RESOLUTION - RDC Nº 36, AUGUST 26, 2015

It provides for the risk classification, the register control systems and registration, labeling requirements and product instructions for use of in vitro diagnosis, including their instruments and other measures.

The Board of the National Health Surveillance Agency, in exercise of the powers conferred on it by sections III and IV of art. 15 of Law No. 9.782, January 26, 1999, item V and §§ 1st and 3rd of art. 58 of the Bylaws approved in accordance with Annex I of the Board Resolution - RDC Nº 29, July 21, 2015, published in the Official Gazette of July 23, 2015, in view of the provisions of sections III of art. 2, III and IV of art. 7 of Law No. 9.782, 1999, and the improvement program of the Agency's Regulatory Process, established by Ordinance Nº 422 of April 16th, 2008, at the Annual Public Meeting Nº 015/2015 held on August 20th, 2015, adopts the following Resolution of the Board and I, the Chairman, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I
Objective
Art. 1st This Resolution is to establish the risk rating, the register control systems and registration and labeling requirements and product use instructions for in vitro diagnosis, including their instruments.

Section II
Coverage
Art. 2nd This resolution applies to products for in vitro diagnosis manufactured in national territory and to those manufactured in other countries that may be imported to Brazil.

Single paragraph. This Resolution does not apply:
I - to the reagents and reference materials intended specifically for quality assessment, for proficiency tests or interlaboratory comparison;
II - to isolated reagents marketed as inputs for manufacturing of in vitro diagnosis products;
III - to the reagents or sets of reagents mounted in clinical laboratories to be used solely in the same institution, following work defined protocols being prohibited its sale or donation;
IV - to the laboratory reagents, which are intended for the diagnosis of any type of non-human sample;
V - to general laboratory use materials;
VI - to products intended exclusively for use in forensics;
VII - to products intended exclusively for sports doping control tests, whose results are not used for the purpose of treatment or health;
VIII – to the exclusive use of products in research, including imported and labeled as RUO - Research Use Only;
IX – to the culture media and freeze-dried supplements that rely on processing and user controls performed prior to use;
X – to the culture media and instruments for environmental control analysis, industrial, food or water; and
XI - to software for in vitro diagnostic not embedded in equipment, which are dealt in a specific regulation.

