ÁMBITO REGULADOR

ÓRGANO OFICIAL REGULADOR
CENTRO PARA EL CONTROL ESTATAL DE MEDICAMENTOS, EQUIPOS Y DISPOSITIVOS MÉDICOS

EDICIÓN ORDINARIA	**LA HABANA 17/12/2019**	**AÑO XX**	**NÚMERO: 00-357**
SUSCRIPCIÓN: ambitor@cecmed.cu			**ISSN 1684-1832**

INFORMACIÓN A LOS LECTORES: En esta edición de nuestro Boletín se publica lo siguiente:

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REPÚBLICA DE CUBA
MINISTERIO DE SALUD PÚBLICA
CENTRO PARA EL CONTROL ESTATAL DE MEDICAMENTOS, EQUIPOS Y DISPOSITIVOS MÉDICOS
CECMED

RAFAEL B. PÉREZ CRISTIÁ
DIRECTOR GENERAL

RESOLUCIÓN No. 159/2019

POR CUANTO: Por Resolución No. 153 de fecha 27 de junio del año 2011, emitida por el Ministerio de Salud Pública, se creó el Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos, en lo adelante CECMED.

POR CUANTO: Por Resolución No. 65 de fecha 1 de junio del año 2016, se designó a la MsC. Yaquelín Rodríguez Valdés como Subdirectora del CECMED, con el alcance de sus respectivos derechos y atribuciones.

POR CUANTO: Por Resolución No. 165 de fecha 14 de abril del año 2014, emitida por el Ministerio de Salud Pública, se aprobaron y pusieron en vigor la misión y las funciones que rigen el funcionamiento del CECMED, disponiendo en su RESUELVO SEGUNDO apartado 1 "Establecer las disposiciones legales, técnicas y administrativas para el ejercicio de las funciones de regulación, fiscalización y vigilancia de productos y servicios para la salud humana así como su implementación, revisión y actualización sistemática en correspondencia con la política nacional y la práctica internacional".

POR CUANTO: Por Resolución No. 31 de fecha 19 de febrero del año 2013, dispuesta por el Director General del CECMED, se aprobó y puso en vigor la Regulación ER 9-2012 *Empleo de las Normas en la Evaluación y Registro de los Equipos Médicos*, la cual establece la Lista Regulatoria de Normas como una herramienta para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos.

POR CUANTO: Por Resolución No. 167 de fecha 5 de diciembre del año 2017, de la Subdirectora del CECMED MsC. Yaquelín Rodríguez Valdés, se aprobó y puso en vigor la Lista Regulatoria de Normas (Lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos), de ese año.

POR CUANTO: La frecuencia de actualización de esta lista es anual, según lo establecido en la Regulación ER 9-2012, por lo

que se hace necesario proceder a su revisión y a la emisión de la correspondiente al año 2019.

POR TANTO: En el ejercicio de las facultades y atribuciones que me están conferidas por Resolución No. 155 de fecha 27 de junio del año 2011, del Ministerio de Salud Púbica,

RESUELVO

PRIMERO: Aprobar y poner en vigor la edición del año 2019 de la Lista Regulatoria de Normas (Lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos, incluyendo Diagnosticadores), que se adjunta a la presente resolución y forma parte integrante de la misma.

SEGUNDO: Derogar la Resolución No. 167 de fecha 5 de diciembre del año 2017, dispuesta por la Subdirectora del CECMED.

TERCERO: Lo establecido en la presente Resolución entrará en vigor a partir de la fecha de su firma.

COMUNÍQUESE a cuantas empresas y compañías relacionadas con la fabricación, distribución importación y suministros de equipos y dispositivos médicos proceda incluyendo diagnosticadores; a la Empresa Medicuba S.A.; a EMSUME; a la Dirección Nacional de Medicamentos y Tecnologías del MINSAP; a la Dirección Nacional de Salud Ambiental del MINSAP; al Comité Técnico de Normalización No. 11 de Equipos Médicos; al Comité Técnico de Normalización No. 102 de Diagnosticadores; al Departamento de Equipos y Dispositivos Médicos; a la Sección de Recepción y Preevaluación de Trámites, a la Sección de Política y Asuntos Regulatorios, al Laboratorio Nacional de Control del CECMED y a cuantas personas naturales o jurídicas resulte necesario.

PUBLÍQUESE en el Ámbito Regulador, órgano oficial del CECMED, para su general conocimiento.

ARCHÍVESE el original de la presente disposición en el registro de resoluciones del Grupo de Asesoría Jurídica del Centro.

DADA en La Habana, a los 12 días del mes de diciembre del año 2019.
"Año 61 de la Revolución".

Dr. Rafael B. Pérez Cristiá
Director General

LISTA REGULATORIA DE NORMAS 2019

Notas a la presente edición

La *Lista Regulatoria de Normas* es la lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de equipos y dispositivos médicos.

La disposición reguladora (DR) *Lista de Normas y Guías para Diagnosticadores*, aprobada por la Resolución del CECMED No. 75/2013, del 5 de junio de 2013, se actualiza en 2019 mediante dos DDRR: (1) *Lista Regulatoria de Normas* con respecto a las normas y (2) *Lista de Guías para Diagnosticadores* (Lista de guías reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de los Diagnosticadores).

A partir de la edición 2019 se incluye en la LRN la categoría Dispositivos Médicos para el Diagnóstico in Vitro (DMDIV), los que se denominan en Cuba diagnosticadores.

En esta edición, se utilizan los acrónimos y abreviaturas, cuyo significado se describe a continuación:

Amd	Amendment
CLSI	Clinical and Laboratory Standards Institute
Cor	Corrigendum
EN	European Norm
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Organization for Standardization
NC	Norma Cubana

Otros cambios incluidos son la adición de 154 normas, de ellas corresponden a diagnosticadores 65 (42,2 %), fueron eliminadas 6 normas y se actualizaron las ediciones de 44. Las categorías que resultaron incrementadas fueron las de OFTALMOLOGÍA, ORTOPEDIA, CALIDAD y RADIOLÓGICOS.

I. Cambios introducidos en la nueva edición 2019 de la Lista Regulatoria de Normas

Categorías
Se agrega la categoría**:** DISPOSITIVOS MÉDICOS PARA EL DIAGNÓSTICO IN VITRO

1. **Normas adicionadas**

NORMA	AÑO	TÍTULO
CLSI EP05	2014	Evaluation of Precision of Quantitative Measurement Procedures
CLSI EP06	2003	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach
CLSI EP07	2018	Interference Testing in Clinical Chemistry
CLSI EP37	2018	Supplemental Tables for Interference Testing in Clinical Chemistry
CLSI EP09	2013	Measurement Procedure Comparison and Bias Estimation Using Patient Samples
CLSI EP10	2014	Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures
CLSI EP12	2008	User Protocol for Evaluation of Qualitative Test Performance
CLSI EP14	2014	Evaluation of Commutability of Processed Samples
CLSI EP15	2014	User Verification of Precision and Estimation of Bias

NORMA	AÑO	TÍTULO
CLSI EP17	2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedure
CLSI EP18	2009	Risk Management Techniques to Identify and Control Laboratory Error Sources
CLSI EP32	2006	Metrological Traceability and Its Implementation
CLSI EP24	2011	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves
CLSI GP16	2009	Urinalysis
CLSI H21	2008	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assay
CLSI H42	2007	Enumeration of Immunologically Defined Cell Populations by Flow Cytometry
CLSI H47	2008	One-Stage Prothrombin Time (PT) Test and Activate Partial Thromboplastin Time (APTT) Test
CLSI I/LA21	2008	Clinical Evaluation of Immunoassays
CLSI M02	2018	Performance Standards for Antimicrobial Disk Susceptibility Tests
CLSI M07	2018	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically
CLSI M100	2018	Performance Standards for Antimicrobial Susceptibility Testing
CLSI M23	2018	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters
CLSI M43-A	2011	Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas
CLSI M60	2017	Performance Standards for Antifungal Susceptibility Testing of Yeasts
CLSI M61	2017	Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi
CLSI MM01	2012	Molecular Methods for Clinical Genetics and Oncology Testing
CLSI MM03	2015	Molecular Diagnostic Methods for Infectious Diseases
CLSI MM05	2012	Nucleic Acid Amplification Assays for Molecular Hematopathology
CLSI MM06	2010	Quantitative Molecular Methods for Infectious Diseases

NORMA	AÑO	TÍTULO
CLSI MM09	2014	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine
CLSI MM12	2006	Diagnostic Nucleic Acid Microarrays
CLSI MM13	2005	Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline
CLSI MM17	2018	Verification and Validation of Multiplex Nucleic Acid Assays
CLSI MM18	2008	Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing
CLSI POCT14	2004	Point-of-Care Monitoring of Anticoagulation Therapy
EN 1618	1997	Catheters other than intravascular catheters. Test methods for common properties
EN 12322/ Amd1:2001	1999	Productos sanitarios para diagnóstico in vitro. Medios de cultivo para microbiología. Criterios para las características funcionales de los medios de cultivo
IEC 61010-2-201	2017	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-201: Particular requirements for control equipment
IEC 61223-3-2	2007	Evaluation and routine testing in medical imaging departments. Part 3-2: Acceptance tests. Imaging performance of mammographic X-ray equipment
IEC 61223-3-5	2004	Evaluation and routine testing in medical imaging departments. Part 3-5: Acceptance tests. Imaging performance of computed tomography X-ray equipment
IEC 61326-2-6	2012	Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 2-6: Particular requirements. In vitro diagnostic (IVD) medical equipment
IEC 62464-1	2019	Magnetic resonance equipment for medical imaging. Part 1: Determination of essential image quality parameters
IEC 62945	2018	Radiation protection instrumentation. Measuring the imaging performance of X-ray computed tomography (CT) security-screening systems

