Certification Rule Complement – Equipment under Health Surveillance Regime

Summary

1 OBJECTIVE

To establish the criteria and procedures of conformity assessment for Equipment under Health Surveillance Regime, focusing on safety, through the mechanism of certification, aiming at accident prevention.

1.1 GROUPING FOR CERTIFICATION PURPOSES

The certification of Equipment under Health Surveillance Regime shall be performed by family, which is defined according to the criteria determined by Annex C of this CRC.

2 ACRONYMS

For purposes of this CRC, the following acronyms are adopted, complemented by the acronyms contained in the supplementary documents cited in chapter 3 of this CRC:

RMF	RMF, Risk Management File [AGR in Portuguese]
ANVISA	National Health Surveillance Agency
CBPF	GMP Certificate, Certificate of Good Manufacturing Practices
CNPJ	National Register of Legal Entities
EM	Medical Electrical Equipment. Note: Includes non-electrical equipment category under Health Surveillance Regime.
GR	Risk Management
IN	ANVISA Normative Instruction
MDP	MOP, Means or Protective Measures
MPO	MOOP, Operator Protection Means or Measures
MPP	MOPP, Means or Measures for Patient Protection
PDS	Software Development Plan
RDC	ANVISA Collegiate Directive Resolution
DHF	DHF, Design History File [RHProj in Portuguese]
DHR	DHR, Device History Record [RHP in Portuguese]
DMR	DMR, Device Master Record [RMP in Portuguese]
SDPD	SOUP, Software of Unknown Provenance [SDPD in Portuguese]
SGR	Risk Management Summary

3 SUPPLEMENTARY DOCUMENTS

For the purposes of this CRC, the following supplementary documents are adopted

[*note of translation: dates are in format dd/mm/yyyy****]***

INMETRO Ordinance No. 118 or substitute 03/06/2015 General Requirements for Product Certification (RGCP)

INMETRO Ordinance No. 384 18/12/2020 Conformity Assessment Requirements for Equipment under Health Surveillance Regime

Ordinance INMETRO No. 46 or substitute 22/01/2016 Metrological Technical Regulation for non-invasive sphygmomanometers

INMETRO Ordinance No. 402 or substitute 23/08/2019 Metrological Technical Regulation for digital clinical thermometers

IN ANVISA No. 49 or substitute 22/11/2019 Approves the list of Technical Standards that should be adopted for certification of Conformity, within the scope of the Brazilian Conformity Assessment System (SBAC), for equipment under the Health Surveillance regime, pursuant to ANVISA RDC Resolution No. 27, of June 21, 2011.

RDC ANVISA No. 16 or replacement 28/03/2013 Provides for the requirements of Good Manufacturing Practices and of Medical Products and Products for in Vitro Diagnostics.

ANVISA RDC No. 23 or substitute 04/04/2012 Provides for the mandatory execution and notification of field actions by health product registration holders in Brazil.

ANVISA RDC No. 27 or substitute 21/06/2011 Provides for the procedures for compulsory certification of equipment under the Health Surveillance Regime.

RDC ANVISA nº 67 or substitute 21/12/2009 Provides for Technovigilance rules applicable to health product registration holders in Brazil.

ABNT NBR IEC 60601 Medical Electrical Equipment, parts 1 and 2, general requirements and particular requirements; internalized standards of the IEC 60601 series 3rd edition including its amendments and corrigenda.

ABNT NBR ISO 80601 Medical Electrical Equipment, particular requirements; internalized standards of the series ISO 80601 including its amendments and corrigenda.

ABNT NBR ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.

ABNT NBR ISO 14971:2009 Medical devices - Application of risk management to medical devices.

ANVISA RDC No. 81 or substitute 05/11/2008 Provides on the Technical Regulation of Imported Goods and Products for Sanitary Surveillance purposes.

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

3.2 In cases where there is an update of the Standard, it is still mandatory to comply with the version of the Standard in the ANVISA Normative Instruction in force; alternatively, the updated standard may be used.

3.3 Normative items referenced in this CRC, in case of an update of ANVISA Normative Instruction or if the manufacturer (or applicant) uses an updated standard, may be replaced by the equivalent items of the normative update.

3.4 New technologies and deviations in the normative basis:

The development of new technologies may, in some cases, alter the application of a standard, change the limits established by a standard, or even annul its application. It responsibility of the manufacturer to justify the deviation from the testing methodology in the RMF, the DMR or the DHF.

3.5 Evaluation of new technologies when there is evidence of deviation from the normative basis:

3.5.1 The TÜV shall always question the manufacturer on the reasons for the decision of change or non-application of a particular standard in the phase of preparation of the Test Plan.
3.5.2 The TÜV shall verify and confirm, in the Test Plan, if the analysis of the manufacturer and justification of normative deviation are correct or, if not, include the missing tests for the evaluation of the conformity of the specific standard in the Test Plan.
3.5.3 The TÜV shall ensure that, regardless of the innovative nature of the product, the tests performed ensure electrical, mechanical, thermal, chemical and electromagnetic safety sufficiently to attest to the safety of the equipment.

4 DEFINITIONS

For the purposes of this CRC, the definitions below and those contained in the supplementary documents cited in item 3 are adopted:

4.0 Risk Management File

The Risk Management File (RMF) is the fundamental file in the prioritization of product risk management, due to the analysis and evaluation, for the definition of acceptability, treatment and control that shall be given to each one of the hazards or dangerous situations identified for a product or EM system. It serves to give traceability to the application of the items 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 all or any change in the project. The RMF is, most of the times, fragmented and may not be seen in a single place (summary), as an example, the part related to software risk management that, almost in all cases, must be audited only in the factory due to the manufacturer's Intellectual Property protection. The RMF shall provide traceability of each identified hazard and also correlate, minimally, all requirements of the standards applicable to the product that were established by ANVISA Normative Instruction, and its risk management process (analysis, evaluation, control and monitoring) in accordance with ABNT NBR ISO 14971, including the hazardous situations that were not foreseen by the standards applicable to the product, but that were identified relevant during the risk analysis.

4.1 Technical Assistance

Technical assistance: Maintenance or repair of a finished product in order to return it to its specifications [ANVISA, RDC No. 16 of 2013, item 1.2.1].

4.1.1 Technical Assistance - Extended Definition [INMETRO].

It is the process in which a professional, with knowledge of specific technical content, provides information and clarification or performs actions to meet identified needs including maintenance or repair of a finished product in order to return it to its specifications:

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

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

4.1.1.3 It depends directly on the competencies and skills developed by its employees, through capacity building and training, as well as the material resources provided for its execution.

4.1.1.4 Needs high priority in quality management systems, demonstrated by repeated efforts with customers to resolve problems.

4.1.1.5 A structure characterized by:

a) use of performers who demonstrate knowledge and skill;

b) constant evaluation of the training of the executants in the application of knowledge to meet the needs of the clients;

c) use of recognised "best practices" and relevant standardising or regulatory documents in response to specific problems; and

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

4.2 Original Features

They comprise technical specifications, indication and purpose of use, physical characteristics, including the list of critical components and accessories, chemical characteristics (when applicable), the content of accompanying documents and markings on the equipment, which constitute the design characteristics of an equipment at the time of granting the product certification, and shall also correspond to the characteristics of the equipment regularized at ANVISA, or to be regularized at ANVISA.

4.3 Critical Component

Component that directly affects patient and/or user safety.

4.4 Usability Engineering

Application of knowledge about human behavior, abilities, limitations and other characteristics to the design of Medical Electrical Equipment or Medical Electrical System achieve proper usability. [ABNT NBR IEC 62366:2010 Amendment 1:2016, definition 3.8]

4.5 Routine (or production) testing

Non-destructive test, performed by the manufacturer, which provides an attestation of conformity of a manufactured batch, at a given moment, performed on a manufactured product, at the end or in the course of a production line, to demonstrate that the assembly of the product was performed according to the design requirements and the conditions specified by this CRC.

4.6 Type (or qualification) testing

Test, destructive or not, which provides an evidence of compliance of an item, in a given moment, performed in one or more units of a product, to demonstrate that this product meets the requirements specified in the design and is in accordance with evaluation requirements established based on national (ABNT), regional and international standards, and the conditions specified by this CRC.

4.7 Large diagnostic or therapeutic equipment

Health application equipment used for diagnosis or therapy, of permanent installation in an environment specially built/adapted for its operation, with individualized and specific power supply network, requiring maintenance actions to be performed at its installation site. Its installation is performed by a specialized team, usually requiring a formal commissioning for its approval.

Note: large-size equipment includes, but is not limited to, interventional x-ray, nuclear medicine, computed tomography and magnetic resonance imaging equipment.

4.8 Manufacturer:

Legal entity responsible for the design, manufacturing, assembly, transformation or processing of a finished product or system, packaging and labeling of a medical product, before it is placed on the market or in operation, regardless of whether such operations are performed by that person or on his behalf, by a third party.

4.9 Contracted Manufacturer:

Outsourced company, duly established as a legal entity, which performs the industrialization of a medical product under the responsibility of a Legal Manufacturer, through a legally established contract.

Note: Fabricante Contratado is derived from the English term "Contract Manufacturer" (CM).

4.10 Legal Manufacturer:

Legal entity responsible for the design, manufacturing, packaging or labeling of a medical product, assembly of a system or adaptation of the product before it is placed on the market or put into operation, regardless of whether such operations are performed by that person or on his behalf, by a third party.

4.11 Family:

Family characterization is as provided in Appendix C of this CRC.

4.12 Risk Management:

Systematic application of policies, procedures and management practices to the tasks of risk analysis, assessment, control and monitoring. [ABNT NBR ISO 14971: 2009, item 2.22]

4.13 ANVISA- IN Normative Instruction

It is a normative act of ANVISA's Collegiate Board of Directors that exceptionally establishes technical requirements to be met by an object.

4.14 Master list of quality documents

This list is the index or equivalent procedures where all the documents of the quality system are listed (procedures, work instructions, etc.) and the versions of the documents that are in force are indicated.

4.15 Means of protection [translation note – see acronyms]

For an Medical Electrical Equipment or system connected by a structured cabling system, the manufacturer shall declare the protection means used to reduce the risk arising from electric shock (MDP), which is divided into two classes: means of reducing the risk of electric shock to

the patient (MPP); and means of reducing the risk of electric shock to the equipment operator (MPO).

4.16 Serial number or batch

Distinct combination of letters or numbers, or both, from which the complete history of purchasing, manufacturing, packaging, labeling and distribution of finished products can be determined. [RDC 16 28/03/2013, item 1.2.15]

4.17 Essential production process

It is the method, system or set of activities essential for the generation of a product, with a certain critical purpose, applied from the beginning to the final delivery of the product.

4.18 Registro histórico do projeto (RHProj)

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

4.19 Product Master Record (RMP)

Compilation of documents containing specifications, instructions and procedures for obtaining a finished product, as well as its installation, technical assistance and maintenance.

4.20 Applicant

Legal entity, public or private, domestic or foreign, legally established in the country, with CNPJ, which perform at least one of the following activities: production, assembly, creation, construction, transformation, import, free distribution or not, or marketing of equipment under the Health Surveillance regime, covered by this CRC. It is responsible for the application for certification of the product with TÜV RHEINLAND DO BRASIL LTDA, has the responsibility of ensuring the performance of the tests provided in this CRC, holds the concession of use of the Conformity Identification Seal, being responsible for the regularization with ANVISA. The term supplier or applicant supplier applied in RGCP refers, in this CRC, to the certification applicant.

