A Guide for

Importing Medical Equipment into Brazil

INMETRO

A Guide to Brazil's Medical Device Requirements

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1. Scope

This Guide addresses all types of medical equipment regulated in Brazil.

2. General Overview of the Brazilian Regulatory Framework

Several agencies at the federal level have the authority to issue technical regulations in the particular areas of their competence. Technical regulations are always published in the Official Gazette and are generally based on international standards.

All agencies follow similar general procedures to issue technical regulations. They can start the preparation of a technical regulation ex officio or at the request of a third party. If the competent authority deems it necessary, a draft regulation is prepared and published in the *Official Gazette,* after carrying out an impact assessment of the new technical regulation. Technical regulations take the form of laws, decrees or resolutions. Brazil normally allows a six-month period between the publication of a measure and its entry into force.

Public hearings are also a way of promoting the public consultation of the technical regulations. Likewise, when the proposed technical regulation is considered to produce trade effects, this is notified to the WTO in order to allow Members to comment.

The National Institute of Metrology, Quality and Technology (INMETRO) is responsible for notifying the proposed technical regulations to the World Trade Organization (WTO) and acts as the national enquiry point under the WTO Agreement on Technical Barriers to Trade (TBT). All the projects of technical regulations that impact on international trade, even if those regulations are identical to international standards, are notified to WTO. It is worth noting that the vast majority of Brazil's technical regulations are prepared based on international standards and performance criteria.

In addition to its regulations and conformity assessment procedures, Inmetro notifies to WTO other government agencies technical requirements, for example, from the National Health Surveillance Agency (ANVISA), Ministry of Agriculture, Livestock and Supply (MAPA), the National Petroleum Agency, Natural Gas and Biofuels (ANP), the Ministry of Mines and Energy (MME), as well as the National Telecommunications Agency (ANATEL).

INMETRO is also responsible for receiving international comments concerning the drafts of technical regulations. The private sector, both domestic and foreign, may partake in discussions. After taking all comments and suggestions into account, the responsible body decides whether to adopt a technical regulation, with or without modifications.

With regard to the preparation of technical regulations, in 2007, Brazil adopted the Guide of Good Regulatory Practices, which offers recommendations on how to prepare, revise, revoke and disseminate technical regulations. This encourages transparency and consistency in regulatory practices. The Guide recommends that public bodies focus on

safety, health, environment and consumer protection issues. Nevertheless, there are no mandatory rules of general application to prepare technical regulations. Each entity is responsible for the adoption of technical regulations based on its own procedures.

INMETRO and all other regulators may develop and adopt conformity assessment procedures. The steps followed for conformity assessment procedures are similar to those taken for the preparation of technical regulations. There is a public consultation period and the measure is published in the Official Gazette. Conformity assessment procedures that differ from international standards or have considerable economic impact are also notified to WTO by INMETRO.

Based on the specific characteristics of the product, conformity assessment can be carried out through certification, labelling, inspection, sampling and/or a conformity declaration by the supplier. Certification is performed by accredited third parties and is usually voluntary. Products and services subject to mandatory certification are those that affect consumer health, safety or the environment.

Brazil recognizes products and systems certifications carried out by foreign certification agencies that signed a memorandum of understanding (MOU) with the Brazilian certification body or that have an agreement with INMETRO.

INMETRO is also the national body responsible for the accreditation of certification bodies, inspection, training, calibration and testing.

In Brazil, the Brazilian Association of Technical Standards (ABNT) is a non-governmental agency that receives financial support from the federal government. It is responsible for the development of voluntary standards. ABNT represents Brazil in The International Organization for Standardization (ISO) and The International Electrotechnical Commission (IEC) and in regional standardization fora.

To ensure that the standards content is updated, standards in effect with more than five years are reviewed. The review process follows international guidelines and includes four months of public consultation through the ABNT website. During the consultation period, interested parties have the opportunity to tell whether the standard should be confirmed, cancelled or updated.

3. Regulatory Authorities for Medical Equipment

3.1. Inmetro (National Institute of Metrology, Quality and Technology).

http://www.inmetro.gov.br/

Inmetro's Technical Regulations:

1. Ordinance Inmetro/MDIC number 501, from 12/29/2011.
Conformity assessment requirements for single use sterile hypodermic needles and single use gum needles.
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC001775.pdf

2. Ordinance Inmetro/MDIC number 350, from 09/06/2010.
Conformity assessment requirements for electrical equipments under the regime of Health Surveillance.
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC001596.pdf

3. Ordinance Inmetro/MDIC number 502, from 12/29/2011.
Conformity assessment requirements for single use appliances for transfusion, gravitational infusion and infusion for use with infusion pump.
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC001776.pdf

4. Ordinance Inmetro/MDIC number 162, from 04/05/2012.
Conformity assessment requirements for breast implants.
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC001804.pdf

5. Ordinance Inmetro/MDIC number 332, from 06/28/2012.
Revision of conformity assessment requirements for surgical and non-surgical gloves made of natural rubber, synthetic rubber and a mixture of synthetic rubbers.
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC001862.pdf

6. Ordinance Inmetro/MDIC number 503, from 12/29/2011.
Conformity Assessment procedure for single use sterile hypodermic syringe.
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC001777.pdf

7. Ordinance Inmetro/MDIC number 230, from 08/17/2009.
Conformity Assessment procedure for Personal Protective Equipment (PPE) – to accessories for filtering facepiece respirators.
http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC001483.pdf

3.2. ANVISA (National Health Surveillance Agency).

http://portal.anvisa.gov.br

ANVISA's Technical Regulations:

Guide for regularization of Medical Equipment in Anvisa:
http://portal.anvisa.gov.br/wps/wcm/connect/991239804745928e9ae1de3fbc4c6735/manual_EquipMed_Anvisa_abr_10.pdf?MOD=AJPERES

1. Resolution RDC number 185, from 10/22/2001 - Approve the Technical Regulations contained in the annex to this resolution, which deals with registration, alteration, revalidation and cancellation of the registration of medical devices through the National Health Surveillance Agency - ANVISA.
http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2001/rdc0185_22_10_2001.pdf

2. Resolution RDC number 27, from 06/21/2011 - Approves the Technical Regulation that establishes the procedure for compulsory certification of equipment under the regime of health surveillance, in the terms of this resolution.
http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/rdc0027_21_06_2011.pdf

3. Resolution RDC number 16, from 03/28/2013 - Approves the Technical Regulation for Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices and gives other provisions.
http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2013/rdc0016_28_03_2013.pdf

4. Normative Instruction number 3, from 06/21/2011 – Establishes the list, attached to this normative instruction, of the technical standards whose prescriptions need to be attended for conformity assessment, in the scope of the Brazilian System for Conformity Assessment (SBAC), of equipment under the regime of health surveillance, in terms of Ordinance RDC ANVISA number 27, from 06/21/2011.
http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/in0003_21_06_2011.pdf

5. Normative Instruction number 4, from 06/15/2012 - Establishes needed requirements for providing use instructions in non-impressed format for health products subjected to cadaster or register, used in health service environments and for qualified professionals.
http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2012/in0004_15_06_2012.pdf

6. Ordinance RDC number 24, from 05/21/2009 - Establishes the scope and application form for the system of registration for the sanitary control of health products.
http://www.anvisa.gov.br/divulga/noticias/2009/pdf/030609_pag47.pdf

7. Ordinance RDC number 56, from 04/06/2001 – Health products must attend to essential safety and effectiveness requirements applied to these products, as referred at the Technical regulation attached to this Ordinance.

Sole Paragraph – Health products included in this Ordinance are those defined as "correlated" by the Law number 6.360/76 and by the Decree number 79.094/77, except for the products intended to diagnosis of in vitro use.
http://www.saude.mg.gov.br/images/documentos/RES_056.pdf

8. Normative Instruction number 13, from 10/22/2009 – Approves a normative instruction (IN) for sending required documents to the sanitary register of medical equipment classified as Risk class I and II, its alteration and validation, under the terms of articles and annexes that follow.
http://www.brasilsus.com.br/legislacoes/instrucao-normativa/100978-13.html

9. Ordinance RDC number 97, from 11/09/2000 – Its defined as "group of products" those to which is appllied the item 5.3 of the Annex II of the Law number 9.782, from 1999, "the family of health products" of the very same manufacturer.
http://portal.anvisa.gov.br/wps/wcm/connect/2107c20049998f0b90adb66dcbd9c63c/RESOLU%C3%87%C3%83O+ANVISA+RDC+N%C2%BA+97-00+FAM%C3%8DLIAS+DE+PRODUTOS.pdf?MOD=AJPERES

4. Standards Developing Organizations

4.1. ABNT (Brazilian Association of Technical Standards).

http://www.abnt.org.br/

Techincal standards can be found by accessing the website: http://www.abntcatalogo.com.br/.

4.1.1 Technical Standards for Implants:

1.	ABNT NBR ISO 4074:2013 Natural latex rubber condoms — Requirements and test methods
2.	ABNT NBR ISO 5832-1:2008 Errata 1:2010 Implants for surgery - Metallic materials Part 1: Wrought stainless steel
3.	ABNT NBR ISO 5832-1:2008 Corrected Version:2010 Implants for surgery - Metallic materials Part 1: Wrought stainless steel
4.	ABNT NBR ISO 5832-2:2001 Implants for surgery - Metallic materials Part 2: Unalloyed titanium
5.	ABNT NBR ISO 5832-3:1997 Implants for surgery - Metallic materials Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
6.	ABNT NBR ISO 5832-4:1997 Implants for surgery - Metallic materials Part 4: Cobalt-chromium-molybdenum casting alloy
7.	ABNT NBR ISO 5832-5:2008 Implants for surgery - Metallic materials Part 5: Wrought cobalt - Chromium - Tungsten-nickel alloy
8.	ABNT NBR ISO 5832-6:1999 Implants for surgery - Metallic materials Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
9.	ABNT NBR ISO 5832-7:1998 Implants for surgery - Metallic materials Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy
10.	ABNT NBR ISO 5832-8:1998 Implants for surgery - Metallic materials Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy
11.	ABNT NBR ISO 5832-9:2008 Implants for surgery - Metallic materials Part 9: Wrought high nitrogen stainless steel
12.	ABNT NBR ISO 5832-11:1997 Implants for surgery - Metallic materials

	Part 11: wrought titanium 6-aluminium 7-niobium alloy
13.	ABNT NBR ISO 5832-12:2008 Implants for surgery - Metallic materials Parte 12: Wrought cobalt-chromium-molybdenum alloy
14.	ABNT NBR ISO 5832-14:2008 Implants for surgery - Metallic materials Part 14: Wrought titanium 15-molibdenium 5-zirconium 3-aluminium alloy
15.	ABNT NBR ISO 5833:2004 Implants for surgery - Acrylic resin cements
16.	ABNT NBR ISO 5834-1:2008 Implants for surgery - Ultra-high-molecular polyethylene Part 1: Powder form
17.	ABNT NBR ISO 5834-2:2013 Implants for surgery — Ultra-high molecular weight polyethylene Part 2: Moulded forms
18.	ABNT NBR ISO 5834-3:2008 Implants for sugery - Ultra-high-molecular-weight polyethylene Implantes Part 3: Accelerated ageing methods
19.	ABNT NBR ISO 5834-4:2008 Surgical implants - Ultrahight-molecular-weight polyethylene Part 4: Oxidation index measurement method
20.	ABNT NBR ISO 5834-5:2008 implants for surgery - Ultra-high-molecular-weight polyethylene Part 5: Morphology assessment method
21.	ABNT NBR ISO 5835:1996 Implants for surgery - Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread - Dimensions
22.	ABNT NBR ISO 5836:1996 Implants for surgery - Metal bone plates - Holes corresponding to screws with asymmetrical thread and spherical under-surface
23.	ABNT NBR ISO 5837-1:1997 Implants for surgery - Intramedullary nailing systems Part 1: Intramedullary nails with cloverleaf or V-shaped cross section
24.	ABNT NBR ISO 5838-1: 2013 Implants for surgery — Metallic skeletal pins and wires Part 1: General requirements
25.	ABNT NBR ISO 5838-2:1996 Implants for surgery - Skeletal pins and wires Part 2: Steinmann skeletal pins - Dimensions
26.	ABNT NBR ISO 5838-3:1996 Implants for surgery - Skeletal pins and wires Part 3: Kirschner skeletal wires
27.	ABNT NBR ISO 6474-1:2013 Implants for surgery — Ceramic materials Part 1: Ceramic materials based on high purity alumina
28.	ABNT NBR ISO 6474-2:2013