NORMA	AÑO	TÍTULO
IEC/TR 61948-1	2016	Nuclear medicine instrumentation. Routine tests. Part 1: Gamma radiation counting systems
IEC/TR 61948-2	2019	Nuclear medicine instrumentation. Routine tests. Part 2: Scintillation cameras and single photon emission computed tomography imaging
IEC/TR 61948-3	2018	Nuclear medicine instrumentation. Routine tests. Part 3: Positron emission tomographs
IEC/TR 61948-4	2019	Nuclear medicine instrumentation. Routine tests. Part 4: Radionuclide calibrators
IEC/TR 60601-4-1	2017	Medical electrical equipment. Part 4-1: Guidance and interpretation. Medical electrical equipment and medical electrical systems employing a degree of autonomy
ISO 643	2012	Steels. Micrographic determination of the apparent grain size
ISO 4967	2013	Steel. Determination of content of non-metallic inclusions. Micrographic method using standard diagrams
ISO 5832-9	2019	Implants for surgery. Metallic materials. Part 9: Wrought high nitrogen stainless steel
ISO 5835	1991	Implants for surgery. Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread. Dimensions.
ISO 5836	1988	Implants for surgery. Metal bone plates. Holes corresponding to screws with asymmetrical thread and spherical under-surface
ISO 5910	2018	Cardiovascular implants and extracorporeal systems. Cardiac valve repair devices
ISO 6475	1989	Implants for surgery. Metal bone screws with asymmetrical thread and spherical under-surface. Mechanical requirements and test methods
ISO 6892-1	2016	Metallic materials. Tensile testing. Part 1: Method of test at room temperature
ISO 7199	2016	Cardiovascular implants and artificial organs. Blood-gas exchangers (oxygenators)
ISO 7492	2019	Dentistry. Dental explorer
ISO 8637-2	2018	Extracorporeal systems for blood purification. Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
ISO 8980-1	2017	Ophthalmic optics. Uncut finished spectacle lenses. Part 1: Specifications for single-vision and multifocal lenses
ISO 8980-2	2017	Ophthalmic optics. Uncut finished spectacle lenses. Part 2: Specifications for power-variation lenses
ISO 8980-3	2013	Ophthalmic optics. Uncut finished spectacle lenses. Part 3: Transmittance specifications and test methods
ISO 8980-4	2006	Ophthalmic optics. Uncut finished spectacle lenses. Part 4: Specifications and test methods for anti-reflective coatings
ISO 8980-5	2005	Ophthalmic optics. Uncut finished spectacle lenses. Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant
ISO 9004	2018	Quality management. Quality of an organization. Guidance to achieve sustained success
ISO 9268	1988	Implants for surgery. Metal bone screws with conical under-surface of head. Dimensions
ISO 9585	1990	Implants for surgery. Determination of bending strength and stiffness of bone plates
ISO 10524-1	2018	Pressure regulators for use with medical gases. Part 1: Pressure regulators and pressure regulators with flow-metering devices
ISO 10524-2	2018	Pressure regulators for use with medical gases. Part 2: Manifold and line pressure regulators
ISO 10637	2018	Dentistry. Central suction source equipment
ISO 10993-9	2019	Biological evaluation of medical devices. Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-15	2019	Biological evaluation of medical devices. Part 15: Identification and quantification of degradation products from metals and alloys
ISO 11133	2014	Microbiology of food, animal feed and water. Preparation, production, storage and performance testing of culture media
ISO 11138-4	2017	Sterilization of health care products. Biological indicators.

NORMA	AÑO	TÍTULO
		Part 4: Biological indicators for dry heat sterilization processes
ISO 11138-5	2017	Sterilization of health care products. Biological indicators. Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
ISO 11138-7	2019	Sterilization of health care products. Biological indicators. Part 7: Guidance for the selection, use and interpretation of results
ISO 11199-1	1999	Walking aids manipulated by both arms. Requirements and test methods. Part 1: Walking frames
ISO 11199-2	2005	Walking aids manipulated by both arms. Requirements and test methods. Part 2: Rollators
ISO 11199-3	2005	Walking aids manipulated by both arms. Requirements and test methods. Part 3: Walking tables
ISO 11249	2018	Copper-bearing intrauterine contraceptive devices. Guidance on the design, execution, analysis and interpretation of clinical studies
ISO 11334-1	2007	Walking aids manipulated by one arm. Requirements and test methods. Part 1: Elbow crutches
ISO 11334-4	1999	Walking aids manipulated by one arm. Requirements and test methods. Part 4: Walking sticks with three or more legs
ISO 11381	2016	Ophthalmic optics. Spectacle frames. Screw threads
ISO 11979-7	2018	Ophthalmic implants. Intraocular lenses. Part 7: Clinical investigations of intraocular lenses for the correction of aphakia
ISO 12189	2008	Implants for surgery. Mechanical testing of implantable spinal devices. Fatigue test method for spinal implant assemblies using an anterior support
ISO 12417-2	2017	Cardiovascular implants and extracorporeal systems. Vascular device-drug combination products. Part 2: Local regulatory information
ISO 12867	2010	Ophthalmic instruments. Trial frames
ISO 12870	2016	Ophthalmic optics. Spectacle frames. Requirements and test methods

NORMA	AÑO	TÍTULO
ISO 13408-2	2018	Aseptic processing of health care products. Part 2: Sterilizing filtration
ISO 13897	2018	Dentistry. Dental amalgam reusable mixing-capsules
ISO 14889:2013 / Amd 1	2017	Ophthalmic optics. Spectacle lenses. Fundamental requirements for uncut finished lenses
ISO 15193	2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for content and presentation of reference measurement procedures
ISO 15194	2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for certified reference materials and the content of supporting documentation
ISO 15197	2013	In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
ISO 15198	2004	Clinical laboratory medicine. In vitro diagnostic medical devices. Validation of user quality control procedures by the manufacturer
ISO 15382	2015	Radiological protection. Procedures for monitoring the dose to the lens of the eye, the skin and the extremities
ISO 15674	2016	Cardiovascular implants and artificial organs. Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags
ISO 15675	2016	Cardiovascular implants and artificial organs. Cardiopulmonary bypass systems. Arterial blood line filters
ISO 16142-2	2017	Medical devices. Recognized essential principles of safety and performance of medical devices. Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
ISO 16256	2012	Clinical laboratory testing and in vitro diagnostic test systems. Reference method for testing the in vitro activity of antimicrobial

NORMA	AÑO	TÍTULO
		agents against yeast fungi involved in infectious diseases
ISO 16840-2	2018	Wheelchair seating. Part 2: Determination of physical and mechanical characteristics of seat cushions intended to manage tissue integrity
ISO 17327-1	2018	Non-active surgical implants. Implant coating. Part 1: General requirements
ISO 17511	2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
ISO 17593	2007	Clinical laboratory testing and in vitro medical devices. Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy
ISO 18113-1	2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements
ISO 18113-3	2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 3: In vitro diagnostic instruments for professional use
ISO 18113-5	2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 5: In vitro diagnostic instruments for self-testing
ISO 18153	2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials
ISO 19227	2018	Implants for surgery. Cleanliness of orthopedic implants. General requirements
ISO 19233-1	2017	Implants for surgery. Orthopaedic joint prosthesis. Part 1: Procedure for producing parametric 3D bone models from CT data of the knee
ISO 20608	2018	Dentistry. Powder jet handpieces and powders
ISO 20697	2018	Sterile drainage catheters and accessory devices for single use
ISO 20698	2018	Catheter systems for neuraxial application. Sterile and single-use catheters and accessories

NORMA	AÑO	TÍTULO
ISO 20776-1	2006	Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices. Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases
ISO 20776-2	2007	Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices. Part 2: Evaluation of performance of antimicrobial susceptibility test devices
ISO 20916	2019	In vitro diagnostic medical devices. Clinical performance studies using specimens from human subjects. Good study practice
ISO 21533	2018	Dentistry. Reprocessable cartridge syringes for intraligamentary injections
ISO 21987	2017	Ophthalmic optics. Mounted spectacle lenses
ISO 28590	2017	Sampling procedures for inspection by attributes. Introduction to the ISO 2859 series of standards for sampling for inspection by attributes
ISO 80000-1 / Cor 1: 2011	2009	Quantities and units. Part 1: General
ISO 80601-2-79	2018	Medical electrical equipment. Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
ISO 80601-2-80	2018	Medical electrical equipment. Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
ISO/IEEE 11073-10419	2019	Health informatics. Personal health device communication. Part 10419: Device specialization. Insulin pump
ISO/TR 8550-1	2007	Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots. Part 1: Acceptance sampling

NORMA	AÑO	TÍTULO
ISO/TR 28980	2007	Ophthalmic optics. Spectacle lenses. Parameters affecting lens power measurement
ISO/TS 10974	2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
ISO/TS 17822-1	2014	In vitro diagnostic test systems. Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens. Part 1: General requirements, terms and definitions
ISO/TS 19218-2	2012	Medical devices. Hierarchical coding structure for adverse events. Part 2: Evaluation codes
ISO/TS 20405	2018	Health informatics. Framework of event data and reporting definitions for the safety of health software
ISO/TS 21726	2019	Biological evaluation of medical devices. Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
ISO/TS 24348	2014	Ophthalmic optics. Spectacle frames. Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames
NC 1281	2019	Esfigmomanómetros automatizados. Métodos y equipos de verificación
NC EN 13532	2006	Requisitos generales de los diagnosticadores para autoensayo (EN 13532:2002, IDT)
NC EN 13612	2006	Evaluación del funcionamiento de los diagnosticadores (EN 13612:2002, IDT)
NC EN 13641	2004	Eliminación o reducción del riesgo de infección relacionado con los diagnosticadores (EN 13641: 2002, IDT)
NC EN 13975	2006	Procedimientos de muestreo utilizados para los ensayos de aceptación de los diagnosticadores. Aspectos estadísticos (EN 13975:2003, IDT)
NC EN 14136	2006	Utilización de programas de evaluación externa de la calidad en la evaluación del desempeño de los procedimientos de diagnóstico in vitro (EN 14136:2004, IDT)
NC ISO 2859-1	2018	Procedimientos de muestreo para la inspeccion por atributos. Parte 1: Planes de muestreo para las inspecciones lote por lote, tabulados según el límite de calidad de aceptación (LCA) [ISO 2859:1999 (+ COR.1:2001 + Amd.1:2011), IDT]
NC ISO 2859-2	2003	Procedimiento de muestreo para inspección por atributos. Parte 2: Planes de muestreo indexados por la calidad límite (cl) para la inspección de un lote aislado. (ISO 2859-2:1985, IDT)
NC ISO 2859-3	2018	Procedimientos de muestreo para la inspección por atributos. Parte 3: Procedimientos de muestreo con lotes no inspeccionados (ISO 2859-3: 2005, IDT)
NC ISO 2859-4	2018	Procedimientos de muestreo para la inspección por atributos. Parte 4: Procedimientos para la evaluación de los niveles de calidad declarados (ISO 2859-4: 2002, IDT)
NC ISO 2859-5	2018	Procedimientos de muestreo para la inspección por atributos. Parte 5: Sistema de planes de muestreo secuencial para la inspección lote por lote tabulados según el límite de calidad de aceptación (LCA) (ISO 2859-5:2005, IDT)
NC ISO 10555-1	2016	Catéteres intravasculares estériles de un solo uso. Parte 1: Requisitos generales (ISO 10555-1: 2013, IDT)
NC ISO 15189	2016	Laboratorios clínicos. Requisitos para la calidad y la competencia (ISO 15189:2012, IDT)
NC ISO 18113-2	2011	Dispositivos médicos para diagnóstico in vitro. Información suministrada por el fabricante (rotulado). Parte 2: Reactivos para diagnóstico in vitro (diagnosticadores) para uso profesional (ISO 18113-2:2009, IDT)
NC ISO 18113-4	2012	Dispositivos médicos para diagnóstico in vitro. Información suministrada por el fabricante (rotulado). Parte 4: Reactivos para diagnóstico in vitro (diagnosticadores) para autoensayo (ISO 18113-4: 2009, IDT)
NC ISO 19001	2019	Dispositivos médicos para diagnóstico in vitro. Información proporcionada por el fabricante con los reactivos para diagnóstico in vitro

