT NBR IEC 60601-1: 2010/2013

General Requirements for basic safety and essential performance Compliance Evaluation Requirements in Audit	
Requirement Description	**Standard Requirement**
General Requirements	4
Process of Risk Management for EM Equipment or EM System	4.2
Essential Performance	4.3
Components of EM Equipment	4.8
Use of Component with High Integrity Characteristic in Equipment	4.9
Power Supply	4.10

EM equipment identification, marking and documents	7
Marking the outside of EM Equipment or parts of EM Equipment.	7.2
Marking and control of instruments.	7.4
Safety signs.	7.5
Colors of insulation of conductors.	7.7
Indicator lights and command keys.	7.8
Accompanying documents.	7.9
Grounding for protection, functional grounding, and power equalization of EM Equipment	8.6
Plugs and outlets	8.6.6
Equalization conductor of plugs and outlets	8.6.7
Leakage current and auxiliary power through the patient	8.7
The dielectric strength test	8.8
Note: The manufacturer shall keep the records with the results of routine tests, performed in 100% of the EM Equipment produced, in accordance with ABNT NBR IEC 60601-1: 2010	

Note 1: The compliance shall be evidenced by the OCP through the confirmation of the requirements of Table 3, of ABNT NBR IEC 60601-1: 2010/2013

Note 2: The requirements of Table 3 have not been changed by the Risk Management.

Table 4 – Items of Verification of ABNT NBR IEC 60601-1-6: 2011/2013

General Requirements for basic safety and essential performance, Collateral standard: Usability Compliance Evaluation Requirements in Audit	
Requirement Description	**Standard Requirement**
Usability	1
Conditions for application to electromedical equipment	4.1
Process of Usability Engineering for Electromedical Equipment	4.2
Substitution of requirements of IEC 62366	5

Table 5 – Items of Verification of ABNT NBR IEC 62366/2010

Application of Usability Engineering to medical devices Compliance Evaluation Requirements in Audit	
Requirement Description	**Standard Requirement**
General Requirements	4.1
Usability engineering process	4.1.1
Residual Risk	4.1.2
Information for safety	4.1.3
Usability Engineering file	4.2
Tailoring the Usability Engineering effort	4.3
Usability Engineering process	5
Specification of application	5.1
Frequently used functions	5.2

Identification of dangers and dangerous situations related to usability	5.3
Identification of safety-related characteristics	5.3.1
Identification of characteristics that are known or predictable dangers and dangerous situations	5.3.2
Functions of primary operations	5.4
Specification of Usability	5.5
Usability Validation Plan	5.6
Design and implementation of user interface	5.7
Verification of Usability	5.8
Validation of Usability	5.9
Accompanying document	6
Training and training materials	7

Table 6 – Items of Verification of Items of Verification of ABNT NBR IEC 60601-1-9/2010 Standard or Risk Management

General Requirements for basic safety and essential performance, environmentally conscious design Compliance Evaluation Requirements in Audit	
Requirement Description	**Standard Requirement**
Identification of environmental aspects	4.1
Instructions to minimize the environmental impact during normal use	4.5.2
Information for management of end of life cycle	4.5.3

The compliance evaluation of item 4.1 shall be performed by the evidence of performance of the activity without the requirement of corresponding actions for each environmental aspect identified during the analysis; though the compliance with the item 4.1 is essential for the preparation of instructions of 4.5.2 and 4.5.3 requirements.

Table 7 – Items of Verification of IEC 62304/2006 Standard

Software and life cycle of the software process Compliance Evaluation Requirements in Audit	
Requirement Description	**Standard Requirement**
Compliance	1.4
General Requirements	4
Quality Management System	4.1
Risk Management	4.2 and 4.3
Software development process	5
Software development plan (PDS)	5.1.1
Keep software development plan updated	5.1.2
Software development plan reference to system design and development	5.1.3
Software development standards, methods and tools planning	5.1.4
Software integration and integration testing planning	5.1.5

Software verification planning	5.1.6
Software risk management planning	5.1.7
Documentation planning	5.1.8
Software configuration management planning	5.1.9
Supporting items to be controlled	5.1.10
Software configuration item control before verification	5.1.11
Software requirements analysis	5.2
Define and document software requirements from system requirements	5.2.1
Software requirements content	5.2.2
Include risk control measures in software requirements	5.2.3
Re-evaluate medical device risk analysis	5.2.4
Update system requirements	5.2.5
Verifiy software requirements	5.2.6
Software architecture design	5.3
Transform software requirements into an architecture	5.3.1
Develop an architecture for the interfaces of software items	5.3.2
Specify functional and performance requirements of soup item	5.3.3
Specify system hardware and software required by soup item	5.3.4
Identify segregation necessary for risk control	5.3.5
Verify software architecture	5.3.6
Software Detailed Design	5.4
Refine software architecture into software units	5.4.1
Develop detailed design for each software unit	5.4.2
Develop detailed design for interfaces	5.4.3
Verify detailed design	5.4.4
Software unit implementation and verification	5.5
Implement each software unit	5.5.1
Establish software unit verification process	5.5.2
Software unit acceptance criteria	5.5.3
Additional software unit acceptance criteria	5.5.4
Software unit verification	5.5.5
Software integration and integration testing	5.6
Integrate software units	5.6.1
Verify software integration	5.6.2
Test integrated software	5.6.3
Integration testing content	5.6.4
Verify integration test procedures	5.6.5
Conduct regression tests	5.6.6
Integration test record contents	5.6.7
Use software problem resolution process	5.6.8
Software system testing	5.7
Establish tests for software requirements	5.7.1
Use software problem resolution process	5.7.2
Retest after changes	5.7.3
Verify software system testing	5.7.4
Software system test record contents	5.7.5
Software release	5.8
Ensure software verification is complete	5.8.1
Document known residual anomalies	5.8.2