4.21 Pilot or Production Unit

The pilot or production unit corresponds to a product unit or set of units produced according to the criteria of the production process established in the product design. The pilot unit uses the

materials that will be used in the production of the product and the exclusive process and tooling necessary for its manufacture, being built after a complete risk management analysis by the manufacturer, through evaluation and testing prior to certification. ***[****translation note – also know as engineering sample****]***

5 CONFORMITY ASSESSMENT MECHANISM

The mechanism of Conformity Assessment used in this document is the Certification, applicable to the Equipment under the Health Surveillance Regime contemplated by this CRC.

6 STAGES OF CONFORMITY ASSESSMENT

The process of conformity assessment is composed of several stages and each stage follows a sequence of procedures. This chapter establishes the conformity assessment process, which shall follow the requirements of RGCP, amended or supplemented by this CRC.

6.1 Definition of the Certification Model used

This CAR establishes the certification based on Certification Model 5 - Type testing, evaluation and approval of the requirements of the Quality Management System of the manufacturer, follow-up through audits in the manufacturers and certification applicants, and tests in sample(s) taken from the manufacturer or conditioned by the manufacturer by determination of TÜV, in accordance with this CRC, traceable, representative of the project and pilot production, conditioned by evaluation, audit and approval of the risk management of the product performed by the manufacturer.

6.2 Initial assessment

The criteria for Initial Certification Evaluation shall follow the requirements of RGCP and may be amended or supplemented by this CRC and ANVISA Normative Instructions in force.

6.2.1 Application for Certification

The Request for Certification starts with the request for certification quote and the criteria for the Request for Certification shall follow the prescriptions of RGCP, observing the standards

and deadlines established by ANVISA Normative Instruction No. 49 of 2019 or substitute, complemented by this CRC.

6.2.1.1 Requirement 6.2.1.1 of RGCP applies in full.

6.2.1.2 The sub-items of requirement 6.2.1.2 of RGCP apply as indicated below.
The beginning of the certification process is conditioned to a formal manifestation of the applicant made directly to TÜV, as a Product Certification Body accredited by INMETRO in the scope of this CRC. The request must be accompanied by documentation that meets the following requirements:

a) The application stage begins with the preliminary analysis of the application for evaluation, by the TÜV, of the feasibility of certification. This step shall meet the requirements 6.2.1.2.1 of this CRC.
b) After agreement by the TÜV and the certification applicant, other documents must be submitted before the certification process can begin. For the approval by the TÜV, in this stage, adjustments may occur in the documentation required in this CRC whenever extra requirements necessary for certification are identified. If any of the documents mentioned in 6.2.1, from this stage on, is not submitted or is not submitted in its final form by the applicant when the delivery of the documentation occurs; and provided that this fact does not interfere in the other stages of the Initial Assessment process, the fact shall be documented and recorded by TÜV, and the conclusion of the certification shall only occur when all documents are in its final form and duly reviewed by the by TÜV, and the results of this review recorded by TÜV.

6.2.1.2.1 Sub-items (a), (d), (g), (l) and Notes (1) and (4) of requirement 6.2.1.2 of RGCP shall be fully applied, the application in this CRC of sub-items (c), (h), (i), (j), (m), (o), (p), (q), (s) and Note (5) of requirement 6.2.1.2 of RGCP, and the other clauses of sub-item 6.2.1.2 of RGCP with the new wording for this CRC apply, as follows.

6.2.1.2.2 Item (b) applies with the following text.

List of model(s) composing the family object of certification, according to the family formation rules established in Annex C of this CRC, when the certification is by family, mentioning its (their) technical description(s) and including the list of all brands traded.

6.2.1.2.3 Item (e) fully supplemented by:
The "Descriptive Memorial" includes the list of technical standards, with justification, defined by the manufacturer as applicable to the product; the identification, with justification, if the product is or is not part of a family; the identification, with justification, if the product is or is part of an Medical Electrical Equipment system; and the description of the products that are part of the system, if applicable.

6.2.1.2.4 Item (f) fully supplemented with the following text applies:
The product user manual, draft or final version shall be submitted to the TÜV according to ABNT NBR IEC 62366:2010, or substitute, item 6 and shall include a summary of the specification of the health product application (according to requirement 5.1).

6.2.1.2.5 The application of the corresponding item (k) of the RGCP in this CRC is replaced by the following wording:
k) Identification of the manufacturer, contract manufacturer, and/or legal manufacturer, when applicable, with complete address, including the manufacturing unit(s) to be certified, headquartered in another country;

6.2.1.2.6 The application of the corresponding item (n) of the RGCP in this CRC is replaced by the following wording:
n) Documents relating to the Quality Management System of the manufacturer, applicable to the object to be certified as provided in Annex B, so that they may be audited by TÜV, as provided herein. As evidence of compliance with the requirements set forth in Annex B of this CRC, based on ABNT NBR ISO 13485, the last audit report of the requirements set forth in Annex B may be provided for certified companies with valid certificates issued by OAC accredited by Inmetro/Cgcre or member of the IAF MLA in accordance with ABNT NBR ISO 13485.

6.2.1.2.7 Item (r) fully applied, supplemented by the following wording: other documents may be requested by TÜV for the execution of item 6.2.4 for the definition of the test plan.

6.2.1.2.8 Notes (2) and (3) of item 6.2.1.2 of RGCP apply with the following text:
Nota 2: The photos mentioned in d) should have adequate resolution to enable TÜV evaluation.
Nota 3: The manufacturer shall inform the list of critical components mentioned in e), and the TÜV is responsible for evaluating such list, and the inclusion of other components may occur.

6.2.1.2.9 The manufacturer shall provide a summary of the product risk management in accordance with item 3 of ABNT NBR ISO 14971, General requirements for product risk management, and include the documents concerning the manufacturer's Quality Management System applicable to the object:
a) Responsibilities of senior management, item 3.2.
b) Personnel qualification, item 3.3.
c) Product risk management plan, item 3.4.
d) Product risk management information, item 3.5.

6.2.2 Application and Review and Documentation conformity
The criteria for Analysis of the Application and of the conformity of the documentation shall follow the prescriptions of RGCP, complemented as follows.

6.2.2.1 Risk Management File Analysis
In this phase the applicant shall forward to the TÜV the parts of the Risk Management File of the manufacturer that are authorized to leave the factory controlled environment. The part of the RMF content sent shall be analyzed by the TÜV for the preparation of the audit. In the audit the RMF documents that could not be sent (e.g. software) shall be audited. The RMF shall be reviewed by the TÜV:

6.2.2.1.1 For preparing the manufacturer's audit; and

6.2.2.1.2 For the preparation of the Test Plan, which establishes the tests required for Conformity Assessment of the product.
The RMF shall be accompanied minimally, among other documents, where applicable, by:
a) technical specifications of the product;

b) electrical diagrams of the product;

c) identification of the functions of the EM equipment or system that constitute essential performance;

d) list of critical components;

e) selection criteria for high integrity components;

f) list of certified components and their respective certificates;

g) flammability classification for insulating materials;

h) insulation diagram including MDP - MPP and MPO;

i) comparative tracking indices for solid insulating materials (CTIs);

j) degree of pollution;

k) wiring specifications;

l) the insulation class of transformers, motors, electric switches, lamp sockets, etc;

m) equipment overvoltage category;

n) list of faults and occurrences;

o) Usability Engineering file;

p) policy for determining acceptable risk and acceptability of residual risk;

q) design calculations of the tensioning safety factor, for equipment with suspended masses;

r) documentation of the Development Life Cycle for Programmable Medical Electrical Equipment Systems (PESS), with hazard identification, risk control, Requirements Specification, architecture, implementation design, verification, validation, modification and connection mode of the PESS to other equipment; and

s) risk management summary.

6.2.3 Initial Audit of the Quality Management System (QMS), Risk Management System (RMMS) and Assessment of the Production Process

The application of requirement 6.2.3 of the RGCP in this CRC is entirely excluded, being replaced by the following wording.

6.2.3.1 The analysis of the risk management of the product, by the manufacturer, is essential to the planning of audits and preparation of the test plan by the TÜV. The execution of the requirement 6.2.3 shall occur after this analysis, and the item 6.2.3 can be performed concurrently or after the completion of the requirement 6.2.4.

6.2.3.2 The TÜV established in Brazil shall prepare the "Audit Plan" and perform the initial audit of the RMS and QMS in the manufacturing unit during the initial assessment stage. In order to conduct the audits, the TÜV may request that it be conducted by an OAC accredited by an MLA member agency, and it shall prove the requirement of outsourcing ISO/IEC 17065, as if it were conducting the audit itself. The audits shall necessarily take into account all requirements of Annexes A and B of this CAR, in order to verify the conformity of the production process and GR. In any case, the results of the audits shall be treated and evaluated by the TÜV established in Brazil. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 of this CRC may be used to meet the requirement of initial audit in the manufacturing unit.

6.2.3.3 The Initial Audits of the Risk Management System (RMS) and Quality Management System (QMS) and the Evaluation of the Production Process shall be performed based on the current edition of standards ABNT NBR ISO 14971, ABNT NBR IEC 60601-1 or ABNT NBR ISO 13485 respectively, when applicable. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 in this CRC may be used to meet the audit requirement of the manufacturer or applicant.

6.2.3.4 The TÜV shall evaluate the documents and records of the RMS and QMS, and conduct audit in the premises of the manufacturing unit, in order to verify the compliance of risk management, the production process including the design, manufacture of the product, and evaluation of facilities and training of personnel. The audit shall seek the objective demonstration that the risk management and the productive process are systematized and effectively monitored, providing evidences of compliance with the quality management and product risk management requirements established in the CAR. All decisions and analysis, which include or exclude the activities established in accordance with all items of this requirement, shall be evidenced in a report. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 of this CRC may be used to fulfill the audit requirement of the manufacturing unit.

6.2.3.5 During the audit, the manufacturer shall make available to the TÜV all documents corresponding to the certification of the RMS and QMS and submit records of the production process where the identification of the object of certification is clearly shown. The TÜV shall analyze the relevant documentation to ensure that the requirements described in Annexes A and B of this CRC have been met. For the audit of certification applicants, in the case of imported products, the OCP shall analyze the relevant documentation to ensure that the applicable requirements described in Annex B of this CRC were met. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 of this CRC may be used to fulfill the audit requirement at the manufacturing unit.

6.2.3.6 During the audit, the manufacturer shall submit, when existing, copy of the reports for evaluation of the items of ABNT NBR ISO 14971 and ABNT NBR IEC 60601-1 of Annex A and ABNT NBR ISO 13485 of Annex B, of any other system assessment, audits / inspections of the RMS and QMS, and the records of corrective actions that have been implemented when identified and applicable. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 in this CRC may be used to comply with the audit requirement in the manufacturing unit.

6.2.3.7 The audit of the SGR in the manufacturer is mandatory, however some audited elements may be performed outside the factory, at the TÜV, if the TÜV justifies this action in the audit planning. The audit plan shall include the search for evidences of risk management aspects demanded by the preliminary analysis of the SGR in item 6.2.3.1. Documents and records of compliance to the requirements to be verified in the factory shall be obtained and analyzed during the audit. The date of the visit for the audit shall be scheduled in agreement with the certification applicant. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 of this CRC may be used to fulfill the audit requirement at the manufacturing unit.

6.2.3.7.1 The audit should be directed by the tables in Annex A of this CRC. The RMF shall demonstrate that:

6.2.3.7.1.1 There are no unacceptable residual risks after all reiterations generated in risk management by changes made to the project during product development have been completed.