NORMA	AÑO	TÍTULO
		utilizados para tinción en biología (ISO 19001:2013, IDT)
NC ISO 23640	2018	Dispositivos médicos para diagnóstico in vitro. Evaluación de la estabilidad de los reactivos para diagnóstico in vitro (ISO 23640: 2011, IDT)
NC ISO/IEC TS 25011	2018	Tecnología de la Información. Requisitos de la Calidad y Evaluación de Software y de Sistemas (SQuaRE). Modelo de la Calidad y los Servicios
NC ISO/IEC 25012	2018	Ingeniería de Software y Sistemas. Requisitos de la Calidad y Evaluación del producto de Software (SQuaRE).
NC ISO/IEC 25022	2018	Ingeniería de Software y Sistemas. Requisitos de la Calidad y Evaluación de Software y Sistemas (SQuaRE). Medición de la Calidad en el uso
NC ISO 31000	2018	Gestión del Riesgo. Directrices [ISO 31000:2018, (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO/IEC 31010	2015	Gestión del Riesgo. Técnicas de Apreciación del Riesgo (ISO/IEC 31010: 2009, IDT)
OIML G 19	2017	The role of measurement uncertainty in conformity assessment decisions in legal metrology

2. **Normas eliminadas**

NORMA	AÑO	TÍTULO
ISO 8638	2010	Cardiovascular implants and extracorporeal systems. Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters *Sustituida por ISO 8637-2:2018*
ISO 14161	2009	Sterilization of health care products. Biological indicators. Guidance for the selection, use and interpretation of results *Sustituida por ISO 11138-7:2019*
ISO 15225	2016	Medical devices. Quality management. Medical device nomenclature data structure *Derogada por la ISO*
ISO/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories *Sustituida por la NC ISO/IEC 17025:2017 [(TRADUCCIÓN CERTIFICADA), corregida en marzo 2018]*
ISO/TS 22911	2016	Dentistry. Preclinical evaluation of dental implant systems. Animal test methods
		Su contenido incluido en ISO 7405:2018
NC ISO/IEC 90003	2006	Ingeniería de software. Directivas para la aplicación de la NC ISO 9001:2001 al software de computación (ISO/IEC 90003:2004, IDT) *La NC ISO 9001 vigente es del año 2015*

3. **Normas actualizadas (reemplazadas)**

NORMA	AÑO	TÍTULO
IEC CISPR 11 (ed. consolidada)	2019	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement *Anteriormente IEC CISPR 11:2016 (ed. consolidada)*
IEC 60601-2-4 (ed. consolidada)	2018	Medical electrical equipment. Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators *Anteriormente IEC 60601-2-4: 2010 (ed. consolidada)*
IEC 60601-2-16	2018	Medical electrical equipment. Part 2-16. Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment *Anteriormente IEC 60601-2-16: 2012*
IEC 60601-2-39	2018	Medical electrical equipment. Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment *Anteriormente IEC 60601-2-39: 2007*
IEC 60601-2-54 (ed. consolidada)	2018	Medical electrical equipment. Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy *Anteriormente IEC 60601-2-54: 2015 (ed. consolidada)*
IEC 80601-2-26	2019	Medical electrical equipment. Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs *Anteriormente IEC 60601-2-26: 2012*
IEC 80601-2-60	2019	Medical electrical equipment. Part 2-60: Particular

NORMA	AÑO	TÍTULO
		requirements for basic safety and essential performance of dental equipment *Anteriormente IEC 80601-2-60: 2012*
IEC/TR 60601-4-3	2018	Medical electrical equipment. Part 4-3: Guidance and interpretation. Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements *Anteriormente IEC/TR 60601-4-3: 2015*
IEC 61010-2-010	2019	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-010: Particular requirements for laboratory equipment for the heating of materials *Anteriormente IEC 61010-2-010: 2014*
IEC 61010-2-051	2018	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-051: Particular requirements for laboratory equipment for mixing and stirring *Anteriormente IEC 61010-2-051: 2015*
IEC 61010-2-101	2018	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment *Anteriormente IEC 61010-2-101: 2015*
IEC 80601-2-30	2018	Medical electrical equipment. Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers *Anteriormente IEC 80601-2-30: 2013*
IEC 80601-2-49	2018	Medical electrical equipment. Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment *Anteriormente IEC 60601-2-47:2011*
ISO/IEC/IEEE 12207	2017	Systems and software engineering. Software life cycle processes

NORMA	AÑO	TÍTULO
		Anteriormente ISO/IEC 12207:2008
ISO 37	2017	Rubber, vulcanized or thermoplastic. Determination of tensile stress-strain properties *Anteriormente ISO 37: 2011*
ISO 5832-2	2018	Implants for surgery. Metallic materials. Part 2: Unalloyed titanium *Anteriormente ISO 5832-2:1999*
ISO 5832-12	2019	Implants for surgery. Metallic materials. Part 12: Wrought cobalt-chromium-molybdenum alloy *Anteriormente ISO 5832-12:2007 / Cor 1: 2008*
ISO 7405	2018	Dentistry. Evaluation of biocompatibility of medical devices used in dentistry *Anteriormente ISO 7405 / Amd 1: 2013*
ISO 7886-4	2018	Sterile hypodermic syringes for single use. Part 4: Syringes with re-use prevention feature *Anteriormente ISO 7886-4:2006*
ISO 8637-1	2017	Extracorporeal systems for blood purification. Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators *Anteriormente ISO 8637:2010/Amd 1:2013*
ISO 10993-1	2018	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process *Anteriormente ISO 10993-1 /Cor 1: 2010*
ISO 11607-1	2019	Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems *Anteriormente ISO 11607-1:2006 / Amd 1:2014*
ISO 11607-2	2019	Packaging for terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing and assembly processes *Anteriormente ISO 11607-2:2006 / Amd 1:2014*

NORMA	AÑO	TÍTULO
ISO 11737-1	2018	Sterilization of medical devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products *Anteriormente ISO 11737-1:2006*
ISO/TR 14283	2018	Implants for surgery. Fundamental principles. *Anteriormente ISO/TR 14283: 2004*
ISO 14607	2018	Non-active surgical implants. Mammary implants. Particular requirements *Anteriormente ISO 14607: 2007*
ISO 14708-2	2019	Implants for surgery. Active implantable medical devices. Part 2: Cardiac pacemakers *Anteriormente ISO 14708-2: 2012*
ISO 14708-6	2019	Implants for surgery. Active implantable medical devices. Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) *Anteriormente ISO 14708-6: 2010*
ISO 16054	2019	Implants for surgery. Minimum data sets for surgical implants Anteriormente *ISO 16054: 2000*
ISO 18472	2018	Sterilization of health care products. Biological and chemical indicators. Test equipment *Anteriormente ISO 18472: 2006*
ISO 25424	2018	Sterilization of medical devices. Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical devices *Anteriormente ISO 25424:2009*
ISO 25841	2017	Female condoms. Requirements and test methods *Anteriormente* ISO 25841: 2014
ISO 80601-2-55	2018	Medical electrical equipment. Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors *Anteriormente ISO 80601-2-55: 2011*
ISO 80601-2-61	2017	Medical electrical equipment. Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment *Anteriormente ISO 80601-2-61:2011*
ISO 81060-2	2018	Non-invasive sphygmomanometers. Part 2: Clinical validation of intermittent measurement type *Anteriormente ISO 81060-2: 2013*
ISO/IEC/IEEE 90003	2018	Software engineering. Guidelines for the application of ISO 9001:2015 to computer software *Anteriormente ISO/IEC 90003: 2014*
NC 146	2017	Almohadillas sanitarias. Requisitos y métodos de ensayo *Anteriormente NC 146: 2005*
NC 599	2019	Esfigmomanómetros. Métodos y equipos de verificación *Anteriormente NC 599: 2014*
NC ISO 9004	2018	Gestión de la calidad. Calidad de una organización. Orientación para lograr el éxito sostenido [ISO 9004:2018, (TRADUCCIÓN CERTIFICADA), IDT] *Anteriormente NC ISO 9004: 2009*
NC ISO 13485	2018	Equipos médicos. Sistemas de gestión de la calidad. Requisitos para propósitos reguladores (ISO 13485:2016, IDT) *Anteriormente NC ISO 13485:2005*
NC ISO/IEC 17025	2017	Requisitos generales para la competencia de los laboratorios de ensayo y calibración [ISO/IEC 17025:2017 (TRADUCCIÓN CERTIFICADA), corregida en marzo 2018, IDT] *Anteriormente NC ISO/IEC 17025:2006*
NC ISO 19011	2018	Directrices para la auditoría de los sistemas de gestión. [ISO 19011: 2018, (TRADUCCIÓN CERTIFICADA), IDT]