Evaluate known residual anomalies	5.8.3
Document released versions	5.8.4
Document how released software was created	5.8.5
Ensure activities and tasks are complete	5.8.6
Archive software	5.8.7
Assure repeatability of software release	5.8.8
Software maintenance process	6
Establish Software maintenance plan	6.1
Problem and modification analysis	6.2
Document and evaluate feedback	6.2.1
Monitor feedback	6.2.1.1
Document and evaluate feedback	6.2.1.2
Evaluate problem report's affects on safety	6.2.1.3
Use software problem resolution process	6.2.2
Analyse change requests	6.2.3
Change request approval	6.2.4
Communicate to users and regulatory bodies	6.2.5
Modification implementation	6.3
Use established process to implement modification	6.3.1
Re-release modified software system	6.3.2
Software risk management process	7
Analysis of software contributing to hazardous situations	7.1
Identify software items that could contribute to hazardous situations	7.1.1
Identify potential causes of contribution to a hazardous situation	7.1.2
Evaluate published soup anomaly lists	7.1.3
Document potential causes	7.1.4
Document sequences of events	7.1.5
Risk control measures	7.2
Definition of risk control measures	7.2.1
Risk control measures implemented in software	7.2.2
Verification of risk control measures	7.3
Verify risk control measures	7.3.1
Document any new sequence of events	7.3.2
Document traceability	7.3.3
Risk management of software changes	7.4
Analyse changes to medical device software with respect to safety	7.4.1
Analyse impact of software changes on existing risk control measures	7.4.2
Perform risk management activities based on analyses	7.4.3
Software configuration management process	8
Configuration identification	8.1
Establish means to identify configuration items	8.1.1
Identify soup	8.1.2
Identify system configuration documentation	8.1.3
Change control	8.2
Approval change requests	8.2.1
Implement changes	8.2.2
Verify changes	8.2.3

Provide means for traceability of change	8.2.4
Configuration status accounting	8.3
Software problem resolution process	9
Prepare problem reports	9.1
Investigate the problem	9.2
Advise relevant parties	9.3
Use change control process	9.4
Maintain records	9.5
Analyse problems for trends	9.6
Verify software problem resolution	9.7
Test documentation contents	9.8

ANNEX B – TECHNICAL REQUIREMENTS FOR THE EVALUATION OF THE QUALITY SYSTEM IN COMPLIANCE WITH ABNT NBR ISO 13485:2004

B-1 The OCP shall verify, during the initial audit and maintenance audit of SGQ of the manufacturer that uses the ABNT NBR ISO 13485:2005 for the product(s) object of certification, the compliance with the minimum requirements listed in Table 8 below:

Table 8 – Items of Verification of ABNT NBR ISO 13485:2004 Standard

Medical Devices Quality Management Systems Requirements for regulatory purposes	
In the evaluation, initial and maintenance, of manufacturing SGQ, using the ABNT NBR ISO 13485:2004 for the product(s) object of certification, shall verify the compliance with the requirements listed below:	
Requirement Description	**Standard Requirement**
Quality management systems	4
General requirements	4.1
Control of Documents	4.2.3
Control of Records	4.2.4
Planning of Product Realization	7.1
Determination of requirements related to the product	7.2.1
Review of requirements related to the product	7.2.2
Customer communication	7.2.3
Referring to item 7.2.3.c “Treatment of Customer Complaints”	
Design and development	7.3
Design and development planning	7.3.1
Design and development inputs	7.3.2
Design and development outputs	7.3.3
Design and development review	7.3.4
Design and development verification	7.3.5
Design and development validation	7.3.6
Control of design and development changes	7.3.7
Verification of purchased product	7.4.3
Control of Production and Service Provision	7.5.1
Validation of processes for production and service provision	7.5.2
Identification and traceability	7.5.3
Preservation of product	7.5.6
Control of Monitoring and Measuring Devices	7.6
Monitoring and measurement of processes	8.2.3
Monitoring and measurement of product	8.2.4
Control of nonconforming product	8.3
Corrective Action	8.5.2
In the evaluation, initial and maintenance, of the SGQ of importers, record and registration holders, certification applicants, in compliance with the requirements of ABNT NBR ISO 13485:2004 for the product(s) object of certification, the OCP shall verify the compliance with the requirements listed below:	
Control of Documents	4.2.3
Control of Records	4.2.4