6.2.3.7.1.2 The requirements of tables 2, 3, 4, 5, 6 and 7 that can be evaluated by TÜV in their documentary form, outside the factory, shall be used as elements of the SGR analysis.

6.2.3.7.1.3 The TÜV shall provide justification for each requirement that is evaluated in documentary form outside the factory.

6.2.3.7.1.4 The TÜV shall evaluate the procedures in place for DMR and DHF.

6.2.3.7.2 The analysis of the audit results, the product testing generated by the RMF review and other relevant information, may lead to the need for further testing or re-auditing. The SGR analysis may only be finalized when all requirements are fully met.

6.2.3.7.3 At the end of the certification process, the TÜV shall evidence that all requirements of the standards in tables 2, 3, 4, 5, 6 and 7 have been analyzed and fulfilled.

Nota 1: Statistical production data for manufacturers in Brazil, or foreign manufacturers starting production of the object of certification, may be available only during the first maintenance audit or if an extraordinary audit occurs before this one.

Nota 2: Statistical production data for foreign manufacturers already producing the object of this certification for other markets should be verified in the initial audit of the factory..

6.2.3.8 Audit of the QMS and Evaluation of the Production Process

6.2.3.8.1 The audit of the QMS at the manufacturer is mandatory. The audit plan shall include the search for evidence of quality management aspects. Documents and records of compliance for the requirements to be verified at the manufacturing site shall be obtained and reviewed. The date of the visit for the audit shall be scheduled in agreement with the certification applicant. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 of this CRC may be used to fulfill the audit requirement at the site.

6.2.3.8.2 The audit of the QMS of the manufacturer and, when applicable in accordance with this CRC, of the applicant, shall be planned and conducted by the TÜV. Alternatively to the audit of the TÜV, the following processes may be used:
a) Evaluation of the latest ISO 13485 report, being verified the requirements foreseen in Annex B of that CRC; or
b) Through the analysis of the last audit report, of the requirements foreseen in Annex B, provided that such Audit report has covered the production line of the product object of certification for certified companies with valid certificates issued by OAC accredited by INMETRO in accordance with ABNT NBR ISO 13485:2016 or substitute; or
c) Through analysis of the conformity of the last audit report of the requirements of Annex B, as provided in the RDC/ANVISA No 16/2013 "Good Manufacturing and Control Practices Certification", for certified companies, with valid certificate issued by ANVISA. In the analysis should be observed the criteria for evaluation of activities in Table 8 of Annex B - Criteria for Conformity Assessment of Activities according to RDC ANVISA 16/2013; or
d) Through the audit reports issued under the Single Audit Program on Health Products (MDSAP). In the analysis, the criteria for evaluation of activities in Table 8 of Annex B - Criteria for Conformity Assessment of Activities according to RDC ANVISA 16/2013 should be observed.

Note: If the product is not in production during the audit period, the TÜV should evaluate the QMS procedures and records related to the manufacturing process.

6.2.3.8.3 In the case of certification based on "pilot unit", the TÜV shall ensure during the audit that the product produced in scale corresponds to the tested "pilot unit".

6.2.3.8.4 Audit Reports of ABNT NBR ISO 13485 or ISO 13485, referring to the Management System, conducted by an OAC accredited by a MLA member organization may be used for QMS evaluation, and shall be translated to Portuguese if in a language other than English or Spanish; or

6.2.3.8.5 The last audit report, issued by the health authority in accordance with the requirements of Annex B, pursuant to RDC/ANVISA No. 16/2013 "Technical Regulation on Good Manufacturing Practices for Medical Products and Diagnostic Products for In Vitro Use" may be used. The report must be analyzed for companies with valid GMP certification issued

by ANVISA. In the analysis should be observed the criteria for evaluation of activities of Table 8 of Annex B - Criteria for Conformity Assessment of Activities as RDC/ANVISA No. 16/2013; or may be used the inspection report issued by entities recognized by ANVISA (e.g. MDSAP), or may be used the inspection report for Class I and II equipment (of ANVISA RDC No. 185/2001 or substitute) regardless of the date of issue, provided that accompanied by the manufacturer's statement of conformity with the RDC/ANVISA No. 16/2013.

6.2.3.9 The evaluation of the RMS and QMS of the productive manufacturing process may contemplate more than one product, for similar technologies, manufacturing instructions and assembly processes, which may allow the inclusion in an existing certificate or the issuance of a new certificate for new products without conducting a new audit, if the following elements are met:

6.2.3.9.1 If the initial audit has already taken place, the TÜV shall verify whether an extraordinary audit is necessary for the inclusion of new products or accessories in a family of products already certified or for issuing a new certificate for new products and their accessories. If the initial audit has not covered all the manufacturing steps required for the new products, an extraordinary audit should be performed. Alternatively, the assessment of the manufacturing steps required for certification of new products, from the same production process and manufacturing unit, may be included in the next maintenance audit.

6.2.3.9.2 The TÜV shall record the analysis and justification for not performing an extraordinary audit for inclusion of a product in the family of products already certified or for issuing a new certificate for new products and their accessories, and shall audit the assembly line of the product or accessory at the time of the next maintenance audit.

6.2.3.10 Handling of non-conformities registered during audits of the Quality Management System (QMS), Risk Management System (RMS) and the Evaluation of the Production Process:

6.2.3.10.1 If one or more non-conformities - in any requirement - are identified during the audits, the non-conformity(ies) shall be notified by the TÜV to the applicant who shall submit an action plan with a defined deadline for the treatment of such non-conformity(ies) identified.

When the action plan or corrective actions involve changes in the design of the product submitted for certification, the applicant shall submit the test plan for evaluation of the impact on safety.

6.2.3.10.2 The TÜV may, from the analysis of the corrective action and/or evidence presented by the applicant, approve the proposed action plan; however it may require, if the analysis determines, the performance of complementary audit to validate the effectiveness of the corrective actions proposed. In both cases, the TÜV must justify the decision in a report.

6.2.3.11 The audit shall be considered complete after all non-conformities have been remedied, corrective actions or corrective action plan are approved by the TÜV without outstanding issues.

6.2.3.12 The TÜV after the audit shall issue a report recording the results of the audit, with this CRC as reference.

6.2.3.13 The certification applicant shall inform the TÜV of changes in the product design, materials used or the production process that impact the conformity of the product, so that the TÜV may assess the need to conduct a new audit.

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

6.2.4 Definition of the Test Plan

The Initial Test Plan shall provide for the tests that prove that the object of conformity assessment meets the requirements defined in the normative basis established in the current ANVISA Normative Instruction and shall be initially agreed between the applicant and the TÜV established in Brazil. The Initial Test Plan shall then be critically analyzed by the laboratory to assess the feasibility of testing. The following requirements shall be used for its preparation:

a) The test methods of the laboratories shall follow the precepts of ABNT NBR IEC 17025.

b) the test plan which shall contain at least the initial tests to be performed, the clear definition of the test methods, the number of samples and the acceptance/rejection criteria for these tests.

c) The proposal of tests forwarded by the applicant for the preparation of the test plan shall be analyzed by the TÜV, and it shall be up to TÜV its acceptance or not.
d) Laboratories shall report measurement uncertainties in test reports if these uncertainties are relevant to the validity or applicability of the test results, or if they affect the compliance with a specification limit.
e) The definition of when the measurement uncertainty values are relevant within the certification process is of the TÜV. When test reports issued by accredited laboratories are used, where the uncertainty values are not mentioned, without prejudice to the certification process, the TÜV shall be able to technically justify the absence of the measurement uncertainty values.

6.2.4.1 Definition of tests to be performed
The Test Plan may be initially suggested by the manufacturer, in accordance with the product risk management. The TÜV is responsible for the final preparation of the Test Plan, observing the requirements of the applicable standards contained in the ANVISA Normative Instruction in force and specific information of the project contained in the RMF.

6.2.4.1.1 The TÜV shall analyze the consistency of the documentation submitted by the applicant in item 6.2.3 for preparation of the Test Plan of the product defined by the summary map of risk management and use of results of tests previously performed, observing the following aspects:
a) Test reports conducted before contracting the TÜV.
To make use of test reports conducted before hiring the TÜV, submitted by the applicant in the initial documentation, the requirement 6.2.4.1.3 of this CRC must be fully complied with.
b) Proposals for additional tests.
Proposals for additional tests forwarded by the applicant shall be analyzed by the TÜV for possible inclusion in the product Test Plan. The planning of additional tests shall contain, at least, a clear definition of test methods, number of samples, and acceptance/rejection criteria for each of the tests.
c) Responsibility and competence
The TÜV is responsible for preparing the Test Plan to be submitted to the laboratory.

6.2.4.1.2 The Test Plan shall be consolidated between the TÜV and the Laboratory prior to the start of the tests, and there shall be interaction between them in order to enable and facilitate the execution of the tests or in case a modification of the Initial Test Plan is necessary.

6.2.4.1.3 The TÜV shall analyze, when submitted by the applicant, the test reports previously performed by the manufacturer. Test reports that meet the following requirement listed below may be accepted:

a) The sample that was used for the tests described in the report shall be traceable by the TÜV in the manufacturer's design documentation.

b) The tests in the Test Reports submitted by the applicant shall meet the following requirements:

i) Type testing shall have been conducted entirely on the pilot sample(s) or production line sample(s) of the equipment under certification without change.

ii) for tests performed by laboratories established in Brazil or not, the equivalence of the test method, the supply voltage and frequency of the equipment tested shall be observed. In addition, these laboratories shall be accredited by INMETRO or by an Accreditation Body that is signatory of a mutual recognition agreement of which INMETRO is also part.

iii) When applicable, the applicant shall submit a document stating that after the date of issuance of the test report the product has not undergone changes, in accordance with item A.1 of Annex A of this CRC.

iv) The evaluation by the TÜV of the tests performed of the equipment initial design; the risk management analysis of the product for which the report was issued; the updated design of the equipment; and the statement of the previous item, when applicable, shall integrate the documentation of the equipment certification process.

v) The tests established in reports shall include all the requirements of this CRC, and complementary tests or actions of TÜV or manufacturer shall be required when necessary.

vi) For all types of equipment under Health Surveillance Regime will be accepted reports of initial tests and their complementary, which validated the design changes that may have occurred and that have relevant impact on product safety, for purposes of product certification.

vii) The TÜV shall evaluate and prove that the equipment tested is the same in production line, and that the standards met are in compliance with the ANVISA's Normative Instruction in force.

viii) When it comes to a product family, in accordance with Annex C of this CRC, the tests shall have been conducted with a sample corresponding to the most critical configuration model

(model that contains the highest number of pre-established requirements by the normative basis of reference). The indication shall be justified by the TÜV.
ix) Other tests may be repeated, at the discretion of the TÜV, when non-conformities are identified in the tests that require corrective actions in critical components; or indicate that a design change occurred that was not informed and/or not controlled by risk management.
x) The TÜV may require the applicant to present in the test report the uncertainties of measurements when the result expressed (in the report) generates doubt to the OCP regarding the compliance with a normative requirement.

c) The testing laboratory(ies) included in the Test Report(s) submitted by the applicant shall meet requirement 6.2.4.3 "Definition of Laboratory" of RGCP.

6.2.4.1.4 When applicable, the Test Plan shall include additional parts, components or parts of the product complementary to the sample(s), which shall receive the same treatment of the requirement 6.2.4.2.1 to also be sent to the laboratory.

6.2.4.1.5 Type tests shall be repeated or complemented by the TÜV evaluation of the impact of changes in the mechanical or electrical-electronic design, or changes of 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, whenever this evaluation concludes that the revisions or changes impact the conformity previously assessed.