	Implants for surgery – Ceramic materials Part 2: Composite materials based on a high purity matrix with zirconia reinforcement
29.	ABNT NBR ISO 6475:1997 Implants for surgery - Metal bone screws with asymmetrical thread and spherical under-surface - Mechanical requirements and test methods
30.	ABNT NBR ISO 7206-1:2008 Implants for surgery - Partial and total hip joint prostheses Part 1: Classification and designation of dimensions
31.	ABNT NBR ISO 7206-2:2012 Implants for surgery — Partial and total hip joint prostheses Part 2: Articulating surfaces made of metallic, ceramic and plastics materials
32.	ABNT NBR ISO 7206-4:2011 Implants for surgery - Partial and total hip joint prostheses Part 4: Determination of endurance properties and performance of stemmed femoral components
33.	ABNT NBR ISO 7206-6:2004 Implants for surgery - Partial and total hip joint prostheses Part 6: Determination of endurance properties of head and neck regions of stemmed femoral components
34.	ABNT NBR ISO 7206-10:2004 Implants for surgery - Partial anf total hip joint prostheses Part 10: Determination of resistance to static load of modular femoral heads
35.	ABNT NBR ISO 7207-1:2008 Errata 1:2013 Implants for surgery — Components for a partial and total knee joint prostheses Parte 1: Classification, definitions and designation of dimensions
36.	ABNT NBR ISO 7207-1:2008 Corrected Version:2013 Implants for surgery - Components for partial and total knee joint protheses Part 1:Classification, definitions and designation of dimensions
37.	ABNT NBR ISO 7207-2:2013 Implants for surgery – Components for a partial and total knee joint prostheses Part 2: Articulating surfaces made of metal, ceramic and plastics materials
38.	ABNT NBR ISO 8615:1999 Implants for surgery - Fixation devices for use in the ends of the femur in adults
39.	ABNT NBR ISO 8827:1996 Implants for surgery - Staples with parallel legs for orthopaedic use - General requirements
40.	ABNT NBR ISO 8828:1997 Implants for surgery - Guidance on care and handling of orthopaedic implants
41.	ABNT NBR ISO 9268:1998 Implants for surgery - Metal bone screws with conical under-surface of head - Dimensions
42.	ABNT NBR ISO 9269:1998 Implants for surgery - Metal bone plates - Holes and slots corresponding to screws with conical under-surface
43.	ABNT NBR ISO 9583:1997 Implants for surgery - Non-destructive testing - Liquid penetrant inspection of metallic surgical implants
44.	ABNT NBR ISO 9584:1997

	Implants for surgery - Non-destructive testing - Radiographic examination of cast metallic surgical implants
45.	ABNT NBR ISO 9585:1996 Implants for surgery - Determination of bending strength and stiffness of bone plates
46.	ABNT ISO/TR 14283:2008 Errata 1:2008 Implants for surgery – Fundamental principles.
47.	ABNT ISO/TR 14283:2008 Corrected Version:2008 Implants for surgery - Fundamental principles
48.	ABNT NBR 12932:2013 Surgical implants — Metallic materials — Surface preparation and marking
49.	ABNT NBR 14396-1:2013 Implants for surgery — Partial and total hip joint prostheses Part 1: Determination of endurance properties and performance of femoral stem without torsion
50.	ABNT NBR 15165:2013 Implants for orthopedics — Guidelines and requirements for marking, packaging and labeling
51.	ABNT NBR 15408-1:2006 Implants for surgery - Passivation of titanium of titanium and titanium alloys by eletrolitic recovering Part 1: Alkaline solution treatment - Solution pH 13 or higher
52.	ABNT NBR 15408-2:2008 Implants for surgery - Passivation of titanium and titanium alloys by eletrolic recovering Part 2: Anodic treatment in solution pH lower than 13
53.	ABNT NBR 15613-1:2009 Surgical implants - Corrosion resistance Part 1: Test method for measuring fretting corrosion of osteosynthesis plates and screws
54.	ABNT NBR 15613-2:2010 Surgical implants - Corrosion resistance Part 2: Determination of corrosion susceptibility of smal implants devices - Cyclic potenciodynamic polarization meansurements
55.	ABNT NBR 15613-3:2008 Surgical implants - Corrosion resistance Part 3: Corrosion fatigue testing of metallic implant meterials
56.	ABNT NBR 15613-4:2008 Surgical implants - Corrosion resistance Part 4: Pitting or crecive corrosion of metallic surgical implant meterials
57.	ABNT NBR 15628-1:2010 Errata 1:2010 Implants for surgery - Metallic components Part 1: Specifications for 18-chromium 12,5-nickel 2,5-molibdenum stainless steel for cast and solution-annealed
58.	ABNT NBR 15628-1:2010 Corrected Version:2010 Implants for surgery - Metallic components Part 1: Specifications for 18-chromium 12,5-nickel 2,5-molibdenum stainless steel for cast and solution-annealed
59.	ABNT NBR 15628-2:2011 Implants for surgery - Metallic components Part 2: Specifications fo titanium 6-aluminum 4-vanadium castings Implantes para cirurgia

60.	ABNT NBR 15628-3:2013 Implants for surgery — Metallic components Part 3: Specifications for cobalt 28-chromium 6-molybdenum alloy forgings
61.	ABNT NBR 15628-4:2013 Surgical implants — Metallic components Part 4: Requirements for alpha plus beta titanium alloy forgings
62.	ABNT NBR 15628-5:2010 Errata 1:2012 Implants for surgery - Metallic components Part 5: Requirements stainless steel forgings
63.	ABNT NBR 15628-5:2010 Corrected Version:2012 Implants for surgery - Metallic components Part 5: Requirements stainless steel forgings
64.	ABNT NBR 15628-6:2013 Implants for surgery — Metallic components Part 6:Specification for metal injection molded cobalt 28-chromium 6-molybdenum alloy
65.	ABNT NBR 15628-7:2013 Implants for surgery — Metallic components Part 7: Specification for metal injection molded titanium 6-aluminum 4-vanadium alloy
66.	ABNT NBR 15664-1:2011 Orthopaedic implants - Product coating Part 1: Test method for stereological evaluation of porous coatings on metal implants
67.	ABNT NBR 15664-2:2009 Amendment 1:2011 Orthopaedic implants - Product coating Part 2: Test method for measuring abrasion resistance of metallic thermal spray coatings by using TaberTM Abraser
68.	ABNT NBR 15664-2:2011 Orthopaedic implants - Product coating Part 2: Test method for measuring abrasion resistance of metallic thermal spray coatings by using rotating surface abraser
69.	ABNT NBR 15664-3:2009 Amendment 1:2011 Orthopaedic implants - Product coating Part 3: Test method for determining shear and bending fatigue strength of calcium phosphate, metallic and composite calcium phosphate/metallic coatings
70.	ABNT NBR 15664-3:2011 Orthopaedic implants - Product coating Part 3: Test method for determining shear and bending fatigue strength of calcium phosphate, metallic and composite calcium phosphate/metallic coatings
71.	ABNT NBR 15664-4:2009 Orthopaedic implants - Product coating Part 4: Test method for determining tension strength of calcium phosphate and metallic coatings
72.	ABNT NBR 15664-5:2009 Amendment 1:2011 Orthopaedic implants - Product coating Part 5: Test method for shear testing of metallic and of calcium phosphate coatings
73.	ABNT NBR 15664-5:2011 Orthopaedic implants - Product coating Part 5: Test method for shear testing of metallic and of calcium phosphate coatings
74.	ABNT NBR 15664-6:2011

	Orthopaedic implants - Product coating Part 6: Test method for evaluation of the environmental stability of calcium phosphate coatings
75.	ABNT NBR 15664-7:2009 Amendment 1:2011 Orthopaedic implants - Product coating Part 7: Specification for calcium phosphate coatings
76.	ABNT NBR 15664-7:2011 Orthopaedic implants - Product coating Part 7: Specification for calcium phosphate coatings
77.	ABNT NBR 15664-8:2009 Orthopaedic implants - Product coating Part 8: Method for X-ray diffraction determination of phase content of plasma-sprayed hydroxyapatite coatings
78.	ABNT NBR 15664-9:2010 Errata 1:2011 Orthopaedic implants - Product coating Part 9: Specifications for unalloyed titanium and titanium 6-aluminiun 4-vanadium alloy powders
79.	ABNT NBR 15664-9:2010 Corrected Version:2011 Orthopaedic implants - Product coating Part 9: Specifications for unalloyed titanium and titanium 6-aluminiun 4-vanadium alloy powders
80.	ABNT NBR 15664-10:2013 Orthopaedic implants — Product coating Part 10: Specifications for cobalt 28-chromium 6-molybdenum alloy powders
81.	ABNT NBR 15665:2009 Orthopaedic implants - Spinal implants - Terminology
82.	ABNT NBR 15666:2012 Orthopedic implants — General requirements for materials, manufacturing and storing of metallic components
83.	ABNT NBR 15668-1:2009 Orthopedic implants - Intramedullary fixation devices Part 1: Specifications
84.	ABNT NBR 15668-2:2009 Orthopedic implants - Intramedullary fixation devices Part 2: Static four-point test method for intramedullar nail
85.	ABNT NBR 15668-3:2009 Orthopedic implants - Intramedullary fixation devices Part 3: Static torsion test method for intramedullar nail
86.	ABNT NBR 15668-4:2009 Orthopedic implants - Intramedullary fixation devices Part 4: Bending fatigue test methodo for intramedullar nail
87.	ABNT NBR 15668-5:2009 Orthopedic implants - Intramedullary fixation devices Part 5: Bending fatigue test methodo for locking screw
88.	ABNT NBR 15669-1:2009 Implants for surgery - Pins for use with external fixation devices Part 1: Specifications and requirements
89.	ABNT NBR 15669-2:2009 Errata 1:2012 Implants for surgry - Pins for use with external fixation devices Part 2: Test method for determining the static four poinbt bending properties

90.	ABNT NBR 15669-2:2009 Corrected Version:2012 Implants for surgry - Pins for use with external fixation devices Part 2: Test method for determining the static four poinbt bending properties
91.	ABNT NBR 15669-3:2009 Errata 1:2010 Implants for surgery - Pins for use with external fixation devices Part 3: Test method for determining the static torsion properties
92.	ABNT NBR 15669-3:2009 Corrected Version:2010 Implants for surgery - Pins for use with external fixation devices Part 3: Test method for determining the static torsion properties
93.	ABNT NBR 15670-1:2009 Orthopaedics implants - Modular orthopaedic prostheses Part 1: Test method for determining the axial disassembly of taper connections of modular prostheses
94.	ABNT NBR 15670-2:2009 Orthopaedics implants - Modular orthopaedic prostheses Part 2: Test method for determining the axial disassembly of modular acetabular device
95.	ABNT NBR 15670-3:2009 Errata 1:2012 Orthopedics implants - Modular orthopaedic prostheses Part 3: Procedure for evaluating modular hip and knee components
96.	ABNT NBR 15670-3:2009 Corrected Version:2012 Orthopedics implants - Modular orthopaedic prostheses Part 3: Procedure for evaluating modular hip and knee components
97.	ABNT NBR 15670-4:2009 Orthopedics implants - Modular orthopaedic prostheses Part 4: Practice for fretting corrosion testing of modular interfaces: hip femoral head-bore and cone taper interface
98.	ABNT NBR 15670-5:2010 Orthopedics implants - Modular orthopaedic prostheses Part 5: Test method for dynamic evaluation of modular connection of proximally fixed femoral hip prosthesis
99.	ABNT NBR 15671-1:2009 Orthopedics implants - Specifications for preformed cranioplasty plates Part 1: Plates tha can not be shaped
100.	ABNT NBR 15671-2:2009 Orthopedics implants - Specifications for preformed cranioplasty plates Part 2: Plates that can be shaped
101.	ABNT NBR 15675-1:2010 Orthopedics implants - Metallic bone screws Part 1: Specifications and requirements
102.	ABNT NBR 15675-2:2009 Orthopedics implants - Metallic bone screws Part 2: Test method for determinantion the torsional properties
103.	ABNT NBR 15675-3:2009 Orthopedics implants - Metallic bone screws Part 3: Test method for determining driving torque
104.	ABNT NBR 15675-4:2009 Orthopedics implants - Metallic bone screws Part 4: Test method for determining the axial pullout strength