Section III
Definitions

Art. 3rd For the purposes of this Resolution, the following definitions shall apply:
I – register or cadaster alteration: information modification presented originally in the registration process or product cadaster;
II - Preliminary analysis: analysis to verify product characteristics with registration purpose, alteration (when applicable) or revalidation;
III - product cadaster: Private act of ANVISA, after evaluation and concessive order of their leader, designed to show the right to manufacture and import the product for in vitro diagnostic exempted from registration as per §1º of art. 25 of Law Nº. 6.360, September 23, 1976, indicating the name, manufacturer, purpose and other elements that characterize;
IV - calibration: set of operations under specified conditions, establishing the correspondence between the values indicated by a measuring instrument and a reference material, with standardization purposes or set of instruments and / or laboratory procedures;
V - sample collector: material, with or without vacuum, intent to specific use of primary containment and preservation of samples taken from the human body for in vitro diagnostic purposes;
VI - clinical performance: evaluation performed to establish or confirm an association between the analyte and the clinical condition or physiological status;
VII - technical Dossier: A document that describes the elements that make up the product, indicating the characteristics, purpose, method of use, content, special care, the potential risks, the production process and additional information;
VIII - high dose pro-zone effect, the result of an antigen-antibody reaction in which antigen or antibody excess results in an incomplete or block reaction;
IX - Packaging: case, container or any form of packaging, removable or not, destined to cover, packaging, bottling, protect or maintain the product;
X - primary packaging: container intended for packaging and bottling of products, in direct contact with them;
XI - secondary packaging: container intended for products packaging in their primary package, not keeping contact with them;
XII - analytical specificity: the ability of an analytical method to determine only the analyte compared to other substances present in the sample;
XIII - clinical specificity: also known as diagnostic specificity, it is the percentage of negative results when the analyte is not present in the sample, recognizing the absence of a particular disease or condition;
XIV - stability: quality of a product related to the maintenance of its essential characteristics over a period and pre-established conditions;
XV - performance studies: performance evaluation of an in vitro diagnostic product based on available data and laboratory or clinical investigations to determine characteristics such as sensitivity, specificity, repeatability and reproducibility;
XVI - manufacturing: set of operations required to obtain the product referred to in this resolution;
XVII - Legal manufacturer: legal entity with responsibility for the project, manufacture, packaging and labeling of the product before putting it on the market under its name, both operations being carried out or not by the company itself;
XVIII - operating instructions: guidance provided by the manufacturer or the register holder for the correct use of the product safely and effectively;
XIX - instrument: equipment or apparatus developed by the manufacturer intended to be used as a product for in vitro diagnosis;
XX - batch: amount of a product obtained in a manufacturing cycle, which is characterized by its homogeneity;
XXI - general laboratory use Material: chemical reagent or device that has general laboratory application, used in the preparation and examination of samples of the human body for diagnostic purposes, and that is not labeled or intended for a specific diagnostic application;
XXII - array: all the components of a material or sample system except the analyte;
XXIII - number or lot code or serial number: any combination of numbers and / or letters through which one can trace the complete history of the manufacture of a product and its movement in the market to consumption;
XXIV - patient: an individual, which obtained the biological material for the purpose of clinical laboratory diagnosis;
XXV - in vitro diagnostic clinical research products: research using samples from humans, to check the performance and validity of the product for the purposes for which it is proposed;
XXVI - point of care testing (PoCT): conducted testing near the site of patient care, including offices and locations outside the technical area of a laboratory, by health professionals or by personnel trained by the Ministry of Health or state and municipal Health Departments;
XXVII - in vitro diagnostic product: reagents, calibrators, standards, controls, sample collectors, materials and tools, used individually or in combination, use intention determined by the manufacturer for in vitro analysis with derived samples of the human body, solely or mainly to provide information for diagnostic purposes, monitoring, screening or to determine compatibility with potential recipients of blood, tissues and organs;
XXVIII - product for self-test: product for monitoring the conditions of a disease or detecting specific conditions intended to help patients, but not conclusive for diagnosis, performed by laypersons, health professionals or clinical laboratory;
XXIX - exclusive use in research product: Product with no medical purpose or goal, which can be used in basic research, pharmaceutical research or as an input of a kit of reagents for research purposes, may not be used for clinical purposes;
XXX - single-use product: In vitro diagnostic, that is used for a single patient during a procedure and then discarded and cannot be reprocessed and used again;
XXXI - product registration: private act of ANVISA, after evaluation and concessive order of their leader, designed to show the right of manufacturing and import of the product submitted to the regime of Law Nº 6.360, 1976, indicating the name, manufacturer, purpose and other elements that characterize;
XXXII - repeatability: results of successive measurements of the same analyte in unchanged operating conditions;
XXXIII - Reproducibility: the results of successive measurements of the same analyte in different operating conditions;
XXXIV - Technical responsible: a legally qualified professional, with registration at professional autarchy, recognized by the health authority for the activity that the company carries;

XXXV – label: printed identification, lithographed, painted, etched with fire, pressure or self-adhesive, applied directly on containers, packages, wrappers or any protective external or internal packaging and cannot be removed or changed while using the product, transportation or storage;

XXXVI - Analytical sensitivity: the ability of an analytical method to get positive results against the positive results obtained by the reference method. The lowest amount of analyte, which can be measured;

XXXVII - Clinical Sensitivity: percentage of positive results when the analyte is present in the sample, recognizing the presence of a particular disease or condition;

XXXVIII - applicant: a legal entity located in Brazil, manufacturer or importer, which requires registration or product cadaster for in vitro diagnostic, assuming full legal responsibilities related to the accuracy of the information and the quality of the product in the country;

XXXIX – manufacturer plant: site where the manufacturing or product manufacturing stage occurs, may be the legal manufacturer, contracted manufacturer or original equipment manufacturer (Original Equipment Manufacturer - OEM);

XL - User: individual, professional or layperson, may be the patient himself, who makes use of the product;

XLI - lay user: individual with no formal technical or scientific training to use the product;

XLII - Cut-off value: value of a reference distribution which represents a clinical decision point; and

XLIII - benchmark: theoretical or established scientific principles that serve as a benchmark agreed for comparison.

CHAPTER II
PRODUCT RISK RATING

Section I
Risk classes

Art. 4 For regulation purposes at ANVISA, the in vitro diagnostic products are classified into the following risk classes:

I - Class I: low risk products to the individual and low risk to the public health;

II - Class II: medium risk products to the individual and or low risk to the public health;

III - Class III high-risk products to the individual and or medium risk to the public health; and

IV - Class IV high-risk products to the individual and high risk to the public health.