6.2.4.2 Definition of Sampling
6.2.4.2.1 To perform the product evaluation tests, "technical model assessment" applies where the sample shall be collected by the TÜV or, by agreement between the parties, may be forwarded to the TÜV or laboratory by the manufacturer.
a) The sample(s) used for testing prior to the start of certification may be used for continued and new testing if the test report and existing records identify that the submitted sample is identical to that used for testing up to the partial or final approval of the design.
b) The sample shall consist of (1) one or more units of the finished goods production line, released and packaged as for marketing or of (1) one or more pilot or serial head or production line unit when not in production.
c) When applicable, the principle of selection and randomness of sample selection shall be used, in accordance with standards ABNT NBR ISO/IEC 17025 and ABNT NBR ISO/IEC

17065. Deviations shall be justified by the TÜV without prejudice to the product evaluation process.

6.2.4.2.2 Either the applicant, when agreed with the TÜV in accordance with requirement 6.2.4.2.1 and under the guidance of the TÜV, or the TÜV, shall prepare the Sample Report before sending it to the laboratory, characterizing and controlling its characteristics. The Sample Report shall contain at least the following information:

a) date of dispatch of the sample;

b) the storage conditions;

c) the identification of the sample (model/ make/ serial number or manufacturing batch);

d) date of manufacture;

e) place of manufacture;

f) the sample shall be sealed by the TÜV or applicant, and shall be sent to the laboratory accompanied by its report.

6.2.4.2.3 The TÜV, when the corrective action for any non-conformity(ies) identified during the initial tests changes the design in a critical way that does not allow the continuation of the tests with the same sample, shall control the characteristics of the new sample(s) to be sent to the laboratory, in accordance with the requirement 6.2.4.2.

6.2.4.2.4 If the applicant deems, with the TÜV, necessary to evaluate more than (1) one sample, the number of samples, acceptance / rejection criteria and exceptional cases shall be negotiated with the applicant for a number greater than or equal to (3) samples. In this case, the following requirements of RGCP apply:

a) Table 4; and

b) item 6.2.4.2.1.

6.2.4.2.5 When applicable, additional parts, components or parts of the product complementary to the sample(s) shall receive be treated in accordance with requirement 6.2.4.2 to be sent to the laboratory together with the product.

6.2.4.2.6 The laboratory shall confirm and list in the test report all the documentation received necessary for performing the tests, listed in item 6.2.1, as well as indicate their current versions whenever practicable.
a) During the execution of the tests, the laboratory may question and request the TÜV to review the test plan and documentation submitted.
b) Type testing shall be performed entirely on the pilot sample or production line sample of the equipment under certification.

6.2.4.2.7 The approval of the pilot unit or serial head in the initial tests does not exempt the TÜV from validating the products on the production line in the factory audit or, when deemed necessary, through tests.

6.2.4.2.8 The tests shall be performed with the sample(s) submitted in accordance with this CRC.

6.2.4.2.9 If the sample fails the tests:
a) In case of non- conformity with a normative requirement that does not prevent the performance or continuation of the tests, the laboratory shall continue the tests and inform the TÜV of the identified deviation(s) by means of the test report.
b) In case of equipment failure or non- conformity with a normative requirement that prevents the operation of the equipment or continuity of tests respectively, the laboratory shall interrupt the activities and inform the TÜV of the problem, so that it may decide on the issue:
i) Authorize the laboratory to contact the applicant;
ii) Inform the applicant to have the equipment maintained in order to continue the tests, or
iii) Discontinue the tests and issue the test report.

Note 1: Maintenance of the equipment consists in returning the equipment to its original characteristics for its correct operation. Maintenance does not include the implementation of corrective action(s) for nonconformity(ies).

Note 2: In case of loss of functionality of the equipment during the tests, the maintenance of the equipment is allowed with the authorization of TÜV for the continuity of the tests.

c) Upon receiving the test report(s), the TÜV issues a report(s), with the analysis of the non-conformity(ies). The decision on the evaluation of the non-conformity(ies) is the responsibility of the TÜV.

6.2.4.2.10 The TÜV shall perform a critical analysis of the test reports from the laboratory, comparing them with the test plan previously established:
a) The TÜV, concluding that the sample failed the tests, shall notify the applicant of the non-conformity.
b) If the applicant does not technically dispute the non- conformity (s), this step shall be suspended and the applicant shall submit a treatment plan with the elimination of the non-conformity (s) observed for the resumption of the tests defined as necessary by the TÜV.
c) From the analysis of the corrective action of the manufacturer or the test that failed the sample, the TÜV may determine the replacement of the sample and repetition of tests.
d) Among the corrective actions that may generate the need for repetition of tests is the change of critical component(s), which will give rise to new tests.

e) If the TÜV determines the need for replacement of the sample(s) initially sent to the laboratory, the new sample(s) shall receive the same treatment as in requirement 6.2.4.2.1 before being sent to the laboratory.
f) The date for the restart of the initial tests shall be agreed upon between the applicant, the TÜV and the laboratory.

6.2.4.2.11 Any change in critical component(s) shall be informed to the TÜV and shall cause the critical analysis between the parties to determine the need to perform new tests. The non-observance of this requirement invalidates the certification process, which shall be suspended immediately if the TÜV identifies the manufacturer's action.

6.2.4.2.12 In case of failure in the tests, and depending on the evaluation of TÜV, the sample shall be considered failed and a new sample shall be sent by the manufacturer to the laboratory. The TÜV shall control all characteristics of the new sample.

6.2.4.3 Definition of the laboratory
For the purposes of this CRC, the criteria of Definition of the laboratory shall follow the requirements of RGCP, amended or supplemented according to this CRC:

6.2.4.3.1 The 6.2.4.3.1 requirement of RGCP shall be fully applied, adding the following Note at the end of the Table:
Note: Where it reads "provided for in the CAR", it refers to the tests provided for in the normative basis of the CAR.

6.2.4.3.2 The 6.2.4.3.2 requirement of RGCP applies with the following modifications:
a) item "a" and Notes 1, 2, 3 and 4 apply in full;
b) item "b" is deleted in its entirety and replaced with the following text:
When the laboratory(ies) accredited by INMETRO/Cgcre or signatory of the mutual recognition agreements ILAC or IAAC, fully in the specific scope do not meet in, at most, 4 (four) months the deadline for the start of the tests provided for in the CAR from the signing of the contract, exceptionally and precariously, the TÜV may use laboratories in accordance with the requirement 6.2.4.3.1 of RGCP. For large-sized equipment according to the definition 4.7, this period extends to a maximum of 6 (six) months.

c) Item "c" is deleted in its entirety; and
d) The accredited 3rd party laboratory has the prerogative to perform tests in external locations in relation to the physical location of the laboratory, as long as its accredited status to perform tests in facilities external to the laboratory is clearly described in the scope of accreditation.

6.2.4.3.3 The full requirement 6.2.4.3.3 of RGCP applies.

6.2.4.3.4 The 6.2.4.3.4 requirement of RGCP applies with the following modifications:
In any of the cases of use of 1st party laboratory accredited in the scope of specific testing, in whole or in part, the TÜV shall witness, record the execution of all tests, including monitoring of the stage of selection and preparation of samples and taking of results.

6.2.4.3.5 The 6.2.4.3.5 requirement of RGCP applies with the following modifications:
In any of the cases of use of 1st or 3rd party laboratory accredited for another testing scope, the TÜV shall, after recognizing and recording the training and infrastructure (including equipment) of the laboratory, witness, record the execution of all tests, including monitoring of the stage of selection and preparation of samples and taking of results.

6.2.4.3.6 The full requirement 6.2.4.3.6 of RGCP applies, adding the following text:

To meet the requirement of formal evidence of experience, the professional of the TÜV shall have record of participation in at least three (3) audits in the last three successive years, in the standard ABNT NBR ISO/IEC 17025:2005 and evidence of knowledge, training and experience in the test to be evaluated and the product to be tested. The formal audit training in ABNT NBR ISO/IEC 17025:2005 shall be provided by an organization independent from TÜV.

6.2.4.3.7 The 6.2.4.3.7 requirement of RGCP applies in full.

6.2.4.3.8 If a single laboratory is not able to perform all the tests provided, more than one laboratory may be used, following the requirements for selection of laboratory of RGCP complemented by this CRC.

6.2.5 Handling of non-conformities at the Initial Assessment stage

The 6.2.5 requirement and items of "Treatment of non- conformity in the stage of Initial Evaluation" of RGCP shall be fully applied.

6.2.6 Issuance of the Certificate of Conformity

The issuance of the Certificate of Conformity shall follow the conditions described in the RGCP and shall be performed by family of equipment under Health Surveillance Regime, as provided in Annex C of this CRC.

6.2.6.1 Critical Analysis and Certification Decision

The 6.2.6.1 requirement and items of "Critical Analysis and Certification Decision" of RGCP, complemented by the following requirements, shall be fully applied:

6.2.6.1.1 In case of certification of non-invasive measuring sphygmomanometers and digital clinical thermometers, which shall meet metrological regulation, the certificate of conformity shall only be granted to the applicant after obtaining the Model Approval Ordinance published by INMETRO.

6.2.6.1.2 Reports of product testing to meet metrological requirements may be used in the certification process of this CRC if they duplicate any specific conformity assessment requirement.

6.2.6.1.3 The Certificate of Conformity shall not expire provided that maintenance activities are performed. The maintenance of the certification shall be linked to the DHF update, performance of maintenance audits and additional tests if there are design changes that critically affect the safety of the Equipment already certified and, consequently, that require additional tests.

Note: The maintenance of the certification is subject to compliance with the standards, in accordance with the ANVISA Normative Instruction in force.

6.2.6.2 Issuance of the Certificate

The 6.2.6.2 "Issue of the Certificate" requirement of RGCP shall be fully applied:

6.2.6.2.1 Requirement 6.2.6.2.1 and 6.2.6.2.2 of RGCP applies in full.

6.2.6.3 Certificate of Conformity

The requirement 6.2.6.3 "Certificate of Conformity" of RGCP shall be fully applied:

6.2.6.3.1 The 6.2.6.3.1 requirement of RGCP shall apply according to the items below:

a) items "a", "d", "e", "g", "l" and "n" and Notes 1 and 2 apply in full; (specific for sphygmomanometers and digital thermometers)

a) item "b" is applied in its entirety, substituting the term "requesting supplier" for "applicant", according to definition 4.20 of this CRC;

b) item "c" shall be fully applied, replacing the term "manufacturer" by "manufacturer, contracted manufacturer, and/or legal manufacturer, when applicable", respectively, according to definitions 4.8. 4.9 and 4.10 of this CRC;

c) item "f" indicating "Model 5" shall apply in full;

d) item "h" shall apply in full supplemented by information on the original characteristics of the product;

e) items "i" and "j" are deleted in their entirety;

f) item "k" shall apply in full supplemented by the identification of the technical standards applied in the certification;
g) Item "m" shall apply in full supplemented by the information of the date(s) of issue of the test report(s);
h) Inform the date of acceptance of the proposal;
i) provide the list of accessories and parts tested together with the product;
j) inform the version of the user manual and of the project of the product evaluated for the granting of certification; and
k) inform the version of the evaluated software, for equipment with embedded software or accompanying software.

6.3 Maintenance Assessment

The Maintenance Assessment shall be performed by the TÜV, according to the conditions established by RGCP, in Annexes A and B of this CAR. Notes 1, 2 and 3 of requirement 6.3 of RGCP are excluded in this CRC.