105.	ABNT NBR 15675-5:2009 Orthopedics implants - Metallic bone screws Part 5: Specification for drive connection
106.	ABNT NBR 15675-6:2010 Orthopedics implants - Metallic bone screws Part 6: Test method for determining the self-tapping performance of self-tapping screws
107.	ABNT NBR 15676-1:2009 Errata 1:2013 Orthopedics implants - Metallic bone plates Part 1: Specification and requirements
108.	ABNT NBR 15676-1:2009 Corrected Version:2013 Orthopedics implants - Metallic bone plates Part 1: Specification and requirements
109.	ABNT NBR 15676-2:2009 Orthopedics implants - Metallic bone plates Part 2: Static bending test method
110.	ABNT NBR 15676-3:2009 Orthopedics implants - Metallic bone plates Part 3: Dynamic bending test method
111.	ABNT NBR 15677:2009 Orthopedics implants - Connection drills - Specification bone screwdriver bits
112.	ABNT NBR 15678:2011 Orthopedics implants - Specifi cation for rigid polyurethane foam for use as a standard material for testing orthopedic implants and instruments
113.	ABNT NBR 15695-1:2009 Orthopedics implants - Metallic bone staples Part 1: Specifications and requirements
114.	ABNT NBR 15695-2:2009 Orthopedics implants - Metallic bone staples Part 2: Test methods for determination of bending fatigue strength
115.	ABNT NBR 15695-3:2009 Orthopedics implants - Metallic bone staples Part 3: Test method for determination of pull-out strength
116.	ABNT NBR 15695-4:2009 Orthopedics implants - Metallic bone staples Part 4: Test method for determination of soft tissue fixation strength
117.	ABNT NBR 15695-5:2009 Orthopedics implants - Metallic bone staples Part 5: Test method for determination of bending stiffness
118.	ABNT NBR 15697:2009 Amendment 1:2011 Orthopedics implants - Articulating total wrist implants
119.	ABNT NBR 15697:2011 Orthopedics implants - Articulating total wrist implants
120.	ABNT NBR 15699-1:2010 Errata 1:2013 Orthopaedic implants - Knee prosthesis Part 1: Specification for total knee prosthesis
121.	ABNT NBR 15699-1:2010 Corrected Version:2013

	Orthopaedic implants - Knee prosthesis Part 1: Specification for total knee prosthesis
122.	ABNT NBR 15699-2:2013 Orthopaedic implants — Knee prothesis Part 2: Test method for determination of total knee replacement constraint
123.	ABNT NBR 15699-3:2009 Orthopaedic implants - Knee prothesis Part 3: Specifications for resurfacing patelar prosthesis
124.	ABNT NBR 15699-4:2013 Orthopedics implants — Knee prostheses Part 4: Guidance for the application of ABNT NBR ISO 14879-1
125.	ABNT NBR 15700-1:2009 Orthopedics implants - External skeletal fixation devices Part 1: Terminology and classification
126.	ABNT NBR 15700-2:2009 Orthopedics implants - External skeletal fixation devices Part 2: Test method for skeletal fixator connectors
127.	ABNT NBR 15700-3:2009 Orthopedics implants - External skeletal fixation devices Part 3: Test methods for determining in-plane compressive prpoperties of cicular ring or ring segments bridge elements
128.	ABNT NBR 15700-4:2009 Orthopedics implants - External skeletal fixation devices Part 4: Test for determining the stiffness and strenght of fixation joints
129.	ABNT NBR 15700-5:2009 Orthopedics implants - External skeletal fixation devices Part 5: Test for determining the stiffness and strength of subassemblies
130.	ABNT NBR 15700-6:2009 Orthopedics implants - External skeletal fixation devices Part 6: Tests for determining performance of constructs
131.	ABNT NBR 15709-1:2009 Orthopedics implants - Metallic angled orthopedic fracture fixation devices Part 1: Specifications and requirements
132.	ABNT NBR 15709-2:2009 Orthopedics implants - Metallic angled orthopedic fracture fixation devices Part 2: Static compression bending test
133.	ABNT NBR 15709-3:2009 Orthopedics implants - Metallic angled orthopedic fracture fixation devices Part 3: Bending dynamic test
134.	ABNT NBR 15711:2012 Amendment 1:2013 Orthopedic implants — Metallic hip femoral prosthesis — Specifications
135.	ABNT NBR 15711:2013 Orthopedic implants — Metallic hip femoral prosthesis — Specifications
136.	ABNT NBR 15712-1:2009 Orthopedic implants - Intervertebral devices Part 1: Testing for static characterization of intervertebral body fusion devices

137.	ABNT NBR 15712-2:2009 Orthopedic implants - Intervertebral prosthesis Part 2: Testing for dynamic characterization of intevertebral body fusion devices
138.	ABNT NBR 15712-3:2009 Orthopedic implants - Intervertebral prosthesis Part 3: Test for measuring load induced subsidence of intervertebral body fusion device under static axial compression
139.	ABNT NBR 15712-4:2009 Orthopedic implants - Intervertebral prosthesis Part 4: Test to static characterization of intervertebral disc prosthesis
140.	ABNT NBR 15712-5:2009 Orthopedic implants - Intervertebral prosthesis Part 5: Test for static characterization of intervertebral disc prosthesis
141.	ABNT NBR 15719:2009 Orthopedics implants - Hip joint prostheses - Specification for acetabular prostheses
142.	ABNT NBR 15720-1:2013 Orthopaedic implants — Ceramic materials Part 1: Specification for high-purity dense magnesia partially stabilized zirconia (Mg-PSZ)
143.	ABNT NBR 15720-2:2009 Orthopaedic implants - Ceramic materials Part 2: Specification for beta-tricalcium phosphate
144.	ABNT NBR 15720-3:2009 Amendment 1:2011 Orthopaedic implants - Ceramic materials Part 5: Specifications for hydroxylpatite
145.	ABNT NBR 15720-3:2011 Orthopaedic implants - Ceramic materials Part 3: Specification for high-purity calcium sulfate hemihidrate or dihidrate
146.	ABNT NBR 15720-4:2009 Orthopaedic implants - Ceramic materials Part 4: Specification for glass and glass ceramic
147.	ABNT NBR 15720-5:2010 Orthopaedic implants - Ceramic materials Part 5: Specifications for hydroxylpatite
148.	ABNT NBR 15720-6:2011 Orthopaedic implants - Product coating Part 6: Test method for evaluation of the environmental stability of powders, granules and fabricates forms of calcium phosphate
149.	ABNT NBR 15721:2009 Orthopedic implant - Prostheses for finger total joint - Specifications for elastomeric flexible hinge finger
150.	ABNT NBR 15722:2009 Orthopedics implants - Test method for determining femoral head penetration into acetabular components of total hip replacement clinical radiographs
151.	ABNT NBR 15723-1:2013 Implants for surgery — Polymeric materials Part 1: Terminology
152.	ABNT NBR 15723-2:2012

	Implants for surgery — Polymeric materials Part 2: Guidelines for extensively irradiation-crosslinked ultra-high molecular weight polyethylene fabricated forms
153.	ABNT NBR 15723-3:2010 Implants for surgery - Polymeric materials Part 3: Specification for polyaryletherketone (PAEK) polymers
154.	ABNT NBR 15723-4:2010 Implants for surgery – Polymeric materials Part 4: Specification for porous polyethylene polymers
155.	ABNT NBR 15723-5:2013 Implants for surgery — Polymeric materials Part 5: Specifications for ultra-high molecular weight polyethylene blended with alpha-tocopherol (vitamin E)
156.	ABNT NBR 15723-6:2010 Implants for surgery - Polymeric materials Part 6: Specification for polytetra fluoroethylene (PTFE) polymers in sheet, tube, and rod shapes
157.	ABNT NBR 15723-7:2013 Implants for surgery — Polymeric materials Part 7: Specification for polyetherketoneether-ketoneketone (PEKEKK) polymers
158.	ABNT NBR 15723-8:2013 Implants for surgery — Polymeric materials Part 8: Specification for polyetheretherketone (PEEK) Polymers
159.	ABNT NBR 15723-9:2010 Implants for surgery - Polymeric materials Part 9: Criteria for defi nition and description of thermoset epoxy plastics
160.	ABNT NBR 15723-10:2012 Implants for surgery — Polymeric materials Part 10: Guide for assessment of the ultra high molecular weight polyethylene (UHMWPE) used in orthopedic and spinal devices
161.	ABNT NBR 15723-11:2013 Implants for surgery — Polymeric materials Part 11: Test Method for the determination of percentual crystallinity by means of specular reflectance Fourier transform infrared spectroscopy (R-FTIR)
162.	ABNT NBR 15723-12:2013 Implants for surgery — Polymeric materials Part 12: Specification for ultra-high molecular weight polyethylene yarns
163.	ABNT NBR 15723-13:2013 Implants for surgery — Polymeric materials Part 13: Specification for polyetherketoneketone (PEKK)
164.	ABNT NBR 15726:2013 Orthopedic implants — Specification for total hip joint prosthesis and hip endoprosthesis bearing surfaces made of metallic, ceramic and polymeric materials
165.	ABNT NBR 15727:2009 Orthopedics implants - Specifications and requirements for strands and cables
166.	ABNT NBR 15728-1:2009 Orthopedic implants - Skeletal spinal fixation devices Part 1: Specification and requirements

167.	ABNT NBR 15728-2:2009 Orthopedic implants - Skeletal spinal fixation devices Part 2: Specification for metallic spinal screws
168.	ABNT NBR 15728-3:2009 Orthopedic implants - Skeletal spinal fixation devices Part 3: Specification and static and dynamic properties evaluation for metallic plates
169.	ABNT NBR 15728-4:2009 Orthopedic implants - Skeletal spinal fixation devices Part 4: Specification and static and dynamic properties evaluation for metallic rods
170.	ABNT NBR 15728-5:2009 Orthopedic implants - Skeletal spinal fixation devices Part 5: Evaluation of static and dynamic properties for pedicular
171.	ABNT NBR 15728-6:2009 Orthopedic implants - Skeletical spinal fixation devices Part 6: Evaluation of static and dynamic properties of interconnection mechanisms and subassemblies used in spinal atthrodesis implants
172.	ABNT NBR 15728-7:2012 Errata 1:2013 Orthopaedic implants — Skeletical spinal fixation devices Part 7: Test methods for implants constructed in a vertebrectomy model
173.	ABNT NBR 15728-7:2012 Corrected Version:2013 Orthopaedic implants — Skeletical spinal fixation devices Part 7: Test methods for implants constructed in a vertebrectomy model
174.	ABNT NBR 15743-1:2013 Orthopaedic implants — Guidance for testing selection and information to provide safety and effectiveness in product design Part 1: General information
175.	ABNT NBR 15743-2:2009 Amendment 1:2010 Orthopedic implants - Guidance for testing selection and information to provide safety and effectiveness in product design Part 2: Product coatings
176.	ABNT NBR 15743-2:2010 Orthopedic implants - Guidance for testing selection and information to provide safety and effectiveness in product design Part 2: Product coatings
177.	ABNT NBR 15743-7:2013 Orthopaedic implants — Guidance for testing selection and information to provide safety and effectiveness in product design Part 7: Components manufactured of bioabsorbable polymers
178.	ABNT NBR 15744-1:2009 Implants for surgery - Test methods for ultra-high-molecular-weight polyethylene (UHMWPE) characterization Part 1: Mechanical behavior characterization of material and manufactured device by small punch testing
179.	ABNT NBR 15744-2:2009 Implants for surgery - Test methods for ultra-high-molecular-weight polyethylene (UHMWPE) characterization Part 2: In situ determination of network parameters of crosslinked material
180.	ABNT NBR 15744-3:2013