Art. 5 The risk classification of products for in vitro diagnosis is based on the following criteria:

I - use indication specified by the manufacturer;

II - technical, scientific or medical knowledge of the user;

III - Importance of the information provided to the diagnosis;

IV - relevance and impact of the results for the individual and public health; and
V - epidemiological relevance.

Section II
Classification Rules

Art. 6º Are classified as Class IV reagents and devices for the following purposes:
I - detect the presence of, or exposure to, transmissible by blood agent, its components and derivatives, cells, tissues or organs, in order to assess their suitability for transfusion or transplantation;
II - monitor or detect the presence of, or exposure to, transmissible agent that causes risk of death or illness, often incurable with a high risk of propagation.

Art. 7º Are classified as Class III reagents and devices for blood grouping or tissue to ensure the immunological compatibility of blood, blood components, cells, tissues or organs that are intended for transfusion or transplant.
Single paragraph. Products for determinations of the ABO system, Rhesus system, the Kell system, Kidd system and Duffy system are classified as Class IV.

Art. 8º Are classified as Class III reagents and devices intended for the diagnosis of diseases requiring a mandatory report provided by Ordinance Nº 1.271, June 6º, 2014 and Decree Nº 1.984, September 12º, 2014, from the Ministry of Health.

Art. 9. Are also classified as Class III reagents and devices intended to:
I - detect the presence of, or exposure to, a sexually transmitted agent;
II - detect the presence of an infectious agent in cerebrospinal fluid or blood, with limited risk of propagation;
III - detect the presence of an infectious agent when there is significant risk that an erroneous result could cause death or severe disability to the individual or fetus;
IV - pre-natal screening of women in order to determine their immune status against transmissible agents;
V - determining the status of an infectious disease or immune status when there is risk that an erroneous result takes to a management decision of the patient, resulting in a situation of imminent danger to his life;
VI - monitor viral load of patients suffering from a generally incurable infectious disease;
VII - screening, staging and diagnosis of cancer;
VIII - Human genetic testing;
IX - screening for congenital disorders in the fetus;
X - control the levels of drugs, substances or biological components when there is a risk that an erroneous result takes to a management decision of the patient, resulting in an immediate situation of risk of death; and
XI - gas determinations and blood glucose for point of care testing - PoCT.
Single paragraph. Other reagents and in vitro diagnostic devices that are intended for use as point of care testing - PoCT, not included in item XI of this article, should be classified independently, using the classification rules set forth in this Section.

Art. 10. Are classified as Class III products intended for self-test.
Single paragraph. Products intended for self-test where the result is not decisive for a clinically critical condition that is preliminary and requires monitoring with appropriate laboratory test, belong to Class II.

Art. 11. Are classified as Class I:
I - reagents or other ancillary items for in vitro diagnostic procedures;
II - products intended for calibration, cleaning or maintenance of instruments in technical assistance procedures or maintenance and cleaning by trained user as required by the manufacturer specified in the instrument manual;
III - culture media and devices intended to the identification of microorganisms;
IV - products for DNA and RNA extraction, ancillary to in vitro diagnostic procedures;
V - sample collectors or collection containers, storage and transportation of biological samples for use in laboratory diagnostic tests;
VI - instrument for preparation and processing of samples for in vitro diagnosis.

Art. 12 Items for in vitro diagnosis not covered by the rules of classification provided in Articles 6th to 11 are classified in Class II.

Single paragraph. The instruments used for in vitro diagnosis of human samples that generate results or analytical determinations are always classified as Class II, excluding instruments intended for self-test, that follow the classification of the respective analytes.

Art. 13 The products used as calibrators, standards or controls for a specific analyte or multiple analytes with pre-defined quantitative or qualitative ranking values follow the same principal reactant classification.

Single paragraph. Calibrators, standards or controls used in cell counters instruments are always classified as Class II.

Art. 14. If the same product applies for more than one rule, with different risk classes assigned, the product should be classified in the highest risk category.

Art. 15. Are not eligible for inclusion as a self-test and therefore cannot be provided to non-technical users, the products that have the following purposes:
I - test samples to verify the presence or exposure to pathogens or transmissible agents, including agents that cause infectious diseases subject to mandatory reporting;
II - perform blood typing;
III - performing genetic testing to determine the presence or predicting susceptibility to disease or physiological condition;
IV - help diagnose or indicate the presence of a disease, cardiac and tumor markers, or conditions with serious implications to health; and
V - indicate the presence of drugs or their metabolites.