6.3.1 Maintenance Audit of Manufacturer's Quality Management System, Risk Management and Production Process.

The maintenance audit shall be performed by the TÜV, according to the conditions established in RGCP and in Annexes A and B of this CRC with the following modifications:

6.3.1.1 Requirement 6.3.1.1 of RGCP replaced by:
6.3.1.1.1 The TÜV shall schedule periodic maintenance auditing in the production process of the manufacturer or service provider, considering, at least, the following stages:
a) verification of the originals of the documentation provided for in item 6.2.1, in particular as to their availability, organization and retrieval;
b) analysis of the records, in particular those related to the compliance with the requirements for the performance of the audits listed in Annexes A and B of this CRC; and
c) The TÜV shall evaluate, in the audit of companies with a production process considered essential to the manufacture of the product subject to this certification, if these companies adopt a Quality Management system certified in accordance with the standard ABNT NBR ISO 13485:2016 or RDC ANVISA No. 16/2013 "Certificate of Good Manufacturing Practices":

(i) that the latest audit report for the product subject to this certification covers the requirements set out in Annex B and that they are compliant;
ii) that in both cases the certificate is valid; and
iii) that the general verification items of Annex A of this CRC have been complied with.
d) Alternatively, compliance with item (c) may be accomplished through the audit reports issued under the Single Audit in Healthcare Product Program (MDSAP).

6.3.1.2 Requirement 6.3.1.2 of RGCP shall be applied, replacing the term "INMETRO/Dconf" by "ANVISA".

6.3.1.3 The TÜV shall witness the performance of routine tests on the production line whenever applicable. Alternatively, the records of tests performed may be used to evidence compliance with this requirement.

6.3.1.3.1 The audit shall be performed in agreement between the TÜV and the manufacturer. The TÜV shall schedule the factory audit preferably for the period in which the production line is producing.

6.3.1.3.2 Upon witnessing operation of the production line and performance of functional and routine tests, when applicable, as scheduled, the TÜV shall record the serial number and model of the product evaluated in the on-site tests.

6.3.1.4 If it is not possible for the TÜV to witness the operation of the assembly line even during the maintenance audit, the records of tests already performed may be used to evidence compliance with this requirement.

6.3.1.5 Provided that there is evidence that justifies them or by instruction of ANVISA, the TÜV may perform extraordinary maintenance audits and type tests to verify the maintenance of conformity of certified products.

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

6.3.2 Maintenance Test Plan

The 6.3.2 requirement of RGCP, complemented and modified as follows applies.

The establishment of the Maintenance Test Plan may occur by determination of the TÜV, based on the audit in accordance with Annex A, due to design changes that may critically affect the safety of the product and that have been identified in audits and have not been informed by the manufacturer or applicant to the TÜV or when there is an update in ANVISA regulations that establish the technical standards applicable to compulsory certification and that require the performance of new tests, or by determination of ANVISA. In these conditions, the Maintenance Test Plan shall follow the requirements of RGCP complemented by this CRC.

Note 1: The Maintenance Test Plan shall not apply to factory tests, previously agreed between TÜV and manufacturer, in accordance with the RMF and Annexes A and B of this CRC when applicable.

Note 2: The definition of when the measurement uncertainty values are relevant within the certification process is of the TÜV. When test reports issued by accredited laboratories are used, where the uncertainty values are not mentioned, without prejudice to the certification process, the TÜV shall be able to technically justify the absence of measurement uncertainty values.

6.3.2.1 Definition of tests to be performed

When applicable, the maintenance tests shall be performed according to the requirements of item 6.2.4.1 of RGCP, observing the current ANVISA Normative Instruction complemented by this CRC.

6.3.2.2 Definition of maintenance sampling

The criteria for Sampling Definition in the Maintenance Assessment shall follow, together with the prescriptions established in RGCP, the following requirements:

6.3.2.2.1 The collection of samples, by family, according to Annex C of this CRC, shall include the most critical configuration model.

6.3.2.2.2 A minimum of (1) one sample shall be collected from the production line, by random selection performed by the TÜV, from products already inspected, released and packed for commercialization.

6.3.2.3 Definition of the laboratory

The criteria of Definition of the laboratory, in case changes in the product are identified during the certification maintenance audit, shall follow, together with the requirements of RGCP, the same requirements of item 6.2.4.3 of this CRC.

6.3.3 Handling of non-conformities in the Maintenance stage

The criteria for the treatment of non- conformities in the maintenance phase shall follow the requirements of RGCP, complemented by the instructions of this CRC.

6.3.3.1 In case of failure of the sample during the tests in item 6.3.2.1, the non- conformity shall be notified to the applicant and the Certificate of Conformity shall be suspended. Should the applicant does not technically contest the non- conformity within 15 days, the applicant shall submit a plan of treatment and elimination of the non- conformity (ies) observed for the resumption of the tests defined as necessary by the TÜV, from the analysis of the corrective action of the manufacturer. A new sample shall be collected in accordance with the requirement 6.3.2.2 of this CRC and new tests shall be performed.

6.3.3.2 If failure occurs during the performance of maintenance tests of item 6.3.2.1, the failed products, which are in the possession of the applicant, shall be treated as non-compliant products according to the requirements of ANVISA regulation RDC 16/2013 or its substitutes.

6.3.3.2.1 This decision shall be duly substantiated to ensure that non-compliant or safety compromised products are not placed on the market.

6.3.3.3 If the non-conformities found during the maintenance tests are solved, the TÜV shall evaluate the need to perform new tests in accordance with item 6.2.5 of this CRC.

6.3.3.4 The TÜV shall inform ANVISA, via e-mail certifica.eletromedicos@anvisa.gov.br about the non-conformities identified in the certification maintenance process, which require field

action or recall, whenever there is sufficient evidence or proof that a health product does not meet the essential requirements of safety and effectiveness applicable. The following information about the identified product and problem should be included in the e-mail:

a) description of the problem;

b) the commercial name and model of the product;

c) lots/series at risk;

d) the registration number at ANVISA;

e) name of the applicant holding the certificate;

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

g) corrective actions related to the product/problem.

6.3.3.5 With the monitoring of the OCP, the certification holder shall initiate a field action, complying with the terms of RDC 23/2012 or substitute, whenever there is sufficient evidence or proof that a health product does not meet the applicable essential safety and efficacy requirements.

6.3.4 Maintenance Confirmation

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

6.3.4.1 The TÜV shall inform ANVISA of the cancellation or suspension of the certificate via e-mail certifica.eletromedicos@ANVISA.gov.br containing the following information:

a) Certificate number and TÜV number;

b) Name of applicant;

c) Make and model of the product;

d) ANVISA regularization number; and

e) an account of the reason for the cancellation or suspension, with the report number where applicable.

7 HANDLING OF COMPLAINTS

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

7.1 Requirement 7, "Complaint Handling", of RGCP fully supplemented by:

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

7.3 The applicant shall ensure that complaints are forwarded to the manufacturer and responses to them from the manufacturer to the customer;

7.4 The applicant shall have a complaint handling system that contemplates requirement 7 of RGCP, expressed in the form of a documented procedure inserted in the Quality Management System.

8 ACTIVITIES PERFORMED BY OCP ACCREDITED BY IAF MLA MEMBER

The criterion "Activities Performed by OCP Accredited by an IAF MLA Member" shall follow the requirements of RGCP.

9 TRANSFER OF CERTIFICATION

The criterion "Transfer of Certification" shall follow the requirements of RGCP:

9.1 The transfer of certificates due to the applicant's dissatisfaction with the performance of the Product Certification Body responsible for issuing the certificate is authorized as long as the following conditions are met:
a) All requirements for "Transfer of Certification" item 9 of this CRC shall be complied with.
b) Only the transfer of certificates that are not suspended, cancelled and that on the date of the transfer request, have no pending issues or non-conformities identified by the responsible OCP, ANVISA or INMETRO, or that are in the process of suspension or cancellation in progress and other conditions established in requirement 9 of RGCP is authorized.
c) In situations whose suspension or cancellation is related to the suspension or cancellation of the accreditation of the OCP, the transfer of certificates and certification processes in progress from one OCP to another shall be allowed, taking as technical basis what was established on the date of application for contracting at the time.

10 TERMINATION OF CERTIFICATION

10.1 In case of termination of certification, which may be due to the termination of manufacture/import of certified products or, at the option of the certificate holder, in case of voluntary certification, the TÜV shall ensure that the objects certified prior to this decision are in compliance with the requirements set forth in this CRC.

10.2 To this end, if deemed necessary, the TÜV may schedule audits, which may be remote, perform tests or simply analyze the most recent records of follow-up tests performed by the responsible manufacturer in the production chain.

10.3 Should any non-conformity be evidenced, the TÜV, before considering the process closed, shall request the relevant treatment from the certificate holder, defining the provisions and deadlines for implementation.

10.4 The TÜV shall notify the termination of the certification to ANVISA through the e-mail certifica.eletromedicos@anvisa.gov.br with the following information:
a) certificate number and OCP number;
b) the name of applicant;
c) make and model of the product;
d) ANVISA regularization number;
e) attach the reason for closure; and
f) the possibility that non-compliant product exists on the market.

10.5 The results of the audit, tests and records of closure shall be documented to integrate the documentation of the product certification process and shall be kept by the TÜV in electronic media or others for at least 5 years from the date of certification closure.

10.6 In the case of compulsory certification, as from the end of certification, the product may no longer be manufactured, and the import, distribution and marketing of the stock produced within the term of certification is allowed, without time limit to exhaust the stock, provided that it complies with ANVISA Regulations.

11 SEAL OF IDENTIFICATION OF CONFORMITY

The criterion "Conformity Identification Mark" shall follow the requirements of RGCP, complemented by the instructions of this CRC:

11.1 The requirement 11.1 of RGCP applies in full.

11.2 The requirement 11.2 of RGCP applies replacing it by the following text:
The Conformity Identification Mark may be printed on the Certificate of Conformity and shall be marked or affixed to the product and/or printed or affixed to the packaging, in accordance with the instructions of Annex II - Conformity Identification Mark, of this Ordinance.

11.3 The requirement 11.3 of RGCP applies replacing it by the following text:
In the case of imported products, the Conformity Identification Mark shall be marked or affixed to the product and/or printed or affixed to the packaging, in accordance with the instructions of Annex C, Conformity Identification Mark, of this CRC, before entering the country.

Exceptionally, considering ANVISA RDC No. 81/2008 or substitute, the Conformity Identification Mark may be affixed after entry into the country provided that:

a) the instructions of the aforementioned RDC are complied with; and
b) It is demonstrated by the applicant the control of the application of the Conformity Identification Mark in Brazil through written procedures and/or documentary evidence of the logistics center that shall be verified in the audit of the applicant. Such documents shall be integrated into the product certification process according to this CRC for authorization and/or maintenance of the use of the Conformity Identification Mark."

11.4 Specification
The specification of the Conformity Identification Mark is defined in Annex II of this Ordinance.

11.5 Traceability
The applicant shall implement a control for the traceability of products bearing the Conformity Identification Mark, and this control shall be available to INMETRO and ANVISA for a period of time equivalent to the expected useful life of the product, but in no case for less than five (5)

years from the date of commercial distribution by the manufacturer. The TÜV shall verify the implementation of this control, as well as the effectiveness of the traceability of certified products.

11.6 Cases in which the available area for application of the Conformity Identification Mark is not sufficient for the use of the smallest size of the seal available in this CRC

Exceptionally, when the available area for application of the Conformity Identification Mark is not sufficient for the use of the smallest size of the seal indicated in this CRC, or in case of sterile equipment for single use, the application of the Seal may be made only on the packaging. The decision of the TÜV shall be substantiated and recorded in the certification process.