	Implants for surgery — Test methods for ultra-high-molecular-weight polyethylene (UHMWPE) characterization Part 3: Evaluating trans-vinylene yield in irradiated components by infrared spectroscopy
181.	ABNT NBR 15744-4:2009 Implants for surgery - Test methods for ultra-high-molecular-weight polyethylene (UHMWPE) characterization Part 4: Measurement of enthalpy of fusion, percent crystallinity, and melting point of ultra-high-molecular weight polyethylene by means of differential scanning calorimetry
182.	ABNT NBR 15752-1:2009 Orthopedics implants - Shoulder joint prostheses Part 1: Specifications
183.	ABNT NBR 15752-2:2009 Orthopedics implants - Shoulder joint prostheses Part 2: Test methods for dynamic evaluation of glenoid loosening
184.	ABNT NBR 15752-3:2009 Orthopedics implantes - Shoulder joint prostheses Part 3: Test method for static evaluation of modular glenoid components locking mechanism in shear
185.	ABNT NBR 15752-4:2009 Orthopedics implants - Shoulder joint prostheses Part 4: Test method for dynamic evaluation ofmodular glenoid components dissociation
186.	ABNT NBR 15774:2009 Implants and medical devices for orthopaedic surgery - Guidance for biocompatibility evaluation of device packaging
187.	ABNT NBR 15796-1:2010 Implants for surgery - Metallic materials - Nickel-titanium shape memory alloy Part 1: Terminology
188.	ABNT NBR 15796-2:2013 Implants for surgery — Metallic materials – Nickel-titanium shape memory alloy Part 2: Determination of transformation temperature by bend and free recovery
189.	ABNT NBR 15796-3:2013 Implants for surgery — Metallic materials — Nickel-titanium shape memory alloy Part 3: Determination of transformation temperature by thermal analysis
190.	ABNT NBR 15796-4:2013 Implants for surgery — Metallic materials – Nickel-titanium shape memory alloy Part 4: Specifications for wrought alloys
191.	ABNT NBR 15796-5:2013 Implants for surgery — Metallic materials – Nickel-titanium shape memory alloy Part 5: Tension testing for superelastic alloy
192.	ABNT NBR 15891-1:2013 Implants for surgery — Absorbable resins Part 1: Specification for semicrystalline poly(lactide) polymer and copolymer resins
193.	ABNT NBR 15891-2:2013 Implants for surgery — Bioabsorbable resins Part 2: Specification for poly(glycolide) and poly(glycolide-co-lactide) virgin resins with mole fractions greater than or equal to 70 % glycolide
194.	ABNT NBR 15891-3:2013

	Implants for surgery — Absorbable resins Part 3: Specification for poly(lactide) and poly(lactid-co-glycolide) virgin amorphous resins
195.	ABNT NBR 15891-4:2013 Implants for surgery — Absorbable resins Part 4: Test method for in vitro degradation testing of hydrolytically degradable polymer resins and fabricated forms
196.	ABNT NBR 15892:2013 Orthopedic implants — Non-destructive testing — Guidelines and requirements for radiographic procedures and inspection of metallic components
197.	ABNT NBR 15893-1:2010 Orthopedic implants - Metallic materials Part 1: Wrought nitrogen strengthened 11manganese-17chromium-3molybdenum low-nickel stainless steel alloy bar and wire (UNS S29225)
198.	ABNT NBR 15893-2:2010 Orthopedic implants - Metallic materials Part 2: Wrought nitrogen strengthened 21chromium-10nickel-3manganese-2.5molybdenum stainless steel alloy bar (UNS S31675)
199.	ABNT NBR 15893-3:2010 Orthopedic implants — Metallic materials Part 3: Wrought nitrogen strengthened 23manganese-21chromium- 1molybdenum low-nickel stainless steel alloy bar and wire (UNS S29108)
200.	ABNT NBR 15893-4:2010 Orthopedic implants - Metallic materials Part 4: Wrought nitrogen strengthened 22chromium-13nickel-5manganese 2.5molybdenum stainless steel alloy bar and wire (UNS S31675)
201.	ABNT NBR 15998-1:2013 Orthopedic implants — Absorbable plates and screws for ostheosynthesis Part 1: Specifications and general requirements
202.	ABNT NBR 15998-2:2013 Orthopedic implants — Absorbable plates and screws for ostheosynthesis Part 2: Test method for determining screw torsion properties
203.	ABNT NBR 15998-3:2013 Orthopedic implants — Absorbable plates and screws for ostheosynthesis Part 3: Test method for determining screw insertion properties
204.	ABNT NBR 15998-4:2013 Orthopedic implants — Absorbable plates and screws for ostheosynthesis Part 4: Test method for determining screw axial pullout insertion strength
205.	ABNT NBR 15998-5:2013 Orthopedic implants — Absorbable plates and screws for ostheosynthesis Part 5: Test method for determining plate static bending strength
206.	ABNT NBR 16005-1:2011 Amendment 1:2012 Surgical implants — Metallic tubes Part 1: Wrought seamless stainless steel tubing specifications
207.	ABNT NBR 16005-1:2012 Surgical implants - Metallic tubes Part 1: Wrought seamless stainless steel tubing specifications
208.	ABNT NBR 16005-2:2011 Amendment 1:2012

	Surgical implants — Metallic tubes Part 2: Wrought seamless or welded and drawn stainless steel small diameter tubing specifications
209.	ABNT NBR 16005-2:2012 Surgical implants — Metallic tubes Part 2: Wrought seamless or welded and drawn stainless steel small diameter tubing specifications
210.	ABNT NBR 16005-3:2011 Amendment 1:2012 Surgical implants — Metallic tubes Part 3: Wrought seamless or welded and drawn cobalt alloy small diameter tubing specifications
211.	ABNT NBR 16005-3:2013 Surgical implants - Metallic tubes Part 3: Wrought seamless and welded and drawn cobalt alloy small diameter tubing specifications
212.	ABNT NBR 16005-4:2013 Surgical implants — Metallic tubes Part 4: Wrought seamless Ni-Ti shape memory alloy tubing specifications
213.	ABNT NBR 16106:2012 Implants for surgery — Composite materials — In-vitro environmental conditioning of polymer matrix composite materials and implant devices
214.	ABNT NBR 16123:2012 Implants for orthopaedics — Guide for bidimensional assessment of surface texture of non-porous materials
215.	ABNT NBR 16148-1:2013 Orthopedics implants — Systems of cranial traction tongs and halo for external cervical spinal distraction devices Part 1: General specification
216.	ABNT NBR 16148-2:2013 Orthopedics implants — Systems of cranial traction tongs and halo for external cervical spinal distraction devices Part 2: Testing and requirements for mechanical integrity assessment
217.	ABNT NBR 16148-3:2013 Orthopedics implants — Systems of cranial traction tongs and halo for external cervical spinal distraction devices Part 3: Test methods and requirements for assessing of effects of exposure in environments of magnetic resonance imaging
218.	ABNT NBR 16203-1:2013 Implants for surgery — Metal surgical fixation wires Part 1: Wrought cobalto 20chromium 15tungsten 10nickel alloy wire (UNS R30605)
219.	ABNT NBR 16203-2:2013 Implants for surgery — Metal surgical fixation wires Part 2: Wrought 18-chromium, 14-nickel and 2,5-molybdenum stainless steel wire (UNS S31673)
220.	ABNT NBR ISO 10334:1997 Errata 1:2008 Implants for surgery - Malleable wire for use as sutures and other surgical applications
221.	ABNT NBR ISO 10334:1997 Corrected Version:2008 Implants for surgery - Malleable wire for use as sutures and other surgical applications
222.	ABNT NBR ISO 12189:2009 Implants for surgery - Mechanical testing of implantable spinal devices - Fatigue test method for

	spinal implant assemblies using an anterior support
223.	ABNT NBR ISO 12891-1:2013 Implants for surgery – Retrieval and analysis of surgical implants Part 1: Retrieval and handling
224.	ABNT NBR ISO 12891-2:2003 Retrireval and analysis of surgical implants Part 2: Analysis of retrieved metallic surgical implants
225.	ABNT NBR ISO 12891-3:2003 Retrieval and analysis of sugical implants Part 3: Analysis of retrieved polymeric implants
226.	ABNT NBR ISO 12891-4:2003 Retrieval and analysis of surgical implants Part 4: Analysis of retrieval ceramic surgical implants
227.	ABNT NBR ISO 13175-3:2013 Implants for surgery — Calcium phosphates Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes
228.	ABNT NBR ISO 13356:2009 Implants for surgery - Ceramic materials bases on yttria-stabilizes tetragonal zirconia (Y-TZP)
229.	ABNT NBR ISO 13779-1:2009 Implants for surgery - Hidroxyapatite Part 1: Ceramic hydroxyapatite
230.	ABNT NBR ISO 13779-2:2009 Implants for surgery - Hydroxyapatite Part 2: Coatings of hydroxyaptite
231.	ABNT NBR ISO 13779-3:2009 Implants for surgery - Hydroxyapatite Part 3: Chemical analysis and characterization of cristalinity and phase purity
232.	ABNT NBR ISO 13779-4:2008 Implants for surgery - Hydroxyapatite Part 4: Determination of coating adhesion strength
233.	ABNT NBR ISO 13782:1998 Implants for surgery - Metallic materials - Unalloyed tantalum for surgical implant applications
234.	ABNT NBR ISO 14242-1:2013 Implants for surgery — Wear of total hip-joint prostheses Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
235.	ABNT NBR ISO 14242-2:2006 Errata 1:2010 Implants for surgery - Wear of total hip-joint prostheses Part 2: Methods of meansurement
236.	ABNT NBR ISO 14242-2:2006 Corrected Version:2010 Implants for surgery - Wear of total hip-joint prostheses Part 2: Methods of meansurement
237.	ABNT NBR ISO 14242-3:2010 Errata 1:2010 Implants for surgery - Wear of total hip-join prostheses Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test

238.	ABNT NBR ISO 14242-3:2010 Corrected Version:2010 Implants for surgery - Wear of total hip-join prostheses Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test
239.	ABNT NBR ISO 14243-1:2012 Implants for surgery — Wear of total knee-joint prostheses Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test
240.	ABNT NBR ISO 14243-2:2012 Implants for surgery — Wear of total knee-joint prostheses Part 2: Methods of measurement
241.	ABNT NBR ISO 14243-3:2008 Errata 2:2010 Surgical implants wear of total knee - Joint prostheses Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test
242.	ABNT NBR ISO 14243-3:2008 Corrected Version 2:2010 Surgical implants wear of total knee - Joint prostheses Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test
243.	ABNT NBR ISO 14602:2011 Non-active surgical implants - Implants for osteosynthesis - Particular requirements
244.	ABNT NBR ISO 14607:2013 Non-active surgical implants — Mammary implants — Particular requirements
245.	ABNT NBR ISO 14630:2013 Corrected Version:2013 Non-active surgical implants — General requirements
246.	ABNT NBR ISO 14879-1:2002 Implants for surgery - Total knee-joint prostheses Part 1: Determination of endurance properties of knee tibial trays
247.	ABNT NBR ISO 14949:2011 Implants for surgery - Two-part addition-cure silicone elastomers
248.	ABNT NBR ISO 15142-1:2006 Errata 1:2013 Implants for surgery - Metal intramedullary nailling systemas Part 1: Intramedullary nails
249.	ABNT NBR ISO 15142-1:2006 Corrected Version:2013 Implants for surgery - Metal intramedullary nailling systemas Part 1: Intramedullary nails
250.	ABNT NBR ISO 15142-2:2006 Implants for surgery - Metal intramedullary nailing systems Part 2: Locking componentes
251.	ABNT NBR ISO 15142-3:2006 Implants for surgery - Metal intramedullary nailing systems Part 3: Conection devices and reamer
252.	ABNT NBR ISO 15374:2000 Implants for Surgery - Requirements for production of forgings
253.	ABNT NBR ISO 15814:2003 Implants for surgery - Copolymeres and blends based on polyactide - In vitro degradation testing

254.	ABNT NBR ISO 16054:2003 Implants for sugery - Minimim data sets for surgical implants
255.	ABNT NBR ISO 16402:2009 Implants for surgery - Acrylic resin cement - Flexural fatigue testing of acrylic resin cements used in orthopaedics
256.	ABNT NBR ISO 16428:2008 Implants for surgery - Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices
257.	ABNT NBR ISO 16429:2008 Implants for surgery - Measurements of open-circuit potencial to assess corrosion behaviour of metallic - Implantable materials and medical devices over extended time periods
258.	ABNT NBR ISO 17853:2013 Wear of implant materials — Polymer and metal wear particles — Isolation and characterization
259.	ABNT NBR ISO 18192-1:2013 Implants for surgery — Wear of total intervertebral spinal disc prostheses Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test
260.	ABNT NBR ISO 18192-2:2011 Implants for surgery - Wear of total intervertebral spinal disc prostheses Part 2: Nucleus replacements
261.	ABNT NBR ISO 20160:2008 Implants for surgery - metallic materials - Classification of microstructures for alpha+beta titanium alloy bars
262.	ABNT NBR ISO 21534:2008 Errata 1:2008 Non-active surgical implants - Joint replacement implants - Particular requiriments
263.	ABNT NBR ISO 21534:2008 Corrected Version:2008 Non-active surgical implants - Joint replacement implants - Particular requiriments
264.	ABNT NBR ISO 21535:2008 Errata 1:2010 Non-active surgical implants - Joint replacement implants - Specific requiriments for hip-joint replacement implants
265.	ABNT NBR ISO 21535:2008 Corrected Version:2010 Non-active surgical implants - Joint replacement implants - Specific requiriments for hip-joint replacement implants
266.	ABNT NBR ISO 21536:2008 Errata 1:2013 Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants
267.	ABNT NBR ISO 21536:2008 Corrected Version:2013 Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants
268.	ABNT NBR ISO 23317:2013 Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials
269.	ABNT NBR 15613-2:2010 Emenda 1:2013 Surgical implants — Corrosion resistance Part 2: Determination of corrosion susceptibility of small implant devices — Cyclic potenciodynamic polarization measurements
270.	ABNT NBR 15613-2:2013