NORMA	AÑO	TÍTULO
		Anteriormente NC ISO 19011:2012

II. Lista Regulatoria de Normas a partir de la presente edición

1. **CALIDAD**		
NORMA	**AÑO**	**TÍTULO**
IEC 62366-1	2015	Medical devices. Part 1: Application of usability engineering to medical devices
ISO 9000	2015	Quality management systems. Fundamentals and vocabulary
ISO 9001	2015	Quality management systems. Requirements
ISO 9004	2018	Quality management. Quality of an organization. Guidance to achieve sustained success
ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes
ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
ISO 15223-2	2010	Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. Part 2: Symbol development, selection and validation
ISO 16142-1	2016	Medical devices. Recognized essential principles of safety and performance of medical devices. Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO 16142-2	2017	Medical devices. Recognized essential principles of safety and performance of medical devices. Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
ISO 80000-1 / Cor 1: 2011	2009	Quantities and units. Part 1: General
ISO 28590	2017	Sampling procedures for inspection by attributes. Introduction to the ISO 2859 series of standards for sampling for inspection by attributes
ISO/TR 8550-1	2007	Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots. Part 1: Acceptance sampling
ISO/TS 19218-1/Amd 1: 2013	2011	Medical devices. Hierarchical coding structure for adverse events. Part 1: Event-type codes
ISO/TS 19218-2	2012	Medical devices. Hierarchical coding structure for adverse events. Part 2: Evaluation codes
NC GUIA 857-1	2011	Organización y ejecución de programas de aseguramiento metrológico. Parte 1: Diagnóstico metrológico a la documentación de proyectos de inversiones
NC GUIA 857-2	2013	Organización y ejecución de programas de aseguramiento metrológico. Parte 2: Elaboración y aprobación de los programas de aseguramiento metrológico
NC ISO 2859-1	2018	Procedimientos de muestreo para la inspeccion por atributos. Parte 1: Planes de muestreo para las inspecciones lote por lote, tabulados según el límite de calidad de aceptación (LCA) [ISO 2859:1999 (+ COR.1:2001 + Amd.1:2011), IDT]
NC ISO 2859-2	2003	Procedimiento de muestreo para inspección por atributos. Parte 2: Planes de muestreo indexados por la calidad limite (cl) para la inspección de un lote aislado. (ISO 2859-2:1985, IDT)
NC ISO 2859-3	2018	Procedimientos de muestreo para la inspección por atributos. Parte 3: Procedimientos de muestreo con lotes no inspeccionados (ISO 2859-3: 2005, IDT)
NC ISO 2859-4	2018	Procedimientos de muestreo para la inspección por atributos. Parte 4: Procedimientos para la evaluación de los niveles de calidad declarados (ISO 2859-4: 2002, IDT)
NC ISO 2859-5	2018	Procedimientos de muestreo para la inspección por atributos. Parte 5: Sistema de planes de muestreo secuencial para la inspección lote por lote tabulados según el límite de calidad de aceptación (LCA) (ISO 2859-5:2005, IDT)
NC ISO 9000	2015	Sistema de gestión de la calidad. Fundamentos y vocabulario [ISO 9000:2015, (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 9001	2015	Sistema de gestión de la calidad. Requisitos. [ISO 9001: 2015 (TRADUCCIÓN CERTIFICADA), IDT]

NC ISO 9004	2018	Gestión de la calidad. Calidad de una organización. Orientación para lograr el éxito sostenido [ISO 9004:2018, (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 13485	2018	Equipos médicos. Sistemas de gestión de la calidad. Requisitos para propósitos reguladores (ISO 13485:2016, IDT)
NC ISO 14971	2012	Equipos médicos. Aplicación de la gestión de riesgos a los equipos médicos (ISO 14971:2007, IDT)
NC ISO 19011	2018	Directrices para la auditoría de los sistemas de gestión. [ISO 19011: 2018, (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 31000	2018	Gestión del Riesgo. Directrices [ISO 31000:2018, (TRADUCCIÓN Certificada), IDT]
NC ISO/IEC 17025	2017	Requisitos generales para la competencia de los laboratorios de ensayo y calibración [ISO/IEC 17025:2017 (TRADUCCIÓN CERTIFICADA), corregida en marzo 2018, IDT]
NC ISO/IEC 17050-2	2005	Evaluación de la Conformidad. Declaración de Conformidad del Proveedor. Parte 2: Documentación de Apoyo [ISO/IEC 17050-2:2004 (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO/IEC 31010	2015	Gestión del Riesgo. Técnicas de Apreciación del Riesgo (ISO/IEC 31010: 2009, IDT)
2. **EVALUACIÓN BIOLÓGICA**		
NORMA	**AÑO**	**TÍTULO**
ISO 10993-1	2018	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
ISO 10993-3	2014	Biological evaluation of medical devices. Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4	2017	Biological evaluation of medical device. Part 4. Selection of tests for interactions with blood
ISO 10993-6	2016	Biological evaluation of medical devices. Part 6: Tests for local effects after implantation
ISO 10993-7 / Cor 1: 2009	2008	Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals
ISO 10993-9	2019	Biological evaluation of medical devices. Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10	2010	Biological evaluation of medical device. Part 10: Tests for irritation and skin sensitization
ISO 10993-11	2017	Biological evaluation of medical devices. Part 11: Tests for systemic toxicity
ISO 10993-12	2012	Biological evaluation of medical devices. Part 12: Sample preparation and reference materials
ISO 10993-13	2010	Biological evaluation of medical devices. Part 13: Identification and quantification of degradation products from polymeric medical devices
ISO 10993-15	2019	Biological evaluation of medical devices. Part 15: Identification and quantification of degradation products from metals and alloys
ISO 10993-16	2017	Biological evaluation of medical devices. Part 16: Toxicokinetic study design for degradation products and leachables
ISO 22442-1	2015	Medical devices utilizing animal tissues and their derivatives. Part 1: Application of risk management
ISO/TR 10993-22	2017	Biological evaluation of medical devices. Part 22: Guidance on nanomaterials
ISO/TR 10993-33	2015	Biological evaluation of medical devices. Part 33: Guidance on tests to evaluate genotoxicity. Supplement to ISO 10993-3
ISO/TR 15499	2016	Biological evaluation of medical devices. Guidance on the conduct of biological evaluation within a risk management process
ISO/TR 37137	2014	Biological evaluation of medical devices. Guidance for absorbable implants
ISO/TS 10993-19	2006	Biological evaluation of medical devices. Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO/TS 10993-20	2006	Biological evaluation of medical devices. Part 20: Principles and methods for immunotoxicology testing of medical devices
ISO/TS 21726	2019	Biological evaluation of medical devices. Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
NC 305	2006	Biomateriales. Hidroxiapatita cerámica. Especificaciones y métodos de ensayo
NC 306	2006	Biomateriales. Adhesivo tisular de 2- cianoacrilato de n-butilo.

		Especificaciones y métodos de ensayo
NC ISO 10993-1	2013	Evaluación biológica de equipos médicos. Parte 1: Evaluación y ensayos mediante un proceso de gestión del riesgo (ISO 10993-1: 2009, IDT)
NC ISO 10993-2	2010	Evaluación biológica de equipos médicos. Parte 2: Requisitos relativos a la protección de los animales (ISO 10993-2:2006, IDT)
NC ISO 10993-3	2005	Evaluación biológica de equipos médicos. Parte 3: Ensayos relativos a la genotoxicidad, la carcinogenicidad y la toxicidad sobre la reproducción. (ISO 10993-3:2003, IDT)
NC ISO 10993-5	2013	Evaluación biológica de equipos médicos. Parte 5: Ensayos de citotoxicidad in vitro (ISO 10993-5:2009, IDT)
NC ISO 10993-6	2010	Evaluación biológica de equipos médicos. Parte 6: Ensayos relativos a los efectos locales después de la implantación (ISO 10993-6:2007, IDT)
NC ISO 10993-7	2005	Evaluación biológica de equipos médicos. Parte 7: Residuos de la esterilización por óxido de etileno (ISO 10993-7:1995, IDT)
NC ISO 10993-9	2012	Evaluación biológica de equipos médicos. Parte 9: Marco para la identificación y cuantificación de productos potenciales de degradación (ISO 10993-9: 2009, IDT)
NC ISO 10993-10	2016	Evaluación biológica de equipos médicos. Parte 10: Ensayos de irritación y de hipersensibilidad retardada (ISO 10993-10:2010, IDT)
NC ISO 10993-11	2010	Evaluación biológica de equipos médicos. Parte 11: Ensayos de toxicidad sistémica (ISO 10993-11:2006, IDT)
NC ISO 10993-12	2010	Evaluación biológica de equipos y dispositivos médicos. Parte 12: Preparación de muestras y materiales de referencia (ISO 10993-12:2007, IDT)
NC ISO 10993-13	2006	Evaluación biológica de equipos médicos. Parte 13: identificación y cuantificación de productos de degradación de equipos médicos poliméricos (ISO 10993-13:1998, IDT)
NC ISO 10993-14	2009	Evaluación biológica de equipos médicos. Parte 14: Identificación y cuantificación de los productos de degradación de materiales
NC ISO 10993-15	2009	Evaluación biológica de equipos médicos. Parte 15: Identificación y cuantificación de los productos de degradación de metales y aleaciones (ISO 10993-15:2000, IDT)
NC ISO 10993-16	2005	Evaluación biológica en equipos médicos. Parte 16: Diseño del estudio toxicocinético de productos de degradación lixiviables. (ISO 10993-16:1997, IDT)
NC ISO 10993-17	2009	Evaluación biológica de equipos y dispositivos médicos. Parte 17: Establecimiento de los límites permisibles para sustancias lixiviables (ISO 10993-17:2002, IDT)
NC ISO 10993-18	2013	Evaluación biológica de equipos médicos. Parte 18: Caracterización química de materiales (ISO 10993-18:2005, IDT)
3. **INVESTIGACIONES CLÍNICAS**		
NORMA	**AÑO**	**TÍTULO**
ISO 14155/Cor 1:2011	2011	Clinical investigation of medical devices for human subjects. Good clinical practice
NC ISO 14155-1	2006	Investigación clínica de equipos médicos en sujetos humanos. Parte 1: Requisitos generales (ISO 14155-1:2003, IDT)
NC ISO 14155-2	2006	Investigación clínica de equipos médicos en sujetos humanos. Parte 2: Planes de investigaciones clínicas (ISO 14155-2:2003, IDT)
4. **EQUIPOS MÉDICOS CON FUNCIÓN DE MEDICIÓN**		
NORMA	**AÑO**	**TÍTULO**
DG 01	2015	Instrumentos de medición sujetos a la verificación obligatoria y a aprobación de modelo según los campos de aplicación donde serán utilizados (nueva revisión aprobada por Resolución de sep. 2014 - vigente desde 1 ene 2015)
NC 599	2019	Esfigmomanómetros. Métodos y equipos de verificación
NC 1168	2017	Termómetros clínicos (de líquido en vidrio, con dispositivo de máxima). Métodos y equipos de verificación
NC 1169	2017	Termómetros eléctricos clínicos con dispositivo de máxima. Métodos y equipos de verificación
NC 1281	2019	Esfigmomanómetros automatizados. Métodos y equipos de verificación
NC ISO 10012	2007	Sistemas de gestión de las mediciones. Requisitos para los