Single paragraph. The sealing supply to the lay members of the caput of this article may be refused by Resolution of the Board of Directors, in view of public policies and strategic actions formally instituted by the Ministry of Health in accordance with ANVISA.

Art. 16. The classification rules may be updated in view of technological progress and post-marketing information, arising from the use or application of products for in vitro diagnosis.
Section III
Regime Control

Art. 17. The products for in vitro diagnostic Classes I and II are subject to registration.
Art. 18. The products for in vitro diagnosis of Classes III and IV are subject to registration.

CHAPTER III
GENERAL REQUIREMENTS AND DOCUMENTARY

Section I
Registration Petitions or Products Registration

Art. 19. For docketing the registration petitions or product registration for in vitro diagnosis, the applicant must submit:
I - proof of payment of Sanitary Surveillance Inspection Fee (TFVS) by Federal Tax Liability Payment Form (GRU) equivalent, or exemption guide;
II – form available by ANVISA in electronic application, duly completed;
III - for products classified in risk classes II, III and IV, technical dossier containing the information required for the corresponding risk category;
IV - for national products that have some kind of outsourced manufacturing step, declaration stating the corporate name and postal address (s) of the company (ies) involved and step (s) corresponded in the manufacturing process;
V - for all imported products, consularized statement, accompanied by a sworn translation, issued by the legal manufacturer for at most two years, when there is no express validity stamped on the document, authorizing the importer to represent and market its product (s) in Brazil, containing at least the following information:
   a) corporate name and full address of the legal manufacturer;
   b) corporate name and full address of the importer;
   c) express authorization to the importer represent and market the product (s) in Brazil;
   d) knowledge and compliance with the requirements of Good Manufacturing Practices for Health Products established in the Board Resolution - RDC Nº 16, March 28th, 2013.
VI – for products classified in risk classes III and IV proof of certificate on Good Manufacturing Practices and Control issued by ANVISA or proof of GMP Certificate Application protocol; and
VII - when required, prior analysis report considered satisfactory, performed per unit of the National Network of Public Health Laboratories as set out in section IV, art. 16 of Law Nº 6.360, September 23, 1976.
§1º shall not be subjected to technical requirement the petition that meets the absence of document, allowing summary dismissal.
§2º the approval of registration is subjected to the publication of the Certificate of Good Manufacturing Practices issued by ANVISA and compliance of the other requirements indicated in this Regulation.

Art. 20. The products for in vitro diagnostics can be registered or recorded in groupings like family when:
I - are from the same legal manufacturer, having similar technology, making use of the same methodology and are included in the family grouping of products for in vitro diagnosis, published in the normative Instruction Nº 3, August, 26th, 2015; or
II - are from the same legal manufacturer, having similar technology, making use of the same methodology and are interdependent and exclusive for the execution of a specific test.
§1º the reagents, calibrators and controls of a specific test may be provided separately as long as they are provided in the cadaster or product family register.
§2º Products that may be used in multiple tests shall be registered or recorded separately as unique products.
Art. 21. At the discretion of the health authority, information concerning the clinical research may be requested according to the Board Resolution - RDC Nº 10 February 20th, 2015.

Section II
Petitions Registration Alteration or Product Registration

Art. 22. For docketing an alteration petition of the cadaster or registration of the in vitro diagnosis product, the applicant must submit:
I - proof of payment of the Sanitary Surveillance Inspection Fee (TFVS) by Federal Tax Liability Payment Form (GRU) correspondent or exemption guide;
II – form available by ANVISA, duly completed identifying clearly and objectively the pleaded alterations;
III - documents that support and prove the pleaded alterations in comparison to earlier versions of documents previously submitted to ANVISA; and
IV - other documents required by the health authority, as petitioned matter described in the electronic application system of ANVISA.
Single paragraph. It shall not be subjected to technical requirement the petition that meets the absence of document, allowing summary dismissal.

Art. 23. In case of alteration, being necessary the exhaustion of stock of finished products, it is permissible the simultaneous import and marketing of the involved versions up to 180 (one hundred eighty) days from the approval of the amendment by ANVISA.
Single paragraph. Alterations made to solve issues of product safety and efficacy are not within the permission of the caput of this article, they must be implemented before the sale and distribution of the product.