	Surgical implants - Corrosion resistance Part 2: Determination of corrosion susceptibility of smal implants devices - Cyclic potenciodynamic polarization meansurements
271.	ABNT ISO/TR 9586:2013 Implants for surgery — Usage of the terms “valgus” and “varus” in orthopaedic surgery
272.	ABNT NBR 16005-5:2013 Surgical implants — Metallic tubes Part 5: Wrought seamless titanium 3-aluminum 2,5-vanadium alloy tubing specifications
273.	ABNT NBR ISO 14630:2013 Errata 1:2013 Non-active surgical implants — General requirements
274.	ABNT NBR 16237-3:2013 Implants for orthopedics — Knee prostheses with mobile bearing Part 3: Evaluating knee dislocation resistance
275.	ABNT NBR 16237-2:2013 Implants for orthopedics — Knee prostheses with mobile bearing Part 2: Evaluating of tibial baseplate/bearing resistance to dynamic disassociation
276.	ABNT NBR 16237-1:2013 Implants for orthopedics — Knee prostheses with mobile bearing Part 1: Evaluating of tibial baseplate rotational stops
277.	ABNT NBR 15628-8:2013 Implants for surgery — Metallic components Part 8: Specification for metal injection molded unalloyed titanium
278.	ABNT NBR 15699-2:2012 Emenda 1:2013 Orthopaedic implants — Knee prothesis Part 2: Test method for determination of total knee replacement constraint
279.	ABNT NBR 16005-3:2012 Emenda 1:2013 Surgical implants — Metallic tubes Part 3: Wrought seamless and welded and drawn cobalt alloy small diameter tubing specifications
280.	ABNT ISO/TR 11175:2014 Dental implants — Guidelines for developing dental implants
281.	ABNT NBR 15699-1:2014 Orthopaedic implants — Knee prosthesis Part 1: Specification for knee prosthesis

4.1.2 Technical Standards for Dental Equipment;

1.	ABNT NBR ISO 1797-1:2013 Dentistry — Shanks for rotary instruments Part 1: Shanks made of metals
2.	ABNT NBR ISO 2157:2012 Dental rotary instruments — Nominal diameters and designation code number
3.	ABNT NBR ISO 6360-1:2010 Dentistry - Number coding system for rotary instruments Part 1: General characteristics
4.	ABNT NBR ISO 6360-2:2012 Dentistry — Number coding system for rotary instruments

	Part 2: Shapes
5.	ABNT NBR ISO 6360-3:2012 Dentistry — Number coding system for rotary instruments Part 3: Specific characteristics of burs and cutters
6.	ABNT NBR ISO 6360-4:2012 Dentistry — Number coding system for rotary instruments Part 4: Specific characteristics of diamond instruments
7.	ABNT NBR ISO 6360-6:2012 Dentistry — Number coding system for rotary instruments Part 6: Specific characteristics of abrasive instruments
8.	ABNT NBR ISO 7711-1:2009 Dental rotary instruments - Diamond instruments Part 1: Dimensions, requirements, marking and packaging
9.	ABNT NBR ISO 7711-3:2012 Dentistry — Diamond rotary instruments Part 3: Grit sizes, designation and colour code
10.	ABNT NBR ISO 7785-1:1999 Dental handpieces Part 1: High-speed air turbine handpieces
11.	ABNT NBR ISO 7785-2:2004 Dental handpieces Part 2: Straight and geared angle handpieces
12.	ABNT NBR ISO 8325:2011 Dentistry – Test methods for rotary instruments
13.	ABNT NBR ISO 9687:2005 Dental equipment - Graphical symbols
14.	ABNT NBR ISO 11144:2001 Dental equipment - Connection for supply and waste lines
15.	ABNT NBR 11780:1990 Dentistry - Alloys for dental amalgam - Specification
16.	ABNT NBR ISO 11953:2012 Dentistry — Implants — Clinical performance of hand torque instruments
17.	ABNT NBR ISO 13397-1:1999 Periodontal curetts, dental scalers and scavators Part 1: General requirements
18.	ABNT NBR ISO 13397-3:2000 Periodontal curettes, dental scalers and excavators Part 3: Dental scalers - H-type
19.	ABNT NBR ISO 13397-4:2000 Periodontal curettes, dental scalers and excavators Part 4: Dental scalers - Discoid type
20.	ABNT ISO/TS 13498:2013 Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems
21.	ABNT NBR ISO 14801:2012 Dentistry — Implants — Dynamic fatigue test for endosseous implants

22.	ABNT NBR ISO 15098-1:2000 Dental tweezers Part 1: General requirements
23.	ABNT NBR ISO 15098-2:2000 Dental tweezers Part 2: Meriam types
24.	ABNT NBR ISO 15098-3:2002 Dental tweezers Part 3: College types
25.	ABNT NBR 15351:2006 Medical devices for dentistry - Requirements
26.	ABNT NBR 15729:2009 Sterilization for dental implants - Radiation - Validation and routine control
27.	ABNT NBR 15967:2011 Dentistry – Test methods for rotary instruments – Test cutting capacity of diamond burs
28.	ABNT NBR 16044:2012 Dental implants — Requirements general for endosseous uncoated metallic implants
29.	ABNT NBR ISO 21531:2012 Dentistry — Graphical symbols for dental instruments
30.	ABNT NBR ISO 22794:2012 Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file
31.	ABNT NBR ISO 22803:2013 Dentistry – Membrane materials for guided tissue regeneration in oral and maxillofacial surgery – Contents of a technical file
32.	ABNT NBR ISO 3823-2:2013 Dentistry — Rotary bur instruments Part 2: Finishing burs
33.	ABNT NBR ISO 3823-1:2013 Dental rotary instruments — Burs Part 1: Steel and carbide burs
34.	ABNT NBR ISO 27020:2014 Dentistry — Brackets and tubes for use in orthodontics
35.	ABNT NBR ISO 6875:2014 Dentistry — Patient chair

4.1.3 Technical Standards for Analysis, Diagnoses and Electromedical Equipment;

1.	ABNT NBR ISO 15883-1:2013 Washer-disinfectors Part 1: General requirements, terms and definitions and tests
2.	ABNT NBR ISO 15883-2:2013 Washer-disinfectors Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

3.	ABNT NBR ISO/IEC 80601-2-58:2013 Corrected Version:2013 Medical electrical equipment Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
4.	ABNT NBR ISO 8536-9:2013 Infusion equipment for medical use Part 9: Fluid lines for use with pressure infusion equipment
5.	ABNT NBR IEC 60601-2-52:2013 Corrected Version:2013 Medical electrical equipment Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
6.	ABNT NBR IEC 60601-2-45:2013 Corrected Version:2013 Medical electrical equipment Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-Ray equipments and stereotactic mammographic devices
7.	ABNT NBR IEC 60601-2-21:2013 Corrected Version:2013 Medical electrical equipment Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
8.	ABNT NBR IEC 80601-2-35:2013 Corrected Version:2013 Medical electrical equipment Part 2:35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use
9.	ABNT NBR IEC 60601-2-41:2012 Medical electrical equipment Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
10.	ABNT NBR IEC 60601-2-43:2012 Corrected Version:2013 Medical electrical equipment Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
11.	ABNT NBR IEC 60601-2-20:2012 Corrected Version:2013 Medical electrical equipment Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
12.	ABNT NBR IEC 60601-2-5:2012 Corrected Version:2013 Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of ultrassonic physiotherapy equipment
13.	ABNT NBR IEC 60601-1-11:2012 Corrected Version:2013 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
14.	ABNT NBR ISO 8536-8:2012 Infusion equipment for medical use Part 8: Infusion equipment for use with pressure infusion apparatus
15.	ABNT NBR IEC 80601-2-30:2012 Corrected Version:2013 Medical electrical equipment

	Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
16.	ABNT NBR IEC 60601-2-22:2012 Corrected Version:2013 Medical electrical equipment Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
17.	ABNT NBR IEC 60601-2-46:2012 Corrected Version:2013 Medical electrical equipment Part 2-46: Particular Requirements for the basic safety and essential performance of operating tables
18.	ABNT NBR IEC 60601-2-23:2012 Corrected Version:2013 Medical electrical equipment Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
19.	ABNT NBR ISO 8536-5:2012 Infusion equipment for medical use Part 5: Burette infusion sets for single use, gravity feed
20.	ABNT NBR IEC 60601-2-28:2012 Corrected Version:2013 Medical electrical equipment Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
21.	ABNT NBR IEC 60601-2-54:2011 Corrected Version:2013 Medical electrical equipment Part 2-54: — Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
22.	ABNT NBR ISO 8536-4:2011 Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed
23.	ABNT NBR IEC 60601-2-1:2011 Corrected Version:2013 Medical electrical equipment Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
24.	ABNT NBR IEC 60601-1-6:2011 Corrected Version:2013 Medical Electrical Equipment Part 1-6: General requirements for basic safety - Collateral Standard: Usability
25.	ABNT NBR IEC 60601-1-3:2011 Corrected Version:2013 Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic x-ray equipment
26.	ABNT NBR ISO 10651-4:2011 Lung ventilators Part 4: Particular requirements for operator-powered resuscitators
27.	ABNT NBR IEC 60601-2-50:2010 Corrected Version:2013 Medical electrical equipment Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
28.	ABNT NBR IEC 60601-2-39:2010 Corrected Version:2013 Medical electrical equipment

	Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
29.	ABNT NBR 15882:2010 Gas mixers for medical use - Mixer autonomous oxygen and nitrous oxide for medical use, construction, installation and operation
30.	ABNT NBR IEC 60601-1:2010 Corrected Version:2013 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
31.	ABNT NBR IEC 60601-1-10:2010 Corrected Version:2013 Medical Electrical Equipment Part 1-10: General requirements for basic safety and essential performace - Collateral standard: Requirements for the development of physiologic closed-loop controllers
32.	ABNT NBR IEC 60601-1-2:2010 Corrected Version:2013 Medical electrical equipment Part 1-2: General requirement for basic safety and essencial performace - Collateral standard: Electromagnetic compatibility - Requirements and test
33.	ABNT NBR IEC 60601-1-8:2010 Corrected Version:2013 Medical electrical equipment Part 1-8: General requirements for basic safety and essential performace - Collateral standards: General requirements, testes and guidance for alarm systems in medical electrical equipment and medical eletrical systems
34.	ABNT NBR IEC 60601-1-9:2010 Corrected Version:2013 Medical electrical equipment Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
35.	ABNT NBR ISO 4135:2009 Anaesthetic and respiratory equipment - Vocabulary
36.	ABNT NBR 15659:2009 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing
37.	ABNT NBR IEC 60601-2-35:2006 Medical electrical equipment Part 2-35: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use
38.	ABNT NBR IEC 60601-2-36:2006 Medical electrical equipment Part 2-36: Particular requirements for the safety of equipments for extracorporeally induced lithotripsy
39.	ABNT NBR IEC 60601-2-4:2005 Medical electrical equipment Part 2-4: Particular requirements for the safety of cardiac defibrillators
40.	ABNT NBR IEC 60601-2-51:2005 Medical electrical equipment Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
41.	ABNT NBR IEC 61331-1:2004 Protective devices against diagnostic medical X-radiation Part 1: Determination of attenuation properties of materials

42.	ABNT NBR IEC 61331-2:2004 Protective devices against diagnostic medical X-radiation Part 2: Protective glass plates
43.	ABNT NBR IEC 60601-1-1:2004 Medical electrical equipment Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
44.	ABNT NBR IEC 61331-3:2004 Protective devices against diagnostic medical X-radiation Part 3: Protective clothing and protective devices for gonads
45.	ABNT NBR IEC 60601-2-12:2004 Medical electrical equipment Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators
46.	ABNT NBR IEC 60601-2-13:2004 Medical electrical equipment Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems
47.	ABNT NBR IEC 60601-1-4:2004 Medical electrical equipment Part 1-4: General requirements for the safety - Collateral Standard: Programmable electrical medical systems
48.	ABNT NBR IEC 60601-2-16:2003 Medical electrical equipment Part 2-16: Particular requirements for safety of haemodialysis, haemodiafiltration and haemofiltration equipment
49.	ABNT NBR IEC 60601-2-37:2003 Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnotic and monitoring equipment
50.	ABNT NBR IEC 60601-2-47:2003 Medical electrical equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
51.	ABNT NBR 11816:2003 Sterilization - Vaccum steam sterilizers for health products
52.	ABNT NBR IEC 60601-2-49:2003 Medical electrical equipment Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
53.	ABNT NBR IEC 60601-2-10:1997 Amendment 1:2002 Medical electrical equipment Parte 2-10: Particular requirements for the safety of nerve and muscle stimulators
54.	ABNT NBR IEC 60601-2-18:2002 Medical electrical equipment Part 2-18: Particular requirements for safety of endoscopy equipment
55.	ABNT NBR IEC 60601-2-2:2013 Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