12 AUTHORIZATION FOR USE OF THE CONFORMITY IDENTIFICATION MARK

The criterion "Authorization for Use of the Conformity Identification Mark" shall follow the requirements of RGCP.

12.1 Requirement 12, "Authorization for Use of the Seal of Conformity Identification ", of RGCP shall be fully applied.

13 RESPONSIBILITIES AND OBLIGATIONS

The criterion "Responsibilities and Obligations" shall follow the prescriptions of RGCP, complemented by the following requirements:

13.1 Obligations of the Applicant Certificate Holder.

13.1.1 Requirement 13.1.11 and 13.1.15 of RGCP are entirely excluded.

13.1.2 The requirement 13.1.12 of RGCP with the following wording applies:

When announcing the field action or recall of certified products that present non-conformities, do so in accordance with the rules of ANVISA RDC No. 23 of 2012 or substitute.

13.1.3 Requirement 13.1.13 of RGCP is replaced with the following wording:

13.1.13 Communicate to ANVISA about the occurrence of technical complaints, adverse events, situations of serious threat to public health and counterfeiting verified in the national territory associated to the certified health product and with ANVISA regularization in its name, respecting the deadlines and criteria for notification set forth in ANVISA Resolution RDC No. 67 of December 21, 2009, or its substitutes.

13.1.13.1 Communicate to ANVISA on the performance of field action involving health product of its responsibility, respecting the deadlines and conditions, respecting the deadlines established in ANVISA Resolution RDC No. 23, of April 4, 2012, or its substitutes.

13.1.4 Requirements 13.1.14 and 13.1.16 apply in full by replacing the term "INMETRO" with "INMETRO and ANVISA".

13.1.5 In addition to the compliance with the requirements of RGCP the applicant shall:

13.1.5.1 Ensure that the requirements stated in Annex A, Table 1, item 5 are met.

13.1.5.2 Perform tests pursuant to item 6.2.4, upon the determination of ANVISA or INMETRO, to prove the maintenance of the conformity of certified products.

13.1.5.3 Ensure that the DHF is kept updated at any time of certification and that changes that may impact the safety of the product or compliance with this regulation are notified, under penalty of suspension or cancellation of certification in case of failure to comply with this requirement.

13.1.5.4 Ensure, in case of sphygmomanometers of non-invasive measurement or digital clinical thermometers, maintenance of the same conditions of the Ordinance of approval of the model, when such product is submitted to certification/maintenance. In case of change in the product, in order to meet the requirements herein approved, this shall be submitted to a new technical model assessment to the Legal Metrology Board - Dimel, through the email

dicol@INMETRO.gov.br, regardless of the impact analysis, which needed to be performed in the pilot unit for approval in the requirements of this CRC.

13.1.5.5 Meet the other legal requirements for manufacturing, importing and marketing of the product, under penalty of suspension or cancellation of the certificate.

13.2 Obligations of the TÜV

13.2.1 The requirement 13.2.4 of RGCP applies, replacing it by the following text:

"Notify ANVISA, within five (5) working days, of cases of termination, suspension or cancellation of certification, through the electronic address certifica.eletromedicos@ANVISA.gov.br."

13.2.2 The requirement 13.2.7 of RGCP applies, replacing it by the following text:

Collect, when applicable by determination of ANVISA, in case of suspicions or duly substantiated complaints, samples to perform the tests defined in this CAR, bearing the costs related to the collection and testing, observing the provisions in item 14 of this CRC.

13.2.3 The full requirement 13.2.10 of RGCP applies, replacing the term "INMETRO" by "INMETRO and ANVISA".

13.2.4 Requirement 13.2.11 of RGCP is fully applied, replacing the term "INMETRO/Cgcre" by "ANVISA"; and the term "ABNT NBR ISO 9001 or ISO 9001" by "ABNT NBR ISO 13485 or RDC ANVISA No. 16/2013".

13.2.5 Requirement 13.2.14 of RGCP is entirely excluded.

13.2.6 The full requirement 13.2.15 of RGCP applies, replacing the term "INMETRO/Dconf" by "INMETRO/Dconf and ANVISA";

13.2.7 In addition to RGCP, the TÜV shall:

13.2.7.1 In case of sphygmomanometers of non-invasive measurement or digital clinical thermometers, when such product suffers any change in the conditions mentioned in the Ordinance of model approval, during the certification/maintenance, request the applicant to submit the product to a new technical model assessment to the Directorate of Legal Metrology - Dimel, through the email dicol@INMETRO.gov.br, regardless of the impact analysis, which needed to be performed in the pilot unit for approval in the requirements of this CRC.

13.2.7.2 Accept any penalties imposed by product regulatory agencies.

13.2.7.3 Pass on to the applicant the requirements established by INMETRO and ANVISA that impact it.

13.2.7.4 Keep updated, on INMETRO's website, the list of all certificates issued, allowing full reading of the texts and information relating to these certificates, or through consultation to reports extracted from database, containing all information included in the certificates issued.

13.2.7.5 Monitoring the publication of health alerts associated to products certified by the regulatory body (ANVISA) on its website. The TÜV shall evaluate whether the published alert has an impact on the certification granted, and if so, shall take appropriate measures with the applicant to monitor the corrective actions taken to solve the problem that caused the alert. This action shall be documented and be part of the product certification process documentation.

13.2.7.6 Follow up and implement the determinations of the regulatory body (ANVISA) regarding the need to carry out tests on certified product.

13.2.7.7 Issuing consolidated reports and other documents determined by the regulatory agency (ANVISA), when requested.

13.2.7.7.1 In order to issue the Certificate of Conformity and its maintenance, the TÜV shall issue a report consolidating all test results that have been carried out.

14 MARKET MONITORING

The criteria for monitoring in the market are the responsibility of ANVISA, being established by regulations of that agency for Equipment under Health Surveillance.

14.1 Metrological equipment, non-invasive measurement electronic sphygmomanometers (INMETRO Ordinance No. 46/2016 and substitute), and digital clinical thermometers (INMETRO Ordinance No. 402/2019 and substitute) are the responsibility of ANVISA and INMETRO/Dimel.

15 PENALTIES

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

15.1 The applicant that fails to meet the requirements of this CRC shall be subject to penalties of suspension and cancellation of certification, defined and operationalized according to INMETRO's certification scheme.

15.2 For products that have the suspension or cancellation of certification, and that are subject to regularization at ANVISA, the applicant company that fails to meet the requirements of this CRC, in the applicable items, may be subject to other sanctions. The following are considered irregularities:

15.2.1 To supply products outside the quality standards with the Conformity Identification Mark established in this CRC;

15.2.2 To use the Conformity Identification Mark on non-certified products;

15.2.3 Do not inform or provide false information regarding certified products;

15.2.4 Prevent auditors from accessing your system documents and records; and

15.2.5 Not accepting the verification and collections within the deadlines provided in this CRC.

16 COMPLAINTS

Requirement 16 "Complaints" of RGCP applies in full.

17 REVISION HISTORY

Revision	Change	Date	Responsible
0	Change in template and document coding from Doc: 703-CRC-001-E Rev. 9 to CRC-P0501_EN Rev.0	15.04.2021	Débora Reis

ANNEX A - AUDIT

A.1 Factory audits shall be conducted in accordance with the requirements of Table 1.

1. The risk management file shall be used as a basis for the evaluation. The RMF shall demonstrate that no change with relevant impact on product safety occurred that is not addressed by control measures. The requirements of tables 2, 3, 4, 5, 6 and 7 shall be audited and for this purpose electronic means and tools for documentary conformity assessment may be used.

A.2 In the initial certification audit the documents that will be used in production will be inspected.

1. Statistical production data for manufacturers in Brazil, or foreign manufacturers initiating production of the subject of certification, may be available only during the first maintenance audit or if an extraordinary audit occurs prior to the first maintenance audit.

2. Production statistics for foreign manufacturers already producing the subject of this certification must be verified in the Initial Factory Audit.

Table 1 - General Requirements for Conformity Assessment

Applying risk management to health products
Conformity Assessment Requirements in Auditing.
1 General Requirements for Conformity Assessment in Auditing.
The TÜV shall proceed to the audit of GR and QMS in the manufacturing unit or request that the audit be performed by OAC accredited by IAF MLA member body, with which the TÜV has Memorandum of Understanding - MoU, through an Audit Plan developed by the TÜV. This audit shall necessarily take into account all requirements of Annexes A and B, in order to verify the conformity of the production process and GR. Alternatively, other audits described in 6.2.3.8.2, 6.2.3.8.4 and 6.2.3.8.5 in this CAR may be used to fulfill the audit requirement in the units audited. The results of these audits shall be treated and evaluated by the Brazilian TÜV.

2 The TÜV shall evaluate the Risk Management File (RMF) and in compliance with the requirements of this CRC and the following standards:
2.1 ABNT NBR ISO 14971/2009, Health products, Application of risk management to health products (Table 2)
2.2 ABNT NBR IEC 60601-1/2010, Medical Electrical Equipment Equipment, Part 1, General requirements for basic safety and essential performance, clause 14, Programmable Medical Electrical Equipment Systems, corrected version 2013 (Table 3)
2.3 ABNT NBR IEC 60601-1-6/2011, Medical Electrical Equipment equipment, Part 1-6, General requirements for basic safety and essential performance, Collateral standard, Usability, corrected version 2013 (Table 4).
2.4 ABNT NBR IEC 62366, Health products, Application of usability engineering to health products (Table 5)
2.5 Verification Items of Standard ABNT NBR IEC 60601-1-9/2010 or by Risk Management
2.6 IEC 62304/2015, Medical Electrical Equipment equipment, software and health software process life cycle (Table 7) Note 1: There is no requirement to modify issued Certificates or to perform new audits for processes initiated or concluded based on IEC 62304/2006 standard; nor is there the need for adjustments in maintenance audits, which may remain in the scope of IEC 62304/2006 standard, with no changes, considering that the normative change serves the purpose of assisting the treatment of legacy products. Therefore, only new processes shall be carried out based on IEC 62304/2015. Note 2: Table 7-b in Annex A is intended as guidance on whether or not the requirements of Table 7 apply depending on the software safety class of the product. 3. The TÜV shall verify through the analysis of RMF the requirements of tables 2, 3, 4, 5, 6 and 7 of this CRC, aiming to identify if there was no change in the product or technical standard that impacts the safety of the product and that has not been validated by laboratory testing.
3.1 The TÜV shall verify changes in DHF and DMR that imply the need for conducting new type tests, according to item 6.2.4 of this CRC.
4. The TÜV shall witness the complete manufacturing, on the assembly line and verify the DHR, of a product, with the purpose of verifying that there are no processes or process changes not documented in the RMF. If certification is by family, the model selected shall

be the most critical configuration of the certified product. Alternatively, manufacturing procedures and records of tests performed may be used to evidence compliance with this requirement.
4.1. The TÜV shall witness the performance of routine tests on the assembly line, provided by the manufacturer, in accordance with the RMF of the product, recording the model and serial number of the product tested in the audit report. The selection of the sample for testing shall follow the guidance of item 6.2.6 of this CRC. Alternatively, the records of tests already performed may be used to evidence compliance with this requirement.
5. Inspection of factory documentation shall prove that the manufacturer takes measures during manufacture to ensure that each item meets all requirements of the standard ABNT NBR IEC 60601-1 even if it is not fully and individually tested during manufacture: These measures can be: (a) production methods (to ensure good manufacturing performance and consistent quality) where quality would be related to safety; or (b) production tests (routine tests) carried out on each item produced; or (c) production trials carried out on a sample, where the results would justify a sufficient level of confidence. The requirements to be verified shall be subject to agreement between the TÜV and the manufacturer so as to ensure the safety of the certified product. 6. The routine electrical safety tests shall prove that the product meets clauses 8.6, 8.7 and 8.8 of ABNT NBR IEC 60601-1:2010 amended version 2013 below: (a) earthing (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 manufacturer and agreed with the TÜV. 6.1 For the performance of routine tests it is recommended to use the verification prescribed in IEC TR 62354: 2014, General test procedures for Medical Electrical Equipment equipment, Routine tests on the production line item K.
7. The TÜV shall analyze the RMF applying all the requirements of ABNT NBR ISO 14971 (Table 2 of this CRC). If it identifies any change in the technical standard or in the design that may cause impact to safety, the OCP shall confirm in the RMF if the product was retested for the analyzed requirement(s) or if control measures were established.