		procesos de medición y los equipos de medición (ISO 10012:2003, IDT)
NC OIML D 23	2002	Principios del control metrológico de equipos usados para la verificación
NC OIML R 7	2002	Termómetros clínicos (de mercurio, con dispositivo de máxima). (OIML R-7:1979, IDT)
OIML D 31	2008	Requisitos generales para los instrumentos de medida controlados por software
OIML G 19	2017	The role of measurement uncertainty in conformity assessment decisions in legal metrology
OIML R 16-1	2002	Non-invasive mechanical sphygmomanometers
OIML R 16-2	2002	Non-invasive automated sphygmomanometers
OIML R 26	1978	Medical syringes
OIML R 89	1990	Electroencephalographs. Metrological characteristics. Methods and equipment for verification
OIML R 90	1990	Electrocardiographs. Metrological characteristics. Methods and equipment for verification
OIML R 114	1995	Clinical electrical thermometers for continuous measurement
OIML R 115	1995	Clinical electrical thermometers with maximum device
OIML R 122	1996	Equipment for speech audiometry
5. **NORMAS ESPECÍFICAS DE PRODUCTO**		
5.1. **DE SIMPLE USO**		
NORMA	**AÑO**	**TÍTULO**
EN 1618	1997	Catheters other than intravascular catheters. Test methods for common properties
ISO 1135-3	2016	Transfusion equipment for medical use. Part 3: Blood-taking set
ISO 1135-4	2015	Transfusion equipment for medical use. Part 4: Transfusion sets for single use
ISO 1135-5	2015	Transfusion equipment for medical use. Part 5: Transfusion sets for single use with pressure infusion apparatus
ISO 3826-1	2013	Plastics collapsible containers for human blood and blood components. Part 1: Conventional containers
ISO 3826-2	2008	Plastics collapsible containers for human blood and blood components. Part 2: Graphical symbols for use on labels and instruction leaflets
ISO 3826-3	2006	Plastics collapsible containers for human blood and blood components. Part 3: Blood bag systems with integrated features
ISO 3826-4	2015	Plastics collapsible containers for human blood and blood components. Part 4: Aphaeresis blood bag systems with integrated features
ISO 4074	2015	Natural rubber latex male condoms. Requirements and test methods
ISO 7439	2015	Copper-bearing contraceptive intrauterine devices. Requirements and tests
ISO 7864	2016	Sterile hypodermic needles for single use. Requirements and test methods
ISO 7886-1	2017	Sterile hypodermic syringes for single use. Part 1: Syringes for manual use
ISO 7886-4	2018	Sterile hypodermic syringes for single use. Part 4: Syringes with re-use prevention feature
ISO 8536-4 / Amd 1:2013	2010	Infusion equipment for medical use. Part 4: Infusion sets for single use, gravity feed
ISO 8536-13	2016	Infusion equipment for medical use. Part 13: Graduated flow regulators for single use with infusion sets
ISO 10282	2014	Single-use sterile rubber surgical gloves. Specification
ISO 10555-1 / Amd 1:2017	2013	Intravascular catheters. Sterile and single-use catheters. Part 1: General requirements
ISO 10555-3	2013	Intravascular catheters. Sterile and single-use catheters. Part 3: Central venous catheters
ISO 10555-4	2013	Intravascular catheters. Sterile and single-use catheters. Part 4: Balloon dilatation catheters
ISO 10555-5	2013	Intravascular catheters. Sterile and single-use catheters. Part 5: Over-needle peripheral catheters
ISO 10555-6	2015	Intravascular catheters. Sterile and single-use catheters. Part 6: Subcutaneous implanted ports
ISO 11070/Amd 1:2018	2014	Sterile single-use intravascular introducers, dilators and guidewires
ISO 11193-1 / Amd 1: 2012	2008	Single-use medical examination gloves. Part 1: Specification for gloves made from rubber latex or rubber solution
ISO 11193-2	2006	Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride)

ISO 11249	2018	Copper-bearing intrauterine contraceptive devices. Guidance on the design, execution, analysis and interpretation of clinical studies
ISO 20697	2018	Sterile drainage catheters and accessory devices for single use
ISO 25841	2017	Female condoms. Requirements and test methods
ISO 20698	2018	Catheter systems for neuraxial application. Sterile and single-use catheters and accessories
NC ISO 4074	2016	Condones Masculinos de Látex de Caucho Natural. Requisitos y Métodos de Ensayo
NC ISO 10555-1	2016	Catéteres intravasculares estériles de un solo uso. Parte 1: Requisitos generales (ISO 10555-1: 2013, IDT)

5.2. **ELECTROMECÁNICOS**

NORMA	**AÑO**	**TÍTULO**
IEC 60601-1	2005	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
IEC 60601-1 (ed. consolidada)	2012	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	2014	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
IEC 60601-1-3 (ed. consolidada)	2013	Medical electrical equipment. Part 1-3: General requirements for basic safety and essential performance. Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6 (ed. consolidada)	2013	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
IEC 60601-1-8 (ed. consolidada)	2012	Medical electrical equipment. Part 1-8: General requirements for basic safety and essential performance. Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-12	2014	Medical electrical equipment. Part 1-12: General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 60601-2-1 (ed. consolidada)	2014	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
IEC 60601-2-2	2017	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
IEC 60601-2-3 (ed. consolidada)	2016	Medical electrical equipment. Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
IEC 60601-2-4 (ed. consolidada)	2018	Medical electrical equipment. Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
IEC 60601-2-5	2009	Medical electrical equipment. Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
IEC 60601-2-6 (ed. consolidada)	2016	Medical electrical equipment. Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
IEC 60601-2-8 (ed. consolidada)	2015	Medical electrical equipment. Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
IEC 60601-2-10 (ed. consolidada)	2016	Medical electrical equipment. Part 2-10. Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-2-11	2013	Medical electrical equipment. Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment
IEC 60601-2-16	2018	Medical electrical equipment. Part 2-16. Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
IEC 60601-2-17	2013	Medical electrical equipment. Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

IEC 60601-2-18	2009	Medical electrical equipment. Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-19 (ed. consolidada)	2016	Medical electrical equipment. Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
IEC 60601-2-20 (ed. consolidada)	2016	Medical electrical equipment. Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
IEC 60601-2-21 (ed. consolidada)	2016	Medical electrical equipment. Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
IEC 60601-2-22 (ed. consolidada)	2012	Medical electrical equipment. Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-23	2011	Medical electrical equipment. Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
IEC 60601-2-24	2012	Medical electrical equipment. Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
IEC 60601-2-25	2011	Medical electrical equipment. Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27	2011	Medical electrical equipment. Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-2-28	2017	Medical electrical equipment. Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-29	2008	Medical electrical equipment. Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
IEC 60601-2-31 (ed. consolidada)	2011	Medical electrical equipment. Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source
IEC 60601-2-33 (ed. consolidada)	2015	Medical electrical equipment. Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC 60601-2-34	2011	Medical electrical equipment. Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-36	2014	Medical electrical equipment. Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
IEC 60601-2-37 (ed. consolidada)	2015	Medical electrical equipment. Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-39	2018	Medical electrical equipment. Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
IEC 60601-2-40	2016	Medical electrical equipment. Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
IEC 60601-2-41 (ed. consolidada)	2013	Medical electrical equipment. Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
IEC 60601-2-43 (ed. consolidada)	2017	Medical electrical equipment. Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-44 (ed. consolidada)	2016	Medical electrical equipment. Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
IEC 60601-2-45 (ed. consolidada)	2015	Medical electrical equipment. Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-46	2016	Medical electrical equipment. Part 2-46: Particular requirements for

		the basic safety and essential performance of operating tables
IEC 60601-2-47	2012	Medical electrical equipment. Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 60601-2-52 (ed. consolidada)	2015	Medical electrical equipment. Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
IEC 60601-2-54 (ed. consolidada)	2018	Medical electrical equipment. Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-2-62	2013	Medical electrical equipment. Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
IEC 60601-2-63	2017	Medical electrical equipment. Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60601-2-64	2014	Medical electrical equipment. Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment
IEC 60601-2-65	2017	Medical electrical equipment. Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 60601-2-66	2015	Medical electrical equipment. Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
IEC 60601-2-68	2014	Medical electrical equipment. Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
IEC 60601-2-75	2017	Medical electrical equipment. Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment
IEC/TR 60601-4-1	2017	Medical electrical equipment. Part 4-1: Guidance and interpretation. Medical electrical equipment and medical electrical systems employing a degree of autonomy
IEC/TR 60601-4-2	2016	Medical electrical equipment. Part 4-2: Guidance and interpretation. Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC/TR 60601-4-3	2018	Medical electrical equipment. Part 4-3: Guidance and interpretation. Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements
IEC 60731 (ed. consolidada)	2016	Medical electrical equipment. Dosimeters with ionization chambers as used in radiotherapy
IEC 60976	2007	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics
IEC 62563-1 (ed. consolidada)	2016	Medical electrical equipment. Medical image display systems. Part1: Evaluation methods
IEC 80601-2-26	2019	Medical electrical equipment. Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 80601-2-30	2018	Medical electrical equipment. Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 80601-2-49	2018	Medical electrical equipment. Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 80601-2-58 (ed. consolidada)	2016	Medical electrical equipment. Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
IEC 80601-2-59	2017	Medical electrical equipment. Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
IEC 80601-2-60	2019	Medical electrical equipment. Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
IEC 80601-2-71	2015	Medical electrical equipment. Part 2-71: Particular requirements for the basic safety and essential performance of functional Near-