56.	ABNT NBR IEC 60601-2-25:1997 Amendment 1:2001 Medical electrical equipment Part 2-25: Particular requirements for the safety of electrocardiographs
57.	ABNT NBR IEC 60601-2-32:2001 Medical electrical equipment Part 2-32: Particular requirements for the safety of associated equipment of X ray equipment
58.	ABNT NBR IEC 60601-2-7:2001 Medical electrical equipment Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
59.	ABNT NBR 11817:2001 Sterilization - Steam sterilizers - Small sterilizers - Requirements
60.	ABNT NBR IEC 60601-2-19:1997 Amendment 1:2000 Medical electrical equipment Part 2: Particular requirements for safety of baby incubators
61.	ABNT NBR IEC 60601-2-24:1999 Medical electrical equipment Part 2: Particular requirements for safety of infusion pumps and controllers
62.	ABNT NBR IEC 60601-2-31:2013 Medical electrical equipment Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
63.	ABNT NBR IEC 60601-2-40:1998 Medical electrical equipment Part 2: Particular requirements for the safety of electromyographs and evoked response equipment
64.	ABNT NBR IEC 60601-2-38:1998 Medical electrical equipment Part 2: Particular requirements for the safety of electrically operated hospital beds
65.	ABNT NBR IEC 60601-3-1:1998 Medical electrical equipment Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment
66.	ABNT NBR IEC 61689:1998 Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz
67.	ABNT NBR IEC 60601-2-14:1998 Medical electrical equipment Part 2: Particular requirements for the safety of eletroconvulsive therapy equipment
68.	ABNT NBR IEC 60601-2-30:1997 Medical electrical equipment Part 2 - Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment
69.	ABNT NBR IEC 60601-2-10:1997 Medical electrical equipment Part 2: Particular requirements for the safety of nerve of nerve and muscle stimulators
70.	ABNT NBR IEC 60601-2-6:1997

	Medical electrical equipment Part 2: Particular requirements for safety of microwave therapy equipment
71.	ABNT NBR 13931:1997 Spirometer - Requirements
72.	ABNT NBR IEC 60601-2-27:2013 Medical electrical equipment Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
73.	ABNT NBR IEC 60601-2-34:1997 Medical electrical equipment Part 2: Particular requirements for the safety of direct blood pressure monitoring equipment
74.	ABNT NBR IEC 60601-2-19:1997 Medical electrical equipment Part 2: Particular requirements for safety of baby incubators
75.	ABNT NBR IEC 60601-2-25:1997 Medical electrical equipment Part 2-25: Particular requirements for the safety of electrocardiographs
76.	ABNT NBR IEC 60601-2-26:1997 Medical electrical equipments Part 2: Particular requirements for the safety of eletroencephalographs
77.	ABNT NBR IEC 60601-2-3:1997 Medical electrical equipment Part 2: Particular requirements for the safety of short-wave therapy equipment
78.	ABNT NBR 8165:1995 Dry heat sterilizers of forced recirculated - Specification
79.	ABNT NBR 8166:1995 Dry heat of gravity - Specification
80.	ABNT NBR IEC 60601-2-20:2012 Corrected Version 2:2014 Medical electrical equipment Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
81.	ABNT NBR IEC 60601-2-41:2012 Corrected Version:2013 Medical electrical equipment Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
82.	ABNT NBR IEC 60601-2-21:2013 Corrected Version 2:2014 Medical electrical equipment Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
83.	ABNT NBR IEC 80601-2-58:2013 Corrected Version 2:2014 Medical electrical equipment Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
84.	ABNT NBR ISO 80601-2-56:2013 Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

85.	ABNT NBR ISO/IEC 80601-2-58:2013 Errata 1:2013 Medical electrical equipment Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
86.	ABNT NBR IEC 80601-2-35:2013 Errata 1:2013 Medical electrical equipment Part 2:35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use
87.	ABNT NBR IEC 80601-2-30:2012 Errata 1:2013 Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
88.	ABNT NBR IEC 60601-2-54:2011 Errata 1:2013 Medical electrical equipment Part 2-54: — Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
89.	ABNT NBR IEC 60601-2-52:2013 Errata 1:2013 Medical electrical equipment Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
90.	ABNT NBR IEC 60601-2-50:2010 Errata 1:2013 Medical electrical equipment Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
91.	ABNT NBR IEC 60601-2-5:2012 Errata 1:2013 Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of ultrassonic physiotherapy equipment
92.	ABNT NBR IEC 60601-2-46:2012 Errata 1:2013 Medical electrical equipment Part 2-46: Particular Requirements for the basic safety and essential performance of operating tables
93.	ABNT NBR IEC 60601-2-45:2013 Errata 1:2013 Medical electrical equipment Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-Ray equipments and stereotactic mammographic devices
94.	ABNT NBR IEC 60601-2-43:2012 Errata 1:2013 Medical electrical equipment Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
95.	ABNT NBR IEC 60601-2-41:2012 Errata 1:2013 Medical electrical equipment Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
96.	ABNT NBR IEC 60601-2-28:2012 Errata 1:2013 Medical electrical equipment Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
97.	ABNT NBR IEC 60601-2-23:2012 Errata 1:2013

	Medical electrical equipment Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
98.	ABNT NBR IEC 60601-2-22:2012 Errata 1:2013 Medical electrical equipment Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
99.	ABNT NBR IEC 60601-2-21:2013 Errata 1:2013 Medical electrical equipment Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
100.	ABNT NBR IEC 60601-2-20:2012 Errata 1:2013 Medical electrical equipment Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
101.	ABNT NBR IEC 60601-2-1:2011 Errata 1:2013 Medical electrical equipment Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
102.	ABNT NBR IEC 60601-1-9:2010 Errata 1:2013 Medical electrical equipment Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
103.	ABNT NBR IEC 60601-1-8:2010 Errata 1:2013 Medical electrical equipment Part 1-8: General requirements for basic safety and essential performace - Collateral standards: General requirements, testes and guidance for alarm systems in medical electrical equipment and medical eletrical systems
104.	ABNT NBR IEC 60601-1-6:2011 Errata 1:2013 Medical Electrical Equipment Part 1-6: General requirements for basic safety - Collateral Standard: Usability
105.	ABNT NBR IEC 60601-1-3:2011 Errata 1:2013 Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic x-ray equipment
106.	ABNT NBR IEC 60601-1-2:2010 Errata 1:2013 Medical electrical equipment Part 1-2: General requirement for basic safety and essencial performace - Collateral standard: Electromagnetic compatibility - Requirements and test
107.	ABNT NBR IEC 60601-1-11:2012 Errata 1:2013 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
108.	ABNT NBR IEC 60601-1:2010 Errata 1:2013 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
109.	ABNT NBR IEC 60601-2-4:2014

	Medical electrical equipment Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
110.	ABNT NBR ISO/IEC 80601-2-58:2013 Errata 2:2014 Medical electrical equipment Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
111.	ABNT NBR IEC 60601-2-18:2014 Medical electrical equipment Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
112.	ABNT NBR IEC 60601-2-6:2014 Medical electrical equipment Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
113.	ABNT NBR IEC 60601-2-49:2014 Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
114.	ABNT NBR IEC 60601-2-3:2014 Medical electrical equipment Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
115.	ABNT NBR IEC 60601-2-10:2014 Medical electrical equipment Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
116.	ABNT NBR IEC 60601-2-21:2013 Errata 2:2014 Medical electrical equipment Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
117.	ABNT NBR IEC 60601-2-20:2012 Errata 3:2014 Medical electrical equipment Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
118.	ABNT NBR IEC 60601-2-20:2012 Errata 2:2014 Medical electrical equipment Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
119.	ABNT NBR IEC 60601-2-19:2014 Medical electrical equipment Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

4.1.4 Other Technical Standards for Medical Equipment.

1.	ABNT NBR ISO 594-1:2003 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 1: General requirements
2.	ABNT NBR ISO 594-2:2003 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings
3.	ABNT NBR ISO 5362:2012 Anaesthetic reservoir bags
4.	ABNT NBR ISO 7153-1:1997 Amendment 1:2006 Surgical instruments - Metallic materials Part 1: Stainless steel
5.	ABNT NBR ISO 7153-1:2006 Errata 1:2008 Surgical instruments - Metallic materials Part 1: Stainless steel
6.	ABNT NBR ISO 7153-1:2006 Errata 2:2010 Surgical instruments - Metallic materials Part 1: Stainless steel
7.	ABNT NBR ISO 7153-1:2006 Corrected Version 2:2010 Surgical instruments - Metallic materials Part 1: Stainless steel
8.	ABNT NBR ISO 7176-1:2009 Wheelchairs Part 1: Determination of static stability
9.	ABNT NBR ISO 7176-3:2009 Wheelchairs Part 3: Determination of brake eficiency
10.	ABNT NBR ISO 7176-7:2009 Wheelchairs Part 7: Measurement of seating and wheel dimensions
11.	ABNT NBR ISO 7176-8:2009 Wheelchairs Part 8: Requirements and test methods for static, impact and fatigue strenghts
12.	ABNT NBR ISO 7176-11:2009 Wheelchairs Part 11: Test Dummies
13.	ABNT NBR ISO 7176-13:2009 Wheelchairs Part 13: Determination of coefficiente of friction of test surfaces
14.	ABNT NBR ISO 7176-15:2009 Wheelchairs Part 15: Requirements for information disclosure, documentation and labeling
15.	ABNT NBR ISO 7176-22:2009 Wheelchairs Part 22: Set-up procedures
16.	ABNT NBR ISO 7740:1997

	Instruments for surgery - Scalpels with detachable blades - Fitting dimensions
17.	ABNT NBR ISO 7864:2010 Sterile hypodermic needles for single use
18.	ABNT NBR ISO 7886-1:2003 Errata 1:2011 Sterile hypodermic syringes for single use Part 1: Syringes for manual use
19.	ABNT NBR ISO 7886-1:2003 Corrected Version:2011 Sterile hypodermic syringes for single use Part 1: Syringes for manual use
20.	ABNT NBR ISO 7886-2:2003 Sterile hypodermic syringes for single-use Part 2: Syringes for use with power-driven syringes pumps
21.	ABNT NBR ISO 8009:2009 Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests
22.	ABNT NBR ISO 8319-1:1998 Orthopaedic instruments - Drive connections Part 1: Keys for use with screws with hexagon socket heads
23.	ABNT NBR ISO 8319-2:1998 Orthopaedic instruments - Drive connections Part 2:Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws
24.	ABNT NBR ISO 8537:2012 Sterile single-use syringes, with or without needle, for insulin
25.	ABNT NBR ISO 8549-1:1999 Prosthetics and orthotics - Vocabulary Parte 1: General terms for external limp protheses and external orthoses
26.	ABNT NBR ISO 8549-2:1999 Prosthetics and orthotics - Vocabulary Part 2: Terms relating to external limp prostheses and weares of these prostheses
27.	ABNT NBR ISO 8549-3:1999 Prosthetics and orthotics - Vocabulary Part 3: Terms relating to external orthotics
28.	ABNT NBR ISO 8835-2:2010 Inhalational anaesthesia systems Part 2: Anaesthetic breathing systems
29.	ABNT NBR 9258:1986 Oropharyngeal Cannulas - Specifications
30.	ABNT NBR ISO 9626:1999 Amendment 1:2003 Stainless steel needle tubing for manufacture of medical devices
31.	ABNT NBR ISO 9626:2003 Stainless steel needle tubing for manufacture of medical devices
32.	ABNT NBR ISO 9714-1:2013 Orthopaedic drilling instruments Part 1: Drill bits, taps and countersink cutters
33.	ABNT NBR 9753:2003