Section III
Revalidation petitions of Product Registration

Art. 24. For docketing revalidation request of product registration for in vitro diagnosis, the applicant must submit:
I - proof of payment of Sanitary Surveillance Inspection Fee (TFVS) by Federal Tax Liability Payment Form (GRU) equivalent or exemption guide;
II – form available by ANVISA, duly completed;
III - for imported products: certified copy of the legal document as described in item V of art. 20; and
IV - proof of Certification on Good Manufacturing Practices and Control issued by ANVISA or proof of GMP Certificate Application protocol. Single paragraph. It shall not be subject to technical requirement the petition that meets the absence of documents, allowing summary dismissal.

Art. 25. The products subject to registration are exempted of revalidation.

Section IV
Cancellation Cadaster or Product Registration Petitions

Art. 26. The holder of the cadaster or product registration for in vitro diagnostic who no longer want to market it in the Brazilian market must apply for cancellation upon submission of the form made available by ANVISA in electronic application, duly completed. Single paragraph. The cancellation of the cadaster or registration does not exempt the holder of the responsibility for products placed on the market.

CHAPTER IV
TECHNICAL DOSSIER

Art. 27. The technical responsible will assume responsibility for the information provided in the technical profile of the product.

Art. 28. The technical dossier must be kept updated by the national manufacturer or importer of the product in its facilities for monitoring purposes by the National Health Surveillance System. Single paragraph. The technical dossier of risk class I products should not be submitted to ANVISA, however, the domestic manufacturer or importer must keep the information and documents provided in the Annex of this Resolution, for health control purposes.

Art. 29. The technical dossier should include the following information in accordance with the risk class:
I - product description, containing the data listed below:
 a) use indication or intended use:
 1. analyte or measuring;
 2. functionality (screening, monitoring, diagnosis or assistance to diagnosis);
 3. specific situation, condition or risk factor of interest to be detected, defined or differentiated;
 4. intended user (professional or lay user);
 5. environment or place of use;
 6. whether it is single or multiple use;
 7. whether it is automated, semi-automated or not automated;
 8. whether it is qualitative or quantitative;
 9. type (s) or sample (s) needed; and
 10. when applicable, target population test;
 b) detailed description of the principle of the test method or instrument operation principles;
 c) the risk class where the product fits;
d) description of the product components and, where appropriate, description of the active ingredients of the components;
e) description of the commercial presentation and packaging (primary and secondary);
f) when applicable, for automated testing, description of the characteristics of the instrument required or dedicated instrument;
g) when applicable, the indication of software to be used with the product for in vitro diagnosis;
h) when applicable, description or complete list of settings / product variations in vitro diagnostic that will be available;
i) where applicable, description of accessories, other products for in vitro diagnostics and any other products that must be used in combination with the target product; and
j) indication of country (ies) in which the product (s) has authorized or approved marketing;
II - Product images (photographs, drawings or diagrams of the product or assembly of its components);
III - Product risk management report (risk analysis and risk reduction measures);
IV - when applicable, the list of adopted technical standards;
V – Conformity Certificate issued under the Brazilian System of Conformity Assessment (SBAC) for instruments with compulsory certification, related by ANVISA in specific regulations;
VI - performance studies, containing, when applicable:
a) biological samples:
   1. characterization and validation of clinical specimens used; and
   2. Storage conditions and samples stability;
b) determination of the metrological traceability of calibrators and controls values ;
c) measurement accuracy;
d) measurement accuracy, including:
   1. repeatability; and
   2. reproducibility;
e) analytical sensitivity or detection limit;
f) Analytical specificity;
g) high dose pro-zone effect;
h) measurement range (limits) or linearity;
i) value definition of cut-off;
j) validation report of the test procedure;
k) validation report of the cleaning and disinfection procedure for instruments that require direct contact with the patient or lay user; and
l) usability report for products intended for lay users;
VII - product stability (except instruments), including:
a) expiration date established from study of at least three (3) batches of product (protocol, acceptance criteria, results, conclusion and recommended storage conditions);
b) stability of the product in use - after it opened or installed in instrument (protocol, acceptance criteria, results and conclusion); and
b) transport stability or dispatch (protocol, acceptance criteria, conclusion and recommended transport conditions) when the transport or shipping are performed under different conditions of storage conditions
VIII - clinical performance, when applicable, including:
a) general overview of clinical evidence, covering clinical sensitivity and clinical specificity;
b) expected values or reference values;
c) clinical evidence evaluation report;
IX - labeling and use instructions, containing:
a) images of the set of primary and secondary labels expected to be applied to products as requirements stated in Chapter V of this Resolution;
b) the product use instructions, as requirements set out in Chapter V of this Resolution; and
c) for tools, technical manual or operator.
X - the manufacturer plants addresses, including the outsourced steps or contracted by the legal manufacturer; and
XI - manufacturing processes containing a flowchart describing the process of production manufacturing stages or steps until obtaining the finished product, including steps in the control process and final product testing, identifying manufacturing plants, when applicable.