		Infrared Spectroscopy (NIRS) equipment
ISO 80601-2-12	2011	Medical electrical equipment. Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-13 / Amd 1: 2015 / Amd 2: 2018	2011	Medical electrical equipment. Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
ISO 80601-2-55	2018	Medical electrical equipment. Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56	2017	Medical electrical equipment. Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61	2017	Medical electrical equipment. Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-69	2014	Medical electrical equipment. Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
ISO 80601-2-70	2015	Medical Electrical Equipment. Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
ISO 80601-2-72	2015	Medical electrical equipment. Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
ISO 80601-2-74	2017	Medical electrical equipment. Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
ISO 80601-2-79	2018	Medical electrical equipment. Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
ISO 80601-2-80	2018	Medical electrical equipment. Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
ISO 81060-1	2007	Non-invasive sphygmomanometers. Part 1: Requirements and test methods for non-automated measurement type
ISO 81060-2	2018	Non-invasive sphygmomanometers. Part 2: Clinical validation of intermittent measurement type
IEC/TR 60513	1994	Fundamental aspects of safety standards for medical electrical equipment
ISO/TR 13154	2017	Medical electrical equipment. Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph

5.3. **DISPOSITIVOS DE APOYO PARA PERSONAS CON DISCAPACIDAD**

NORMA	**AÑO**	**TÍTULO**
ISO 7176-2	2017	Wheelchairs. Part 2: Determination of dynamic stability of electrically powered wheelchairs
ISO 11199-1	1999	Walking aids manipulated by both arms. Requirements and test methods. Part 1: Walking frames
ISO 11199-2	2005	Walking aids manipulated by both arms. Requirements and test methods. Part 2: Rollators
ISO 11199-3	2005	Walking aids manipulated by both arms. Requirements and test methods. Part 3: Walking tables
ISO 11334-1	2007	Walking aids manipulated by one arm. Requirements and test methods. Part 1: Elbow crutches
ISO 11334-4	1999	Walking aids manipulated by one arm. Requirements and test methods. Part 4: Walking sticks with three or more legs
ISO 16840-2	2018	Wheelchair seating. Part 2: Determination of physical and mechanical characteristics of seat cushions intended to manage tissue integrity
NC 214	2002	Silla de ruedas de propulsión manual. Requisitos y métodos de ensayo.

5.4. **RADIOLÓGICOS PARA DIAGNÓSTICO Y TERAPIA**

NORMA	**AÑO**	**TÍTULO**
IEC CISPR 11 (ed. consolidada)	2019	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement
IEC 60825-1	2014	Safety of laser products. Part 1: Equipment classification and requirements
IEC 61223-3-2	2007	Evaluation and routine testing in medical imaging departments. Part 3-2: Acceptance tests. Imaging

		performance of mammographic X-ray equipment
IEC 61223-3-4	2000	Evaluation and routine testing in medical imaging departments. Part 3-4: Acceptance tests. Imaging performance of dental X-ray equipment
IEC 61223-3-5	2004	Evaluation and routine testing in medical imaging departments. Part 3-5: Acceptance tests. Imaging performance of computed tomography X-ray equipment
IEC 61331-1	2014	Protective devices against diagnostic medical X-radiation. Part 1: Determination of attenuation properties of materials
IEC 61331-2	2014	Protective devices against diagnostic medical X-radiation. Part 2: Translucent protective plates
IEC 61331-3	2014	Protective devices against diagnostic medical X-radiation. Part 3: Protective clothing, eyewear and protective patient shields
IEC 62464-1	2019	Magnetic resonance equipment for medical imaging. Part 1: Determination of essential image quality parameters
IEC 62945	2018	Radiation protection instrumentation. Measuring the imaging performance of X-ray computed tomography (CT) security-screening systems
IEC/TR 61948-1	2016	Nuclear medicine instrumentation. Routine tests. Part 1: Gamma radiation counting systems
IEC/TR 61948-2	2019	Nuclear medicine instrumentation. Routine tests. Part 2: Scintillation cameras and single photon emission computed tomography imaging
IEC/TR 61948-3	2018	Nuclear medicine instrumentation. Routine tests. Part 3: Positron emission tomographs
IEC/TR 61948-4	2019	Nuclear medicine instrumentation. Routine tests. Part 4: Radionuclide calibrators
ISO 3665	2011	Photography. Intra-oral dental radiographic film and film packets. Manufacturer specifications
ISO 4090	2001	Photography. Medical radiographic cassettes/screens/films and hard-copy imaging films. Dimensions and specifications
ISO 9236-1	2004	Photography. Sensitometry of screen/film systems for medical radiography. Part 1: Determination of sensitometric curve shape, speed and average gradient
ISO 9236-3	1999	Photography. Sensitometry of screen/film systems for medical radiography. Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography
ISO 15382	2015	Radiological protection. Procedures for monitoring the dose to the lens of the eye, the skin and the extremities
ISO 15708-1	2017	Non-destructive testing. Radiation methods for computed tomography. Part 1: Terminology
ISO 15708-2	2017	Non-destructive testing. Radiation methods for computed tomography. Part 2: Principles, equipment and samples
NC 352	2005	Dosímetros clínicos de referencia con cámaras de ionización utilizados en radioterapia. Métodos de verificación

5.5. **ESTOMATOLOGÍA**

NORMA	**AÑO**	**TÍTULO**
ISO 6872 /Amd 1:2018	2015	Dentistry. Ceramic materials
ISO 7405	2018	Dentistry. Evaluation of biocompatibility of medical devices used in dentistry
ISO 7492	2019	Dentistry. Dental explorer
ISO 7885	2010	Dentistry. Sterile injection needles for single use
ISO 10271	2011	Dental metallic materials. Corrosion test methods
ISO 10451	2010	Dentistry. Contents of technical file for dental implant systems
ISO 10637	2018	Dentistry. Central suction source equipment
ISO 13897	2018	Dentistry. Dental amalgam reusable mixing-capsules.
ISO 14801	2016	Dentistry. Implants. Dynamic loading test for endosseous dental implants
ISO 20608	2018	Dentistry. Powder jet handpieces and powders.
ISO 21533	2018	Dentistry. Reprocessable cartridge syringes for intraligamentary injections
ISO 22794	2007	Dentistry. Implantable materials for bone filling and augmentation in oral and maxillofacial surgery. Contents of a technical file
ISO 22803	2004	Dentistry. Membrane materials for guided tissue regeneration in oral and maxillofacial surgery. Contents of a technical file
ISO/TS 11405	2015	Dentistry. Testing of adhesion to tooth structure

5.6. **HOSPITAL GENERAL**

NORMA	**AÑO**	**TÍTULO**

BP	2015	Farmacopea Británica
FEUM	2017	Farmacopea de los Estados Unidos Mexicanos. Suplemento para Dispositivos Médicos. 4ta ed.
ISO 37	2017	Rubber, vulcanized or thermoplastic. Determination of tensile stress-strain properties
ISO 188	2011	Rubber, vulcanized or thermoplastic- Accelerated ageing and heat resistance tests
ISO 1658	2015	Natural rubber (NR). Evaluation procedure
ISO 7153-1	2016	Surgical instruments. Materials. Part 1: Metals
ISO 8600-1	2015	Endoscopes. Medical endoscopes and endotherapy devices. Part 1: General requirements
ISO 9626	2016	Stainless steel needle tubing for the manufacture of medical devices. Requirements and test methods
ISO 10334	1994	Implants for surgery. Malleable wires for use as sutures and other surgical applications
ISO 10524-1	2018	Pressure regulators for use with medical gases. Part 1: Pressure regulators and pressure regulators with flow-metering devices.
ISO 10524-2	2018	Pressure regulators for use with medical gases. Part 2: Manifold and line pressure regulators.
ISO 10819 / Amd 1: 2019	2013	Mechanical vibration and shock. Hand-arm vibration. Measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand
ISO 12891-1	2015	Retrieval and analysis of surgical implants. Part 1: Retrieval and handling
ISO 12891-2	2014	Retrieval and analysis of surgical implants. Part 2: Analysis of retrieved surgical implants
ISO 13402	1995	Surgical and dental hand instruments. Determination of resistance against autoclaving, corrosion and thermal exposure
ISO 14644-1	2015	Cleanrooms and associated controlled environments. Part 1: Classification of air cleanliness
ISO 14644-2	2015	Cleanrooms and associated controlled environments. Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 16054	2019	Implants for surgery. Minimum data sets for surgical implants
ISO 19227	2018	Implants for surgery. Cleanliness of orthopedic implants. General requirements
ISO 21171	2006	Medical gloves. Determination of removable surface powder
ISO 80369-3 / Amd 1: 2019	2016	Small-bore connectors for liquids and gases in healthcare applications. Part 3: Connectors for enteral applications
ISO 80369-7	2016	Small-bore connectors for liquids and gases in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications
ISO/TR 14283	2018	Implants for surgery. Essential principles of safety and performance.
NC 20-13	1985	Materiales y curación. Piezas, bastones y rollos de gasa. Especificaciones de calidad
NC 20-28	1987	Ciencias médicas. Instrumentos médicos metálicos. Especificaciones generales de calidad
NC 146	2017	Almohadillas sanitarias. Requisitos y métodos de ensayo
NC 887	2012	Aparatos de laboratorio. Baño termostático. Requisitos y especificaciones de calidad
NC 963	2013	Colectores de sangre arterial. Requisitos
NC 964	2013	Capilares de vidrio. Requisitos
Ph Eur	2015	Farmacopea Europea, 8va ed.
Ph. Int.	2018	The international pharmacopoeia. 8th ed.
USP 40 – NF 35	2017	Farmacopea de los Estados Unidos de América
5.6.1. **ESTERILIZACIÓN**		
NORMA	**AÑO**	**TÍTULO**
EN 556-2	2015	Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Part 2: Requirements for aseptically processed medical devices
ISO 11135 / Amd 1:2018	2014	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11137-2	2013	Sterilization of health care products. Radiation. Part 2: Establishing the sterilization dose
ISO 11137-3	2017	Sterilization of health care products. Radiation. Part 3: Guidance on dosimetric aspects of development, validation and routine control
ISO 11138-1	2017	Sterilization of health care products. Biological indicators. Part 1: General requirements
ISO 11138-2	2017	Sterilization of health care products. Biological indicators. Part 2: Biological indicators for ethylene oxide sterilization processes