	Scalp, sterile and for single use
34.	ABNT NBR 10334:2003 Babie´s dummies - Safety
35.	ABNT NBR 10335:1988 Tracheal tubes - connectors - Specification
36.	ABNT NBR 10555:1988 Trachel tubes - Especification
37.	ABNT NBR ISO 10555-1:2003 Sterile, single-use intravascular catheter Part 1: General requirements
38.	ABNT NBR ISO 10555-2:2003 Sterile single-use intravascular catheters Part 2: Angiographic catheters
39.	ABNT NBR ISO 10555-3:2003 Sterile, single-use intravascular catheters Part 3: Central venous catheter
40.	ABNT NBR ISO 10555-4:2003 Sterile, single-use intravascular catheter Part 4: Balloon dilatation catheters
41.	ABNT NBR ISO 10555-5:2003 Sterile, single-use intravascular catheter Part 5: Over-needle peripheral catheter
42.	ABNT NBR ISO 10993-1:2013 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
43.	ABNT NBR ISO 10993-12:2005 Biological evaluation of medical devices Part 12: Sample preparation and reference materials
44.	ABNT NBR ISO 10993-15:2005 Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys
45.	ABNT NBR ISO 11138-2:2004 Sterilization of health care products - Biological indicators Part 2: Biological indicators for ethylene oxide sterilization
46.	ABNT NBR ISO 11138-3:2004 Sterilization of health care products - Biological indicators Part 3: Biological indicators for moist heat sterilization
47.	ABNT ISO/TS 11139:2009 Sterilization of health care products - Vocabulary
48.	ABNT NBR ISO 11195:2000 Gas mixers for medical use - Stand-alone gas mixers
49.	ABNT NBR 11280:2008 Glass ampoules - Test methods and requirements
50.	ABNT NBR 11773:1989 Dental inlay casting wax - Specification
51.	ABNT NBR 11906:2011

	Connections threaded for use ranks, under low pressure, of medicinal gases, gases for medical devices and vacuum, for use in health establishments
52.	ABNT NBR 12188:2012 Centralized supply of medical gases, gases for medical devices and vacuum for use in health care services
53.	ABNT NBR 12510:1992 Cylinder plain valves for medicinal gases - System of safety indicator pin - Standardization
54.	ABNT NBR 13164:1994 Low pressure flexible tubes for use with medical gas
55.	ABNT NBR ISO 13402:1997 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure
56.	ABNT NBR ISO 13405-1:1999 Prosthetics and orthotics - Classification and description of prosthetic components Part 1: Classification of prosthetic components
57.	ABNT NBR ISO 13405-2:1999 Prosthetics and orthotics - Classification and description of prosthetic components Part 2: Description of lower-limb prosthetic
58.	ABNT NBR ISO 13405-3:1999 Phosthetics and orthotics - Classification and description of prosthetic components Part 3: Description upper-limb prosthetic components
59.	ABNT NBR 13475:1995 Sockets and connectors for breathing systems - Specification
60.	ABNT NBR 13476:1995 Screw threaded weight-bearing connectors for use in breathing systems - Dimensions - Specification
61.	ABNT NBR ISO 13485:2004 Medical devices - Quality mmanagements systems - Requirements for regulatory purpose
62.	ABNT NBR 13587:1996 Errata 1:1998 Health assistance instittion - Oxygen concentrator for use with medical oxygen pipeline systems
63.	ABNT NBR 13587:1996 Corrected Version:1998 Health assistance instittion - Oxygen concentrator for use with medical oxygen pipeline systems
64.	ABNT NBR 13730:2010 Anaesthesic machine — Continuous fl ow section – Performance requirements and security
65.	ABNT NBR ISO 13781:1998 Poly (L-lactide) resins and fabricated forms fore surgical implants - In vitro degradation testing
66.	ABNT NBR 13793:2012 Safety of feeding bottles
67.	ABNT NBR 13851:1997 Surgical and dental hand instruments - Resistance against autoclaving, corrosion and thermal exposure - General requirements
68.	ABNT NBR 13852:1997 Surgical and dental hand instruments - General requirements for marking, packaging and labelling
69.	ABNT NBR 13854:1997 Arteio-venous fistula needle sterile and for single use - Requirements and method of test

70.	ABNT NBR 13904:2003 Sutures
71.	ABNT NBR 13905:1997 Plain and chromic catgut (raw material) non - Sterile
72.	ABNT NBR 13911:2013 Surgical instruments — Metallic material — Specifications for wrought stainless steel
73.	ABNT NBR 13912:1997 Surgical instruments - Scissors and shears - Requirements and methods of test
74.	ABNT NBR 13913:1997 Non-cutting, articulated surgical instruments - General requirements
75.	ABNT NBR 13914:1997 Surgical instruments - Forceps - Requirements
76.	ABNT NBR 13915:1997 Stainless steel surgical instruments - Retractors - General requirements
77.	ABNT NBR 13916:1997 Stainless steel surgical and dental hands instruments - Surface finishing and treatment
78.	ABNT NBR 14058:1998 Instruments for surgery - Needle holders - Requirements and test methods
79.	ABNT NBR 14059:1998 Instruments for surgery - Forceps with bow handles - Requirements and test method
80.	ABNT NBR ISO 14155-1:2004 Clinical investigation of medical devices for human subject Part 1: General requirements
81.	ABNT NBR ISO 14155-2:2004 Clinical investigation of medical devices for human subjects Part 2: Clinicalinvestigation plans
82.	ABNT NBR 14174:1998 Stainless steel surgical and dental hands instruments - Guidance on care, handiling and storage
83.	ABNT NBR 14175:1998 Stainless steel surgical and dental hands instruments - General requirements
84.	ABNT NBR 14332:1999 Stainless steel surgical and dental hands instruments - Guidance on handling - cleaning and sterilisation
85.	ABNT NBR 14333:1999 Errata 1:1999 Instruments of surgery - Microsurgery needle holders - Requirements and test methods
86.	ABNT NBR 14333:1999 Corrected Version:1999 Instruments of surgery - Microsurgery needle holders - Requirements and test methods
87.	ABNT NBR 14377:1999 Instruments for surgery - Kinifes and scalpels - Requirements and test methods
88.	ABNT NBR 14396-3:2001 Amendment 1:2005 Partial and total hip joint prostheses Parte 2: Fatigue strength of femoral stem without torsion
89.	ABNT NBR 14396-3:2005 Partial and total hip joint prostheses Part 3: Determination of resistance to static load of head and neck region os stemmed femoral

	components
90.	ABNT NBR 14396-4:2005 Implants for surgery - Partial and total hip joint prostheses Part 4: Determination of resistance to torque of head fixation of stemmend femoral components
91.	ABNT NBR 14431:2000 Prosthetics and orthotics - General requirements for marking, packaging and labeling of components
92.	ABNT NBR ISO 14971:2009 Medical devices - Application of risk management to medical
93.	ABNT NBR 14990-1:2004 Packaging systems and materials for health products sterilization Part 1: General requirements
94.	ABNT NBR ISO 15223-1:2010 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
95.	ABNT NBR ISO 15223-2:2013 Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied Part 2: Symbol development, selection and validation
96.	ABNT NBR 15245:2005 Medical devices - Validation and routine control of ethylene oxide sterilization
97.	ABNT NBR 15249:2011 Medical devices - Metallic materials processing - Periodic test plan for processing solutions
98.	ABNT NBR 15252:2005 Medical devices - Passivation of stainless steel using eletropolishing
99.	ABNT NBR 15260:2005 Child care articles - Soother holder - Safety requeriments and test methods
100.	ABNT NBR 15667:2009 Instrumentas for orthopaedic surgery - Specification for intramedullary reamers
101.	ABNT NBR 15804-1:2010 Ed 2 Polymeric materials for medical applications Part 1: Specification for polycarbonate resin
102.	ABNT NBR 15804-1:2010 Amendment 1:2010 Polymeric materials for medical applications Part 1: Specification for polycarbonate resin
103.	ABNT NBR 15804-2:2013 Polymeric materials for medical applications Part 2: Specification for polyethylene plastics for short-term implantable devices
104.	ABNT NBR 15804-3:2013 Polymeric materials for medical applications Part 3: Guide for assessment of thermoplastic polyurethane solids and solutions
105.	ABNT NBR 15804-4:2012 Polymeric materials for medical applications Part 4: Specification for polysulfone resin
106.	ABNT NBR 15804-5:2010

	Polymeric materials for medical applications Part 5: Specification for polyoxymethylene (acetal)
107.	ABNT NBR 15943:2011 Recommended good practice for medical equipment management program
108.	ABNT NBR 15949:2011 Pressure vessel f or human occupancy (PVHO) for therapeutical use — Manufacturing, installation and operation
109.	ABNT NBR ISO 16037:2009 Rubber condom for clinical trials - Measurements of physical properties
110.	ABNT NBR ISO 16061:2010 Instrumentation for use in association with non-active surgical implants- General requirements
111.	ABNT ISO/TR 16142:2009 Medical devices - Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices
112.	ABNT NBR ISO 17665-1:2010 Sterilization of health care products - Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
113.	ABNT ISO/TS 19128:2009 Errata 1:2009 Medical devices - Coding structure for adverse event type and cause
114.	ABNT ISO/TS 19218:2009 Corrected Version:2009 Medical devices - Coding structure for adverse event type and cause
115.	ABNT NBR IEC 60789:2001 Characteristics and test conditions of radionuclide imaging devices - Anger type gamma cameras
116.	ABNT NBR IEC 62366:2010 Medical devices - Application of usability engineering to medical devices
117.	ABNT NBR ISO 80369-1:2013 Small-bore connectors for liquids and gases in healthcare applications Part 1: General requirements
118.	ABNT ISO/TS 17665-2:2013 Sterilization of health care products – Moist heat Part 2: Guidance on the application of ISO 17665-1
119.	ABNT NBR ISO 11607-2:2013 Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
120.	ABNT NBR ISO 11607-1:2013 Packaging for terminally sterilized medical devices Part 1: Requirements for material, sterile barrier systems and packaging systems

5. Certifications and Testing Bodies

5.1. Certifying Laboratories Listed by Inmetro

I. Associação NCC Certificações do Brasil

Address: Rua Conceição, 233 - Sala 2510 a 2515, Centro - Campinas - SP. Brasil.

Phone: (19) 3731-6990 e Fax (19) 3232-9828

E-mail: qualidade@ncc.org.br

Site: http://www.ncc.org.br

II. BRTÜV Avaliações da Qualidade S. A.

Address: Alameda Madeira, 222 - 3º A CJ 31, Alphaville - Barueri – SP. Brasil.

Phone: (11) 4689-9400 e Fax (11) 4689-9404

E-mail: thfuto@tuv-nord.com

Site: http://www.brtuv.com.br/

III. Instituto Falcão Bauer da Qualidade - IFBQ

Address: Rua Aquinos, 111 - 3º andar, Agua Branca - São Paulo - SP. Brasil.

Phone: (11) 3611-1729

E-mail: dferreira@ifbauer.org.br e sgqifbq@ifbauer.org.br

Site: http://www.ifbauer.org.br

IV. TÜV RHEINLAND DO BRASIL LTDA.

Address: Avenida Paulista, 302 - 2º ao 4º andar, Bela Vista - São Paulo - SP. Brasil.

Phone: (11) 3638-5700 e Fax (11) 3638-5844

E-mail: executivo.senior@br.tuv.com

Site: http://www.tuvbrasil.com.br

V. UL DO BRASIL CERTIFICAÇÕES S/C

Address: Rua Fidêncio Ramos, 195 - 2º andar, Vila Oímpia - São Paulo - SP. Brasil.

Phone: (11) 3049-8300 e Fax (11) 3049-8252

E-mail: pericles.arilho@br.ul.com

VI. INSTITUTO DE CERTIFICAÇÕES BRASILEIRO S/A - ICBR

Address: Rua Maestro Francisco Manoel da Silva, 71, Santa Genebra - Campinas - SP. Brasil.

Phone: (19) 3259-1450

E-mail: ismar@icbr-certlab.org.br

VII. Instituto Nacional de Tecnologia - INT

Address: Avenida Venezuela, 82, Centro - Rio de Janeiro - RJ. Brasil.

Phone: (21) 2123-1168/1169 e Fax (21) 2206-1179

E-mail: ediralv@int.gov.br

Site: http://www.int.gov.br

VIII. ICEPEX - INSTITUTO DE CERTIFICAÇÃO PARA EXCELÊNCIA NA CONFORMIDADE

Address: Rua Oscar Bressane, 520, Jardim Saúde - São Paulo - SP. Brasil.

Phone: (11) 5539-5911

E-mail: icepex@icepex.org.br

5.2 Testing Laboratories Listed by Inmetro

I. LABORATÓRIO MÉDICOS DR. SÉRGIO FRANCO LTDA

Address: RUA XAVIER PINHEIRO, 439 - QUADRA 29, PRQ. DUQUE DE CAXIAS - DUQUE DE CAXIAS - RJ. Brasil.