Single paragraph. For cases in which the stability studies are presented using the fast model, the real-time data from the study should be presented in the registration revalidation.

Art. 30. The need for provision of information required for each item of the technical dossier, according to risk classes, is indicated in the Annex of this Resolution.

Single paragraph. For technical reasons, in order to prove the safety and efficacy of the product, in potentially hazardous risks to health or to products considered strategic for the Ministry of Health, ANVISA may require the submission of documents and information.

CHAPTER V
LABELING REQUIREMENTS AND USE INSTRUCTIONS

Art. 31. The labels and use instructions should be able to identify the product and its legal manufacturer and point of information related to safety and efficacy of the product for the user, professional or layperson.

Art. 32. The language used in labels and use instructions should be compatible with the technical knowledge, experience, education or training of the desired user(s).
§1º The use of standardized international symbols for labels and use instructions for health products are allowed, according to the standard ABNT NBR ISO 15223 - "Health products - Symbols to be used on labels, labeling and information provided to health products".
§2º the symbols on products for the general public must be accompanied by a caption.
§3º It is allowed in professional use products, the use of symbols other than those referred to in the standard ABNT NBR ISO 15223, provided it is accompanied by a caption.
§4 the use of graphs and charts in the use instructions are allowed provided that facilitate the capacity of users' understanding.

Art. 33. The use of use instructions in non-print format must conform to the provisions of Instruction Nº 4, June 15, 2012.

Art. 34. The labeling of the product must be in Portuguese or making use of appropriate symbology.
§1 The secondary labeling (external) of in vitro diagnostic products, must contain the following information:
I - technical name or trade name of the product;
II – necessary detailing to enable the user to identify the product and its use;
III – corporate name and address of the legal manufacturer;
IV – corporate name, address and CNPJ of the applicant;
V - the name of the responsible technician, with initials and number of registration at the professional autarchy;
VI - registration number or cadaster at ANVISA preceded by the MS acronym;
VII - indication that the product is for "in vitro diagnostic use";
VIII - when destined for the lay public, the terms "Carefully read the instructions before performing the test" and "Self-test to (specify parameter or condition to which the test is proposed), without diagnostic purposes";
IX - number, lot code or serial number, preceded by the term that identifies, or equivalent symbols;
X - Clear indication of the date by which the product can be used, except for instruments;
XI - indication of storage conditions and can be also mentioned specific transport conditions and / or handling;
XII - if the product is supplied sterile, indication of its status and the method of sterilization;
XIII - warnings or precautions to be taken by the user of the product;
XIV - when relevant, whether the product is of single use and whether there is potential risk of reuse, the indication of this fact; and
XV - list of components that make up the product set, informing the respective quantities.

§2 The primary labeling of in vitro diagnostics products, except instruments, must contain the following information:
I - technical name or trade name of the product and component indication;
II - number or lot code preceded by the term that identifies it, or equivalent symbols;
III - Clear indication of the date by which the product can be used safely;
IV - indication of the appropriate storage conditions of the product.

§3 The primary instruments labeling shall be indelible and contain the following information:
I - technical name or trade name of the product and business model;
II - serial number preceded by the term that identifies it or equivalent symbols;
III - Identification of the legal manufacturer;
IV - registration number or cadaster at ANVISA.