ISO 11138-3	2017	Sterilization of health care products. Biological indicators. Part 3: Biological indicators for moist heat sterilization processes
ISO 11138-4	2017	Sterilization of health care products. Biological indicators. Part 4: Biological indicators for dry heat sterilization processes
ISO 11138-5	2017	Sterilization of health care products. Biological indicators. Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
ISO 11138-7	2019	Sterilization of health care products. Biological indicators. Part 7: Guidance for the selection, use and interpretation of results
ISO 11607-1	2019	Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2	2019	Packaging for terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-1	2018	Sterilization of medical devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products
ISO 11737-2	2009	Sterilization of medical devices. Microbiological methods. Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 13408-1 / Amd 1:2013	2008	Aseptic processing of health care products. Part 1: General requirements
ISO 13408-2	2018	Aseptic processing of health care products. Part 2: Sterilizing filtration
ISO 13408-7	2012	Aseptic processing of health care products. Part 7: Alternative processes for medical devices and combination products
ISO 14160	2011	Sterilization of health care products. Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives. Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
ISO 14937	2009	Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO/TS 16775	2014	Packaging for terminally sterilized medical devices. Guidance on the application of ISO 11607-1 and ISO 11607-2
ISO 17664	2017	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17665-1	2006	Sterilization of health care products. Moist heat. Part 1. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 18472	2018	Sterilization of health care products. Biological and chemical indicators. Test equipment
ISO 20857	2010	Sterilization of health care products. Dry heat. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 25424	2018	Sterilization of medical devices. Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical devices
ISO/TS 17665-3	2013	Sterilization of health care products. Moist heat. Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization
NC EN 556-1	2007	Esterilización de equipos y dispositivos médicos. Requisitos de los equipos y dispositivos médicos para ser designados “estéril”. Parte 1: Requisitos de los equipos y dispositivos médicos esterilizados en su estado final (EN 556-1:2001, IDT)
NC EN 556-2	2007	Esterilización de equipos y dispositivos médicos. Requisitos de los equipos y dispositivos médicos para ser designados “estéril”. Parte 2: Requisitos de los equipos y dispositivos médicos procesados asépticamente (EN 556-2: 2003, IDT)
NC ISO 11135	2004	Equipos Médicos. Validación y control de rutina de la esterilización por óxido de etileno (ISO 11135:1994, IDT)
NC ISO 11137-1	2017	Esterilización de productos para uso médico. Radiación. Parte 1: Requisitos para el desarrollo, la

		validación y el control de rutina de un proceso de esterilización para equipos médicos (ISO 11137-1:2006, IDT)
NC ISO 11137-2	2016	Esterilización de productos para uso médico. Radiación. Parte 2: Establecimiento de la dosis de esterilización (ISO 11137-2: 2006, IDT)
NC ISO 11137-3	2016	Esterilización de productos para uso médico. Radiación. Parte 3: Recomendaciones sobre los aspectos dosimétricos (ISO 11137-3: 2006, IDT)
NC ISO 17664	2010	Evaluación de equipos médicos. Información a proporcionar por el fabricante para el procesamiento de equipos médicos reesterilizables (ISO 17664:2004, IDT)
5.7. **IMPLANTES ACTIVOS**		
NORMA	**AÑO**	**TÍTULO**
ISO 14708-1	2014	Implants for surgery. Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-4	2008	Implants for surgery. Active implantable medical devices. Part 4: Implantable infusion pumps
ISO 14708-7	2013	Implants for surgery. Active implantable medical devices. Part 7: Particular requirements for cochlear implant systems
ISO/TS 10974	2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.
5.7.1. **CARDIOLOGÍA**		
NORMA	**AÑO**	**TÍTULO**
ISO 14708-2	2019	Implants for surgery. Active implantable medical devices. Part 2: Cardiac pacemakers
ISO 14708-3	2017	Implants for surgery. Active implantable medical devices. Part 3: Implantable neurostimulators
ISO 14708-6	2019	Implants for surgery. Active implantable medical devices. Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
ISO 25539-1	2017	Cardiovascular implants. Endovascular devices. Part 1: Endovascular prostheses
ISO 25539-2	2012	Cardiovascular implants. Endovascular devices. Part 2: Vascular stents
5.8. **IMPLANTES NO ACTIVOS**		
NORMA	**AÑO**	**TÍTULO**
ISO 5832-1	2016	Implants for surgery. Metallic materials. Part 1: Wrought stainless steel
ISO 5832-2	2018	Implants for surgery. Metallic materials. Part 2: Unalloyed titanium
ISO 5832-3	2016	Implants for surgery. Metallic materials. Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 5832-4	2014	Implants for surgery. Metallic materials. Part 4: Cobalt-chromium-molybdenum casting alloy
ISO 5832-6	1997	Implants for surgery. Metallic materials. Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
ISO 5832-9	2019	Implants for surgery. Metallic materials. Part 9: Wrought high nitrogen stainless steel
ISO 5832-11	2014	Implants for surgery. Metallic materials. Part 11: Wrought titanium 6-aluminium 7-niobium alloy
ISO 5832-12	2019	Implants for surgery. Metallic materials. Part 12: Wrought cobalt-chromium-molybdenum alloy
ISO 14602	2010	Non-active surgical implants. Implants for osteosynthesis. Particular requirements
ISO 14607	2018	Non-active surgical implants. Mammary implants. Particular requirements
ISO 14630	2012	Non active surgical implants. General requirements
ISO 16061	2015	Instrumentation for use in association with non-active surgical implants. General requirements
ISO 17327-1	2018	Non-active surgical implants. Implant coating. Part 1: General requirements
5.8.1. **ORTOPEDIA**		
NORMA	**AÑO**	**TÍTULO**
ISO 643	2012	Steels. Micrographic determination of the apparent grain size
ISO 4967	2013	Steel. Determination of content of non-metallic inclusions. Micrographic method using standard diagrams
ISO 5835	1991	Implants for surgery. Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread. Dimensions.
ISO 5836	1988	Implants for surgery. Metal bone plates. Holes corresponding to

		screws with asymmetrical thread and spherical under-surface
ISO 6475	1989	Implants for surgery. Metal bone screws with asymmetrical thread and spherical under-surface. Mechanical requirements and test methods
ISO 6892-1	2016	Metallic materials. Tensile testing. Part 1: Method of test at room temperature
ISO 8828	2014	Implants for surgery. Guidance on care and handling of orthopaedic implant
ISO 9268	1988	Implants for surgery. Metal bone screws with conical under-surface of head. Dimensions
ISO 9585	1990	Implants for surgery. Determination of bending strength and stiffness of bone plates
ISO 12189	2008	Implants for surgery. Mechanical testing of implantable spinal devices. Fatigue test method for spinal implant assemblies using an anterior support
ISO 19233-1	2017	Implants for surgery. Orthopaedic joint prosthesis. Part 1: Procedure for producing parametric 3D bone models from CT data of the knee
ISO 21534	2007	Non-active surgical implants. Joint replacement implants. Particular requirements
NC 298	2012	Vendas enyesadas. Especificaciones
NC 20-02	1983	Artificios ortopédicos. Términos y definiciones
NC 20-05	1984	Juego ortopédico para fijaciones externas. Tipo RALCA
5.8.2. **CARDIOLOGÍA**		
NORMA	**AÑO**	**TÍTULO**
ISO 5840-1	2015	Cardiovascular implants. Cardiac valve prostheses. Part 1: General requirements
ISO 5840-2	2015	Cardiovascular implants. Cardiac valve prostheses. Part 2: Surgically implanted heart valve substitutes
ISO 5840-3	2013	Cardiovascular implants. Cardiac valve prostheses. Part 3: Heart valve substitutes implanted by transcatheter techniques
ISO 5910	2018	Cardiovascular implants and extracorporeal systems. Cardiac valve repair devices.
ISO 7198	2016	Cardiovascular implants and extracorporeal systems. Vascular prostheses. Tubular vascular grafts and vascular patches
ISO 7199	2016	Cardiovascular implants and artificial organs. Blood-gas exchangers (oxygenators)
ISO 8637-1	2017	Extracorporeal systems for blood purification. Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
ISO 8637-2	2018	Extracorporeal systems for blood purification. Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
ISO 12417-1	2015	Cardiovascular implants and extracorporeal systems. Vascular device-drug combination products. Part 1: General requirements
ISO 12417-2	2017	Cardiovascular implants and extracorporeal systems. Vascular device-drug combination products. Part 2: Local regulatory information
ISO 15674	2016	Cardiovascular implants and artificial organs. Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags
ISO 15675	2016	Cardiovascular implants and artificial organs. Cardiopulmonary bypass systems. Arterial blood line filters
5.9. **OFTALMOLOGÍA Y EQUIPOS ÓPTICOS**		
NORMA	**AÑO**	**TÍTULO**
ISO 8980-1	2017	Ophthalmic optics. Uncut finished spectacle lenses. Part 1: Specifications for single-vision and multifocal lenses
ISO 8980-2	2017	Ophthalmic optics. Uncut finished spectacle lenses. Part 2: Specifications for power-variation lenses
ISO 8980-3	2013	Ophthalmic optics. Uncut finished spectacle lenses. Part 3: Transmittance specifications and test methods
ISO 8980-4	2006	Ophthalmic optics. Uncut finished spectacle lenses. Part 4: Specifications and test methods for anti-reflective coatings
ISO 8980-5	2005	Ophthalmic optics. Uncut finished spectacle lenses. Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant
ISO 11381	2016	Ophthalmic optics. Spectacle frames. Screw threads
ISO 11979-2	2014	Ophthalmic implants. Intraocular lenses. Part 2: Optical properties and test methods
ISO 11979-3	2012	Ophthalmic implants. Intraocular lenses. Part 3: Mechanical properties and test methods