Phone: (21) 2672-7070

E-mail: carmen@lsf.com.br

II. L. A. FALCÃO BAUER - CENTRO TECNOLÓGICO DE CONTROLE QUALIDADE LTDA – LABORATÓRIO DE TECNOLOGIA DE MATERIAIS E PRODUTOS - LABORATÓRIO DE TECNOLOGIA DE MATERIAIS E PRODUTOS

Address: RUA AQUINOS Number 111, ÁGUA BRANCA - SÃO PAULO - SP. Brasil. Phone: (11) 3611-0833 (R. 247) e Fax (11) 3861-0170.

E-mail: qualidade@falcaobauer.com.br

III. INSTITUTO NACIONAL DE TECNOLOGIA – INT

Address: AV. VENEZUELA, 82, SAÚDE - RIO DE JANEIRO - RJ. Brasil.

Phone:: (21) 2123-1170 e Fax: (21) 2123-1058

E-mail: serviços@int.gov.br

IV. INSTITUTO DE ELETROTÉCNICA E ENERGIA DA UNIVERSIDADE DE SÃO PAULO - IEE/USP - LABORATÓRIO DE ENSAIO

Address: AV. PROFESSOR LUCIANO GUALBERTO, 1.289, CIDADE UNIVERSITÁRIA - SÃO PAULO - SP. Brasil.

Phone: (11) 3091-2612/2507/2604 e Fax: (11) 3032-7750

E-mail: ensaios@iee.usp.br

V. INSTITUTO DE PESQUISAS TECNOLÓGICAS DO ESTADO DE SÃO PAULO – IPT - LABORATÓRIO DE EQUIPAMENTOS ELÉTRICOS E ÓPTICOS DO CENTRO DE INTEGRIDADE DE ESTRUTURAS E EQUIPAMENTOS

Address: AV. PROF. ALMEIDA PRADO, 532, CIDADE UNIVERSITÁRIA - SÃO CARLOS - SP. Brasil.

Phone: (11) 3767-4823 e Fax: (11) 3767-4007

E-mail: mleite@ipt.br

VI. PONTIFÍCIA UNIVERSIDADE CATÓLICA DO RIO GRANDE DO SUL - PUC/RS - LABORATÓRIOS ESPECIALIZADOS EM ELETRO-ELETRÔNICA - LABELO

Address: AV. IPIRANGA, 6681- PRÉDIO 30 - BLOCO 3 - SALA 200 – PARTENON - PORTO ALEGRE, RS. Brasil.

Phone: (51) 3320-3551 e Fax: (51) 3320-3901

E-mail: labelo@pucrs.br

VII. CIENTEC- FUNDAÇÃO DE CIÊNCIA E TECNOLOGIA - DEPARTAMENTO DE ENGENHARIA ELETROELETRÔNICA

Address: AV. DAS INDÚSTRIAS, 2.270 - DISTRITO INDUNSTRIAL – CACHOEIRINHA - RS. Brasil.

Phone: (51) 3287-2088 e Fax: (51) 3470-2089

E-mail: flavio@cientec.rs.gov.br

VIII. TÜV RHEINLAND DO BRASIL LTDA. - LABORATÓRIO DE ENSAIOS - DIVISÃO UCIEE

Address: RUA DOS COMERCIÁRIOS, 220 – JABAQUARA - SÃO PAULO - SP. Brasil.

Phone: (11) 5588-6123 e Fax: (11) 5588-6156

E-mail: oswaldo.martins@br.tuv.com

IX. INSTITUTO BRASILEIRO DE ENSAIOS DE CONFORMIDADE LTDA. - IBEC

Address: RO. JORN. FRAN. AG. PRO KM 9 COND.TECH TOWN PR 32 - CHÁCARA ASSAY – HORTOLÂNDIA - SP. Brasil.

Phone: (19) 3845-5965 e Fax: (19) 3845-5964

E-mail: fbarbarini@ibec.com.br

X. ESCOLA POLITÉCNICA DA UNIVERSIDADE DE SÃO PAULO - DIVISÃO DE ENSAIOS E CALIBRAÇÃO DO LABORATÓRIO DE ENGENHARIA BIOMÉDICA DA ESCOLA POLITÉCNICA

Address: AV. PROF. LUCIANO GUALBERTO, TRAV.3, NÚM. 158 - CID. UNIVERSITÁRIA - SÃO PAULO - SP. Brasil.

Phone: (11) 3091-5652/5269/5651 e Fax: (11) 3091-5652

E-mail: jcmoraes@leb.usp.br e dec@leb.usp.br

XI. FUNDAÇÃO CPQD - CENTRO DE PESQUISA E DESENVOLVIMENTO EM TELECOMUNICAÇÕES - LABORATÓRIOS DA FUNDAÇÃO CPQD

Address: RODOVIA CAMPINAS - MOGI MIRIM KM 118,5 – CAMPINAS - SP. Brasil.

Phone: (19) 3705-7132/6410/6182 e Fax: (19) 3705-6120

E-mail: betecida@cpqd.com.br

XII. INSTITUTO LAB SYSTEM DE PESQUISAS E ENSAIOS LTDA. - LAB SYSTEM

Address: AVENIDA GUINLE, 106 - CIDADE INDUSTRIAL SATÉLITE – GUARULHOS - SP. Brasil.

Phone: (11) 2446-0053 e Fax: (11) 2446-0041

E-mail: ilspe@labsystem.com.br

XIII. FACULDADE DE CIÊNCIAS FARMACÊUTICAS DA UNIVERSIDADE DE SÃO PAULO - FCF/USP/CONFAR - CONFAR - LAB. DE CONTROLE DE MEDICAMENTOS, COSMÉTICOS, DOMISSANITÁRIOS, PRODUTOS AFINS E AS RESPECTIVAS MATÉRIAS-PRIMAS

Address: AV. PROFESSOR LINEU PRESTES - 580 - BL 13 A - CIDADE UNIVERSITÁRIA - SÃO PAULO - SP. Brasil.

Phone: (11) 3091-3626/2218 e Fax: (11) 3091-3626

E-mail: roryama@usp.br

XIV. INSTITUTO DE TECNOLOGIA DO PARANÁ – TECPAR - CENTRO DE ANÁLISES E ENSAIOS TECNOLÓGICOS - CETEC

Address: RUA PROF. ALGACYR MUNHOZ MAEDER, 3775 – CIC - CURITIBA, PR. Brasil.

Phone: (41) 3316-3083 e Fax: (41) 3316-3103

E-mail: marta@tecpar.br

XV. INSTITUTO DE PESQUISAS TECNOLÓGICAS DO ESTADO DE SÃO PAULO – IPT - CENTRO DE METROLOGIA EM QUÍMICA

Address: AV. PROFESSOR ALMEIDA PRADO, 532 - CIDADE UNIVERSITÁRIA - SÃO PAULO - SP. Brasil.

Phone: (11) 3767-4569 e Fax: (11) 3767-4572

E-mail: mpapai@ipt.br

XVI. INSTITUTO NACIONAL DE PESQUISAS ESPACIAIS – INPE - LABORATÓRIO DE EMI/EMC/ANTENAS

Address: AV. DOS ASTRONAUTAS, 1758 - JARDIM DA GRANJA - SÃO JOSÉ DOS CAMPOS - SP. Brasil.

Phone: (12) 3208-6275/7245/6306 e Fax: (12) 3941-1884

E-mail: emc@lit.inpe.br

XVII. UNIVERSIDADE FEDERAL DE SANTA CATARINA - MAGLAB - LABORATÓRIO DE ELETROMAGNETISMO E COMPATIBILIDADE ELETROMAGNÉTICA

Address: CAMPOS UNIVERSITÁRIO CP. 5024 - TRINDADE - FLORIANÓPOLIS - SC. Brasil.

Phone: (48) 3721-7557 e (48) 9148-0216 e Fax: (48) 3721-2350

E-mail: mikaelfonseca@gmail.com

XVIII. ITEN - INSTITUTO TECNOLOGICO DE ENSAIOS LTDA.

Address: AVENIDA VICTOR CIVITA, 2064 - JARDIM TEREZA - OSASCO - SP. Brasil.

Phone: (11) 3591-4296 e (11) 3431-4145 e Fax: (11) 3591-4296

E-mail: seixas@itensp.com.br e comercial@itensp.com.br

XIX. CENTRO DE QUALIDADE ANALÍTICA LTDA - CQA LABORATÓRIOS

Address: AV. JÚLIO DINIZ Number 27 - JD. N. SENHORA AUXILIA - CAMPINAS - SP. Brasil.

Phone: (19) 3241-1555 e Fax: (19) 3241-1555

E-mail: marcelo@cqa.com.br

XX. INSTITUTO DE CERTIFICAÇÕES BRASILEIRO S/A. - CertLab

Address: Rua Maestro Francisco Manoel da Silva, 71 - Santa Genebra - CAMPINAS - SP. Brasil.

Phone: (19) 3112-9887/9801/9808/9834

E-mail: ismar@certlab.org.br

XXI. No Risk Serviços Técnicos Especializados Ltda.

Address: RUA BORDINI, Number 109 - PARQUE DAS INDÚSTRIAS - ITU - SP. Brasil.

Phone: (11) 4024-6302

E-mail: norisk@noriskste.com.br

XXII. SERTIN - COMÉRCIO E SERVIÇOS TÉCNICOS DE INSTRUMENTAÇÃO LTDA. - SERTIN - LABORATÓRIO DE CALIBRAÇÃO - LABOCAL

Address: RUA PADRE JOÃO ÁLVARES, 428 - VILA RENATA - GUARULHOS - SP. Brasil.

Phone: (11) 2485-5460 e Fax: (11) 2485-5481

E-mail: vendas1@sertin.com.br

XXIII. CENIC - LABORATÓRIO DE ENSAIOS ESPECIAIS LTDA. ME

Address: Rua Oswaldo Denari, 165 - Jardim Munique - São Carlos - SP. Brasil.

Phone: (16) 3371-5490

E-mail: ivan@laboratoriocenic.com

XXIV. ACCUMED PRODUTOS MÉDICO-HOSPITALARES LTDA - Accumed

Address: Rodovia WASHINGTON LUIZ ,4370/N/A - VILA SÃO SEBASTIÃO - DUQUE DE CAXIAS - RJ. Brasil.

Phone: (21) 2126-1600 e Fax: (21) 2126.1600

E-mail: aloisio.hausen@accumed.com.br

XXV. LABORATÓRIO DE METROLOGIA LENZI LTDA. - K&L LABORATÓRIO DE METROLOGIA

Address: RUA SERGIPE, 113 - SALA B - BONECA DO IGUAÇU - SÃO JOSÉ DOS PINHAIS - PR. Brasil.

Phone: (41) 3382-7666 e Fax: (41) 3382-7666

E-mail: gerencia.sjp@kellab.com.br

XXVI. Controlbio Assessoria Técnica Microbiológica S/S Ltda. - Controlbio

Address: Rua Comendador Elias Assi, 645 - Jd. Caxingui - SÃO PAULO - SP. Brasil.

Phone: (11) 3721-7760

E-mail: controlbio@controlbio.com.br

6. Government Partners

I. National Institute of Metrology, Quality and Technology (Inmetro).

General Coordination of International Affairs (CAINT)

Overcoming Technical Barriers Division (DISBT)

Phone: (+ 55 21) 2563-5543 and Fax: (+ 55 21) 2563-5637

Address: Rua Santa Alexandrina 416, 5th floor. Rio Comprido. Rio de Janeiro/RJ, Brasil.

http://www.inmetro.gov.br/barreirastecnicas/

II. Agência Nacional de Vigilância Sanitária (Anvisa).

Address: Setor de Indústria e Abastecimento (SIA) – Trecho 5, Área Especial 57, Brasília/DF, Brasil.

Phone: (+55 61) 3462 - 5772

http://portal.anvisa.gov.br

III. Brazilian Association of Technical Standards (ABNT)

Address: Av. 13 de Maio, 13/27th floor. Center - Rio de Janeiro, Brasil.

Phone: (+55 21) 3974 2337 and Fax (+55 21) 3974-2317

www.abnt.org.br / www.abntnet.com.br

7. Major Market Entities

I. Brazilian Medical Devices Manufacturers Association - ABIMO

http://www.abimo.org.br/

II. Brazilian Association of the High Technology Industry of Medical Equipment, Products and Supplies - ABIMED

http://www.abimed.org.br/

III. Brazilian Dental Association – ABO

http://www.abo.org.br/