8. Among the changes documented in the RMF on the subject of review, changes in mechanical design, electrical design, software, product assembly, materials and electronic components that may affect or alter the functional safety, and electromagnetic compatibility (EMC) and electrical safety of the product shall be listed.
9. Product samples that need to be collected for testing during a factory audit shall meet the item 6.2.4.2 of this CRC.
10. The TÜV shall evaluate the Quality Management System of the manufacturer and audit the regularization holder, certification applicant in Brazil, to ensure compliance for the affixing of the Conformity Identification Mark with the requirements of Annex B of this CRC, by evaluating the records of this activity during the audit of the certification applicant. The certification in accordance with ABNT NBR ISO 13485:2016 is optional. In case of external certification, the certificate shall be valid and the audit report of the certifier shall ensure the compliance of the items of Annex B of this CRC. The manufacturer may also evidence the compliance with the requirements of RDC ANVISA No. 16/2013 Good Manufacturing Practices for Medical Products and Diagnostic Products for In Vitro Use, or through the audit reports issued under the Single Audit Program on Health Products (MDSAP).

Note to translation: the following tables were machine translated, and as such, the wording in the requirement descriptions may be different from the official standard text. Please consider the Standard Requirement numbers for better reference.

Table 2 - Evaluation requirements of Standard ABNT NBR ISO 14971

Application of risk management to health products Conformity Assessment Requirements in Auditing.	
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
Identification of hazards	4.3
Estimation of risk for each hazardous situation	4.4
Risk evaluation	5
Risk control	6
Risk control option analysis	6.2
Implementation of risk control measures	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 overall residual risk acceptability	7
Risk management report	8
Production and post-production information	9

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

General requirements for basic safety and essential performance, Conformity Assessment Requirements in Auditing.	
Requirement description	**Standard Requirement**
General Requirements	4
Risk Management Process for EM Equipment or EM System	4.2
Essential Performance	4.3
Components of the EM Equipment	4.8
Use of Component with High Integrity Feature in Equipment	4.9
Power Supply	4.10
Identification, marking and documents of the EM Equipment.	7
Marking on the outside of EM Equipment or parts of EM Equipment.	7.2
Marking and control of instruments.	7.4

Safety signs.	7.5
Colours of conductor insulations.	7.7
Indicator lights and control keys.	7.8
Accompanying documents.	7.9
Grounding for protection, functional grounding, and potential equalization of EM Equipment:	8.6
Plugs and sockets	8.6.6
Equalizing conductor for plugs and sockets	8.6.7
Leakage and auxiliary current through the patient	8.7
The dielectric strength test	8.8
Note: The manufacturer shall maintain procedures and records of tests of the EM Equipment produced that prove the correct operation of the product and safety, as applicable, and in accordance with ABNT NBR IEC 60601-1.	

Note 1: Compliance is evidenced by the TÜV by confirming that the requirements of Table 3, of Standard ABNT NBR IEC 60601-1: 2010 / 2013.

Note 2: The requirements in Table 3 are not changed through Risk Management.

Note 3: Routine Dielectric Strength Testing may follow the prescriptions of Annex K of IEC TR 62354:2014.

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

General Requirements for Basic Safety and Essential Performance, Collateral Standard: Usability Conformity Assessment Requirements in Auditing.	
Requirement description	**Standard Requirement**
Usability	1
Conditions for application to Medical Electrical Equipment	4.1
Usability Engineering process for Medical Electrical Equipment	4.2
Replacement of IEC 62366 requirements	5

Table 5 - Verification Items of the Standard ABNT NBR IEC 62366:2010

Application of usability engineering to health products Conformity Assessment Requirements in Auditing.	
Requirement description	**Standard Requirement**
General requirements	4.1
Usability Engineering Process	4.1.1
Residual risk	4.1.2
Information for security	4.1.3
Usability Engineering Archive	4.2
Usability Engineering effort dimensioning	4.3
Usability Engineering Process	5
Application Specification	5.1
Frequently used functions	5.2
Identification of hazards and dangerous situations related to usability	5.3
Identification of security related features	5.3.1
Identification of features that are known or foreseeable hazards and dangerous situations	5.3.2
Primary operation functions	5.4
Usability Specification	5.5
Usability Validation Plan	5.6
User interface design and implementation	5.7
Usability check	5.8
Usability validation	5.9
Accompanying document	6
Training and training materials	7

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

General Requirements for Basic Safety and Essential Performance, Eco Responsible Design Conformity Assessment Requirements on Auditing	
Requirement description	**Standard Requirement**
Identification of environmental aspects	4.1
Instructions for minimizing environmental impact during normal use	4.5.2
Information for end of life management	4.5.3

The conformity evaluation of item 4.1 shall be done through the proof of the accomplishment of the activity, without the requirement of corresponding actions for each environmental aspect identified during the analysis; however the fulfillment of item 4.1 is essential for the preparation of the instructions of the requirements 4.5.2 and 4.5.3.

Table 7 - Verification Items of the IEC 62304:2015 Standard

Software and software process life cycle Conformity Assessment Requirements in Auditing.	
Requirement description	**Standard Requirement**
Compliance	1.4
General requirements	4
Quality Management System	4.1
Risk management	4.2 e 4.3
Software development process	5
Software Development Plan (SDP)	5.1.1
Maintenance of the updated PDS	5.1.2
Keeping the references between the software development plan and the system design and development up to date	5.1.3
Standards, methods and tools for software development planning	5.1.4
Software integration and integration test plan	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
Support items to be controlled	5.1.10
Software configuration item control before verification	5.1.11
Analysis of software requirements	5.2
Definition and documentation of system software requirements	5.2.1
Content of software requirements	5.2.2
Inclusion of risk control measures in software requirements	5.2.3
Reassessment of the health risk analysis of the product	5.2.4
Requirements Maintenance	5.2.5
Verification of software requirements	5.2.6
Software architecture design	5.3
Transformation of software requirements into an architecture	5.3.1
Development of the architecture for the interfaces of the software items	5.3.2
Specification of functional and performance requirements of the SOUP items	5.3.3
Specification of the software and hardware systems required for the SOUP item.	5.3.4
Identification of the separation required for risk control	5.3.5
Software Architecture Verification	5.3.6
Detailed Software Design	5.4
Subdivision of software into software units	5.4.1
Development of the detailed design of each software unit	5.4.2
Development of the detailed design of interfaces	5.4.3
Detailed design verification	5.4.4
Implementation of the software unit	5.5
Creating individual software units	5.5.1
Establishment of software unit verification process	5.5.2
Software unit acceptance criteria	5.5.3

Acceptance criteria for additional software unit	5.5.4
Verification of the software unit	5.5.5
Software integration and integration testing	5.6
Integration of software units	5.6.1
Verification of software integration	5.6.2
Software integration test	5.6.3
Content of the software integration test	5.6.4
Assessment of software integration test procedures	5.6.5
Conducting the regression test	5.6.6
Content of the integration test records	5.6.7
Use of software problem solving processes	5.6.8
Testing of the software system	5.7
Establishment of tests for software requirements	5.7.1
Use of the software problem solving process	5.7.2
Re-testing after changes	5.7.3
Evaluation of the testing of the software system	5.7.4
Content of the test records of the software system	5.7.5
Release for use of the software at system level	5.8
Guarantee of full software verification	5.8.1
Documenting known residual anomalies	5.8.2
Assessment of known residual anomalies	5.8.3
Version Release Documentation	5.8.4
Document how the released software was created	5.8.5
Ensuring the completion of activities and tasks	5.8.6
Software archiving	5.8.7
Ensuring reliability of delivery of software authorized for use	5.8.8
Software maintenance process	6
Establishment of the software maintenance plan	6.1
Problem analysis and modification	6.2
Documentation and assessment of information received from customers and the market	6.2.1
Monitoring of information received about the product	6.2.1.1

Documentation and assessment of product information received	6.2.1.2
Assessment of the effects of problem reporting on safety	6.2.1.3
Use of the software problem solving process	6.2.2
Analysis of requests for change	6.2.3
Approval of change request	6.2.4
Communication to users and regulatory bodies	6.2.5
Implementing Changes	6.3
Use of established processes for implementing the changes	6.3.1
Relaunch of modified software system	6.3.2
Software risk management process	7
Analysis of software contributing to hazardous situations	7.1
Identification of software items that may contribute to hazardous situations	7.1.1
Identification of potential causes contributing to the hazardous situation	7.1.2
Assessment of published SOUP deficiency lists	7.1.3
Documentation of potential causes	7.1.4
Risk control measures	7.2
Definition of risk control measures	7.2.1
Risk control measures implemented in the software	7.2.2
Verification of risk control measures	7.3
Checking risk control measures	7.3.1
Traceability of documentation	7.3.3
Software change risk management	7.4
Analysis of changes to health product software related to safety	7.4.1
Analysis of the impact of software changes on existing risk control measures	7.4.2
Performing analytically based risk management activities	7.4.3
Software configuration management process	8
Configuration identification	8.1
Establishment of means of identification of configuration items	8.1.1
Software Identification of Unknown Origin - SOUP	8.1.2

Identification of system configuration documentation	8.1.3
Change Control	8.2
Approval of change requests	8.2.1
Implementation of changes	8.2.2
Change Verification	8.2.3
Creation of mechanisms for traceability of changes	8.2.4
Configuration status accounting	8.3
Software problem solving process	9
Preparation of the problem report	9.1
Investigation of the problem	9.2
Communication of information to relevant parties	9.3
Using change control processes	9.4
Record keeping	9.5
Problem analysis for trend assessment	9.6
Verification of software problem resolution	9.7
Content of the test documentation	9.8

Table 7- b Summary of the application of the requirements of Table 7 by software class

Requirement	Applicable requirements	A-Class	B-Class	C-Class
4	All Requirements	X	X	X
5.1	5.1.1, 5.1.2, 5.1.3, 5.1.6, 5.1.7, 5.1.8, 5.1.9	X	X	X
5.1	5.1.5, 5.1.10, 5.1.11, 5.1.12		X	X
5.1	5.1.4			X
5.2	5.2.1, 5.2.2, 5.2.4, 5.2.5, 5.2.6	X	X	X
5.2	5.2.3		X	X
5.3	5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.6		X	X
5.3	5.3.5			X
5.4	5.4.1		X	X
5.4	5.4.2, 5.4.3, 5.4.4			X
5.5	5.5.1	X	X	X

5.5	5.5.2, 5.5.3, 5.5.5		X	X
5.5	5.5.4			X
5.6	All Requirements		X	X
5.7	All Requirements	X	X	X
5.8	5.8.1, 5.8.2, 5.8.4, 5.8.7, 5.8.8	X	X	X
6	All Requirements	X	X	X
7.1	All Requirements		X	X
7.2	All Requirements		X	X
7.3	All Requirements		X	X
7.4	7.4.1	X	X	X
7.4	7.4.2, 7.4.3		X	X
8	All Requirements	X	X	X
9	All Requirements	X	X	X

Note: The inclusion of Table 7-b in Annex A "Summary of the application of the requirements of Table 7 by software class" does not imply changes in the certificates of conformity issued before its inclusion and also does not change conformity assessment processes that are already in progress before the publication of this Ordinance.