Art. 35. The use instructions for in vitro diagnostic products must be in the Portuguese language and contain the information listed below:
I - technical name or trade name of the product;
II - corporate name and address of the legal manufacturer, along with a telephone number or fax or electronic site address where you can get technical assistance (of Customer Service);
III - purpose and use of the product, including indication that it is for "in vitro diagnostic use";
IV - intended user, when applicable;
V - storage conditions indications or applicable handling;
VI - operating principle of the test or instrument;
VII - sample types or arrays to be used, when applicable;
VIII - conditions for collection, handling, preparation and preservation of samples;
IX - product description, including accessories and any limitations on its use, such as use of
dedicated instrument, and if applicable, software version;
X - in-use stability of the product, except for instruments, including storage conditions after
opening primary packaging and storage conditions and stability of working solutions, when
relevant;
XI - details of any processing or handling of the products before they are ready for use, such
as installation, reconstruction, calibration, among others;
XII - when applicable, recommendations for quality control procedures;
XIII - the test procedure, including calculation and interpretation of results;
XIV - information on interfering substances or limitations that may affect the performance of
the test;
 XV - performance characteristics, such as sensitivity, specificity, accuracy and precision,
except for instruments;
 XVI - identified residual risks;
 XVII - reference intervals, when applicable;
 XVIII - when relevant, special installation requirements (such as a clean room) or special
 training (as in radiation safety) or specific product user qualifications;
 XIX - if the product is supplied sterile, instructions on how to act if the packaging is damaged
before use;
 XX - information of other products, materials or tools needed to perform the test or reaction;
 XXI - warnings or precautions to be taken regarding disposal of the product, its accessories
and consumables used, including infection or microbiological, physical and environmental
 risks;
 XXII - to products intended for lay users, the circumstances in which the user should consult a
health professional;
 XXIII - issue date or latest revision of the use instructions and, when appropriate, a numeric
ID; and
 XXIV - an outline of terms and product warranty and quality conditions.

CHAPTER VI
CADASTER OR REGISTRATION CANCELLATION

Art. 36. ANVISA will cancel the product cadaster or registration for vitro diagnostic in cases
when:
I - the information falsehood provided is proved or if any of the documents listed in Chapter
III are canceled; or
II - is proven that the product or manufacturing process may present a risk to the consumer’s
health, patient, operator or third party.

CHAPTER VII
FINAL AND TRANSITIONAL PROVISIONS
Art. 37. The regularization maintenance of all products for in vitro diagnosis is bound to observe the requirements of Good Manufacturing Practices, technical standards and specific standards, when existent.

Art. 38. The processes for in vitro diagnostic products registration granted prior to the effective date of this Resolution shall be adequate or supplemented in the act of their revalidation.

Single paragraph. Products registered in the risk class II until the entry date in force of this Resolution are now considered as registered, keeping the same registry identification number without the need for revalidation.

Art. 39. The documents specified in sections III, IV and V of art. 19 shall be added to the processes containing pending analysis petitions.

Art. 40. Maintaining consistency between the information relating to products and those declared in the registration process or registry is the responsibility of the requesting company.

Art. 41. The documents referred to in this resolution issued in a foreign language must be translated into Portuguese.

Single paragraph. Are exempted from translation documents that are part of the technical dossier, indicated in art. 29, according to the rules defined in the Board Director - RDC N° 25, June 16, 2011, and RDC N° 50, November 6, 2013.

Art. 42. Failure to comply with the provisions of this Resolution constitutes a sanitary infraction, pursuant to Law N° 6.437, August 20, 1977, subject to any civil, administrative and criminal liabilities.

Art. 43. Are therefore repealed with effect from the date of entry into force of this Resolution, the Board of Directors Resolution RDC N°- 206, November 17, 2006 and the Board of Directors Resolution RDC No. 61, November 18, 2011.

Art. 44. This Resolution shall be effective sixty (60) days after the date of its publication.

Single paragraph. It is established the period of 365 (three hundred sixty-five) days from the date of publication of this resolution for the adjustments in labels, products use instructions and maintenance of the technical dossier, according to the criteria laid down in Articles 29 and 30.

JARBAS BARBOSA DA SILVA JR.

ATTACHMENT

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<thead>
<tr>
<th>Technical Dossier</th>
<th>Class I</th>
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<th>Class III</th>
<th>Class IV</th>
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<td>Product description</td>
<td>All applicable criteria of do art. 29, item 1.</td>
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<td>Product images</td>
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Note 1 - In the items identified as report it is expected to be presented:
- Description of the protocol used;
- Study results; and
- Study Conclusions.

Note 2 - For technical reasons, in order to prove the safety and efficacy of the product, ANVISA may require the submission of additional documents and information.

Note 3 - The technical dossier of risk class I products should not be submitted to ANVISA, however it must be kept updated by the national manufacturer or importer of the product in their National Health Surveillance System.