Customers communication	7.2.3
Verification of purchased product	7.4.3
Identification and traceability	7.5.3
Preservation of product	7.5.5
Control of monitoring and measuring devices	7.6
Customer satisfaction	8.2.1
Control of nonconforming product	8.3
Corrective Action	8.5.2

B-2 Technical Assistance, when applicable, shall be verified in SGC, in compliance with the Anvisa Normative Instruction no. 8, of December 26th, 2013, and of manufacturers, in compliance with Anvisa RDC no. 16/2013 or through the corresponding requirements of ABNT NBR ISO 13485:2004 standard.

B.2.1 Optionally the Technical Assistance, when applicable, may be performed in accordance with the definition 4.1.1 – Technical Assistance – Extended definition.

B-3 The audit of importers, record and registration holders, certification applicants, shall evaluate in SGQ the compliance with the requirements of ABNT NBR ISO 13485:2004, Table 8 and the fulfillment of item 7 Treatment of Complaints of RGCP.

Table 9 - Criteria for the Compliance Evaluation of the Activities of Anvisa RDC no. 16/2013

	Company/Activities	Requirement of CBPFC
I	MANUFACTURER: Performs all manufacturing stages: Design, production/assembly, quality control and distribution.	YES
II	MANUFACTURER (LEGAL): Specifies the design and production requirements, performs at least one manufacturing stage (in addition to design and distribution) and subcontracts (outsources) the others.	YES
III	CONTRACT MANUFACTURER: Responsible for 100% of the production under specification of other company (legal manufacturer), with or without commercial distribution	YES According to the applicable requirements of Anvisa RDC no. 16/2013
IV	CONTRACT MANUFACTURER: Performs the final stage of production (final product, but not necessarily finished product).	YES According to the applicable requirements of Anvisa RDC no. 16/2013
V	CONTRACT MANUFACTURER: Performs intermediate production stages (manufacturer of components and parts intended to be part of the finished health product)	NO The legal manufacturer is responsible for the required controls (purchase control and qualification of suppliers).
VI	MANUFACTURER (LEGAL): Does not perform production stages	NO

ANNEX C – COMPLIANCE IDENTIFICATION MARK

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

C.2 The applicant shall follow the following requirements in order to use the Compliance Identification Mark:

a) The mark, according to Figure 1, may only be used on products listed in the current NI/Anvisa, which sets forth the technical standards adopted for compliance certification of Medical Electrical Equipment subject to the Health Surveillance Policy;

b) The mark, according to Figure 2, is applied to Equipment not included in item C.2.a.

c) The mark shall be printed or shall be used as a label, provided that it meets the minimal dimensions defined in Figure 1 and 2 of this RAC and as long as it is indelible and permanent;

d) When the Compliance Identification Mark is stamped, printed or inserted onto the product by means of a label defined in Figure 1 and 2 of this RAC and does not fit in the frontal portion of the Equipment, it may be affixed to other parts;

e) When the Compliance Identification Mark may not be affixed in accordance with items C.2.a, C.2.b and C.2.d, due to lack of space in the frontal part of the Equipment, it may be affixed to other parts of the same; and

f) 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 applicant.

Figure 1 – Compliance Identification Mark for products with compulsory certification

Figure 2 – Compliance Identification Mark for products with voluntary certification

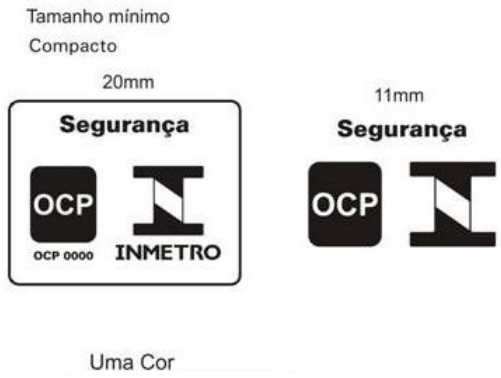

Figure 3 – Compact Compliance Identification Mark for products with compulsory certifications

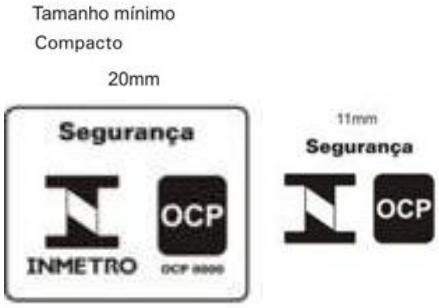

Figure 4 - Compact Compliance Identification Mark for products with voluntary certifications

ANNEX D – CHARACTERIZATION OF THE FAMILY