ANNEX B - TECHNICAL REQUIREMENTS FOR THE ASSESSMENT OF THE QUALITY SYSTEM ACCORDING TO ABNT NBR ISO 13485:2016

B.1 In the initial assessment and during the maintenance audit of the QMS of the manufacturer using ABNT NBR ISO 13485:2016 for the product(s) subject(s) of certification, the TÜV shall verify compliance with the minimum requirements listed in Table 8 below:

Note to translation: the following tables were machine-translated, and as such, the wording in the requirement descriptions may be different from the official standard text. Please consider the Standard Requirement numbers for better reference.

Table 8 - Verification Items of the Standard ABNT NBR ISO 13485:2016

Health Products Quality management systems Requirements for regulatory purposes	
In the assessment, initial and maintenance, of the manufacturing QMS using ABNT NBR ISO 13485:2016 for the product(s) subject to certification shall verify compliance with the requirements listed below:	
Requirement description	**Standard Requirement**
Quality management systems	4
General requirements	4.1
Document Control	4.2.4
Records Control	4.2.5
Product Realization Planning	7.1
Determination of product-related requirements	7.2.1
Critical analysis of requirements related to the product	7.2.2
Communication	7.2.3
With reference to item 7.2.3.c "Handling of Customer Complaints".	
Design and development	7.3
Project planning and development	7.3.2
Design and development inputs	7.3.3

Design and development output	7.3.4
Critical design and development analysis	7.3.5
Design and development verification	7.3.6
Design and development validation	7.3.7
Design and development change control	7.3.9
Verification of Purchased Product	7.4.3
Production Control and Service Delivery	7.5.1
Validation of production processes and service provision	7.5.6
Identification	7.5.8
Traceability	7.5.9
Product Preservation	7.5.11
Control of Measuring and Monitoring Devices	7.6
Process Monitoring and Measurement	8.2.5
Product Monitoring and Measurement	8.2.6
Control of Non-conforming Product	8.3
Corrective Action	8.5.2
In the initial and maintenance evaluation of the QMS of certification applicants, in accordance with the requirements of ABNT NBR ISO 13485:2016 for the product(s) subject(s) of certification, the TÜV shall verify compliance with the requirements listed below:	
Document Control	4.2.4
Records Control	4.2.5
Communication	7.2.3
Identification	7.5.8
Traceability	7.5.9
Verification of Purchased Product	7.5.3
Product Preservation	7.5.11
Control of Monitoring and Measuring Equipment	7.6
Feedback	8.2.1
Control of Non-conforming Product	8.3
Corrective Action	8.5.2

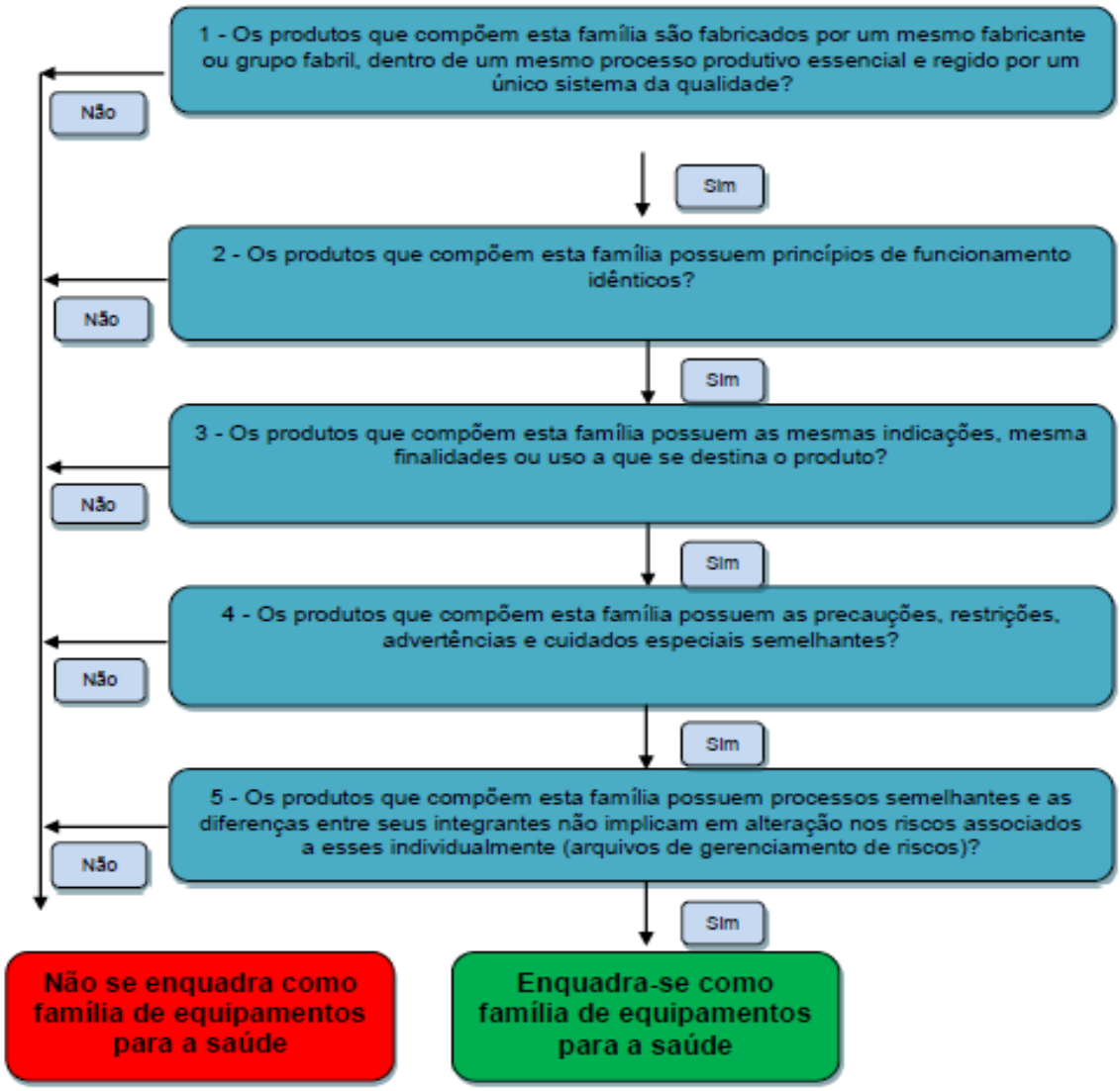
B.2 Technical Assistance, when applicable, shall be verified in the QMS, in accordance with ANVISA Normative Instruction No. 8 of 26/12/2013, and from manufacturers, in accordance

with ANVISA RDC No. 16 of 2013 or through the corresponding requirements of ABNT NBR ISO 13485:2016.

B.2.1 Optionally Technical Assistance, where applicable, may be performed in accordance with definition 4.1.1 - Technical Assistance - Extended Definition.

B.3 The audit of certification applicants, shall assess in the QMS the compliance with the requirements of ABNT NBR ISO 13485:2016, Table 8 and the compliance with item 7 Complaint Handling of RGCP.

ANNEX C – FAMILY CHARACTERIZATION



Note to translation: the steps 1 to 5 can be translated as follows:

1- Are the products in this family manufactures by the same manufacturer our manufacturing group, under the same essential productive process and regulated by the same QMS?

2- Do the products in this family have identical principle of operation?

3- Do the products in this family have the same intended use?

4- Do the products in this family have similar precautions, restrictions, warnings and special care indications?

5- Do the products in this family have similar processes and the differences between its members do not imply in alterations in the risks associated to each one individually (Risk Management File)?

If answered YES to all questions, the products can be regarded as a family (green box)

If any answer is NO, then the products cannot be regarded as a family (red box).

ANNEX II – CONFORMITY IDENTIFICATION MARK

1. The identification of the certified product shall contain the information set out in this Annex according to the field of application, compulsory or voluntary.

2. The applicant shall comply with the following requirements for the use of the Conformity Identification Mark:

a) The seal, according to Figure 1, can only be used on products that are in force in the IN/ANVISA, which establishes the technical standards, adopted for purposes of conformity certification of the Equipment under the Health Surveillance Regime;

b) The seal as shown in Figure 2 applies to Equipment not included in item 2.a;

c) On the package, the seal shall be printed or a label shall be used, with characteristics of indefeasibility and permanence, provided that it complies with the minimum dimensions, defined in Figure 1 and 2 of this Annex;

d) On the product, when the Conformity Identification Mark printed or inserted by means of a label does not fit on the front part of the Equipment, the Conformity Identification Mark described in Figure 3 (compulsory certification) and Figure 4 (voluntary certification) may be used;

e) On the product, when the Conformity Identification Mark cannot be fixed according to items 2.a, 2.b and 2.d, because it does not fit on the front part of the Equipment, it can be affixed on the other parts of it; and

f) The black and white version may be used on the packaging only in case it has a color similar to the colored seal.

3. The TÜV shall ensure that the affixing of the Conformity Identification Mark is made in an indelible, permanent and visible manner, as well as the possibility of the Equipment under the Health Surveillance Regime being traced by sequential numbering or other form deliberated by the TÜV in agreement with the applicant.

NOTE TO TRANSLATION: these are sample drawings. Please contact the TÜV Rheinland Brazil for the official artwork files.

The captions are translated as follow:

Figure 1: Conformity Identification Mark for products with mandatory certification.

Inside notes: minimum size 50mm [*note: 50 mm wide, keeping proportions*]

Font: Univers and **Univers Black**

Figure 2: Conformity Identification Mark for products with voluntary certification.

Inside notes: minimum size 50mm [*note: 50 mm wide, keeping proportions*]

Font: Univers and **Univers Black**

Figure 3: Compact Conformity Identification Mark for products with mandatory certification.

Inside notes: minimum size 20mm [*left image – bordered mark*]; minimum size 11mm [*right image – borderless mark*]

Figure 4: Compact Conformity Identification Mark for products with voluntary certification.

Inside notes: minimum size 20mm [*left image – bordered mark*]; minimum size 11mm [*right image – borderless mark*]

Figure 1 - Conformity Identification Mark for products with compulsory certification

Figure 2 - Conformity Identification Mark for products with voluntary certification

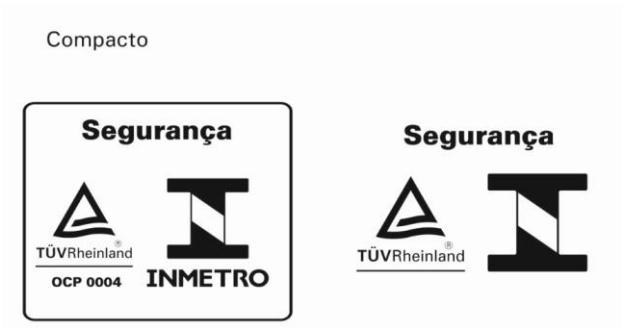


Figure 3 - Conformity Identification Mark compact for products with compulsory certification

Figure 4 - Conformity Identification Mark compact for products with voluntary certification

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