ISO 11979-7	2018	Ophthalmic implants. Intraocular lenses. Part 7: Clinical investigations of intraocular lenses for the correction of aphakia.
ISO 11979-8	2017	Ophthalmic implants. Intraocular lenses. Part 8: Fundamental requirements
ISO 11980	2012	Ophthalmic optics. Contact lenses and contact lens care products. Guidance for clinical investigations
ISO 12867	2010	Ophthalmic instruments. Trial frames
ISO 12870	2016	Ophthalmic optics. Spectacle frames. Requirements and test methods
ISO 14889:2013 / Amd 1	2017	Ophthalmic optics. Spectacle lenses. Fundamental requirements for uncut finished lenses
ISO 15004-1	2006	Ophthalmic instruments. Fundamental requirements and test methods. Part 1: General requirements applicable to all ophthalmic instruments
ISO 21987	2017	Ophthalmic optics. Mounted spectacle lenses
ISO/TS 24348	2014	Ophthalmic optics. Spectacle frames. Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames
ISO/TR 28980	2007	Ophthalmic optics. Spectacle lenses. Parameters affecting lens power measurement
NC 20-27	1983	Armaduras metálicas de espejuelos. Especificaciones de calidad
5.10. **EQUIPOS DE ANESTESIA Y RESPIRACIÓN**		
NORMA	**AÑO**	**TÍTULO**
ISO 5361	2016	Anaesthetic and respiratory equipment. Tracheal tubes and connectors
ISO 5366	2016	Anaesthetic and respiratory equipment. Tracheostomy tubes and connector.
ISO 18190	2016	Anaesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 18562-1	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 1: Evaluation and testing within a risk management process
ISO 18562-2	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 2: Tests for emissions of particulate matter
5.11. **DISPOSITIVOS MÉDICOS PARA EL DIAGNÓSTICO IN VITRO**		
NORMA	**AÑO**	**TÍTULO**
CLSI EP05	2014	Evaluation of Precision of Quantitative Measurement Procedures
CLSI EP06	2003	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach
CLSI EP07	2018	Interference Testing in Clinical Chemistry
CLSI EP37	2018	Supplemental Tables for Interference Testing in Clinical Chemistry
CLSI EP09	2013	Measurement Procedure Comparison and Bias Estimation Using Patient Samples
CLSI EP10	2014	Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures
CLSI EP12	2008	User Protocol for Evaluation of Qualitative Test Performance
CLSI EP14	2014	Evaluation of Commutability of Processed Samples
CLSI EP15	2014	User Verification of Precision and Estimation of Bias
CLSI EP17	2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedure
CLSI EP18	2009	Risk Management Techniques to Identify and Control Laboratory Error Sources
CLSI EP32	2006	Metrological Traceability and Its Implementation
CLSI EP24	2011	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves
CLSI GP16	2009	Urinalysis
CLSI H21	2008	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assay
CLSI H42	2007	Enumeration of Immunologically Defined Cell Populations by Flow Cytometry
CLSI H47	2008	One-Stage Prothrombin Time (PT) Test and Activate Partial Thromboplastin Time (APTT) Test
CLSI I/LA20	2016	Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities
CLSI I/LA21	2008	Clinical Evaluation of Immunoassays
CLSI M02	2018	Performance Standards for Antimicrobial Disk Susceptibility Tests

CLSI M07	2018	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically
CLSI M100	2018	Performance Standards for Antimicrobial Susceptibility Testing
CLSI M23	2018	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters
CLSI M43-A	2011	Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas
CLSI M60	2017	Performance Standards for Antifungal Susceptibility Testing of Yeasts
CLSI M61	2017	Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi
CLSI MM01	2012	Molecular Methods for Clinical Genetics and Oncology Testing
CLSI MM03	2015	Molecular Diagnostic Methods for Infectious Diseases
CLSI MM05	2012	Nucleic Acid Amplification Assays for Molecular Hematopathology
CLSI MM06	2010	Quantitative Molecular Methods for Infectious Diseases
CLSI MM09	2014	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine
CLSI MM12	2006	Diagnostic Nucleic Acid Microarrays
CLSI MM13	2005	Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline
CLSI MM17	2018	Verification and Validation of Multiplex Nucleic Acid Assays
CLSI MM18	2008	Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing
CLSI POCT14	2004	Point-of-Care Monitoring of Anticoagulation Therapy
EN 12322/ Amd1:2001	1999	Productos sanitarios para diagnóstico in vitro. Medios de cultivo para microbiología. Criterios para las características funcionales de los medios de cultivo
ISO 11133	2014	Microbiology of food, animal feed and water. Preparation, production, storage and performance testing of culture media
ISO 15193	2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for content and presentation of reference measurement procedures
ISO 15194	2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for certified reference materials and the content of supporting documentation
ISO 15197	2013	In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
ISO 15198	2004	Clinical laboratory medicine. In vitro diagnostic medical devices. Validation of user quality control procedures by the manufacturer
ISO 16256	2012	Clinical laboratory testing and in vitro diagnostic test systems. Reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases
ISO 17511	2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
ISO 17593	2007	Clinical laboratory testing and in vitro medical devices. Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy
ISO 18113-1	2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements
ISO 18113-3	2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 3: In vitro diagnostic instruments for professional use
ISO 18113-5	2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 5: In vitro diagnostic instruments for self-testing
ISO 18153	2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials
ISO 20776-1	2006	Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices. Part 1: Reference method for testing the

		in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases
ISO 20776-2	2007	Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices. Part 2: Evaluation of performance of antimicrobial susceptibility test devices
ISO 20916	2019	In vitro diagnostic medical devices. Clinical performance studies using specimens from human subjects. Good study practice
ISO/TS 17822-1	2014	In vitro diagnostic test systems. Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens. Part 1: General requirements, terms and definitions
NC EN 13532	2006	Requisitos generales de los diagnosticadores para autoensayo (EN 13532:2002, IDT)
NC EN 13612	2006	Evaluación del funcionamiento de los diagnosticadores (EN 13612:2002, IDT)
NC EN 13641	2004	Eliminación o reducción del riesgo de infección relacionado con los diagnosticadores (EN 13641: 2002, IDT)
NC EN 13975	2006	Procedimientos de muestreo utilizados para los ensayos de aceptación de los diagnosticadores. Aspectos estadísticos (EN 13975:2003, IDT)
NC EN 14136	2006	Utilización de programas de evaluación externa de la calidad en la evaluación del desempeño de los procedimientos de diagnóstico in vitro (EN 14136:2004, IDT)
NC ISO 15189	2016	Laboratorios clínicos. Requisitos para la calidad y la competencia (ISO 15189:2012, IDT)
NC ISO 18113-2	2011	Dispositivos médicos para diagnóstico in vitro. Información suministrada por el fabricante (rotulado). Parte 2: Reactivos para diagnóstico in vitro (diagnosticadores) para uso profesional (ISO 18113-2:2009, IDT)
NC ISO 18113-4	2012	Dispositivos médicos para diagnóstico in vitro. Información suministrada por el fabricante (rotulado). Parte 4: Reactivos para diagnóstico in vitro (diagnosticadores) para autoensayo (ISO 18113-4: 2009, IDT)
NC ISO 19001	2019	Dispositivos médicos para diagnóstico in vitro. Información proporcionada por el fabricante con los reactivos para diagnóstico in vitro utilizados para tinción en biología (ISO 19001:2013, IDT)
NC ISO 23640	2018	Dispositivos médicos para diagnóstico in vitro. Evaluación de la estabilidad de los reactivos para diagnóstico in vitro (ISO 23640: 2011, IDT)

6. **SOFTWARE MÉDICO**

NORMA	**AÑO**	**TÍTULO**
IEC 62304 (ed. consolidada)	2015	Medical device software. Software life cycle processes
IEC 82304-1	2016	Health software. Part 1: General requirements for product safety
IEC/TR 80002-1	2009	Medical device software. Part 1: Guidance on the application of ISO 14971 to medical device software
IEC/TR 80002-3	2014	Medical device software. Part 3: Process reference model of medical device software life cycle processes (IEC 62304)
ISO/IEC 25000	2014	Systems and software engineering. Systems and software Quality Requirements and Evaluation (SQuaRE). Guide to SQuaRE
ISO/IEC/IEEE 90003	2018	Software engineering. Guidelines for the application of ISO 9001:2015 to computer software
ISO/IEC/IEEE 12207	2017	Systems and software engineering. Software life cycle processes
ISO/IEC/IEEE 15288	2015	Systems and software engineering. System life cycle processes
ISO/IEEE 11073-10419	2019	Health informatics. Personal health device communication. Part 10419: Device specialization. Insulin pump
ISO/TR 80002-2	2017	Medical device software. Part 2: Validation of software for medical device quality systems
ISO/TS 20405	2018	Health informatics. Framework of event data and reporting definitions for the safety of health software
NC ISO/IEC 12119	2005	Tecnología de la información. Paquetes de software. Requisitos de calidad y ensayos/pruebas (ISO/IEC 12119: 1994, IDT)
NC ISO/IEC 25010	2016	Ingeniería de software y sistemas. Requisitos de la calidad y evaluación de software (SQuaRE). Modelos de la calidad de software

		y sistemas (ISO/IEC 25010:2011, IDT)
NC ISO/IEC/TS 25011	2018	Tecnología de la información. Requisitos de la calidad y evaluación de software y de sistemas (SQuaRE). Modelo de la calidad y los servicios (ISO/IEC TS 25011: 2017, IDT)
NC ISO/IEC 25012	2018	Ingeniería de software y sistemas. Requisitos de la calidad y evaluación del producto de software (SQuaRE). (ISO/IEC 25012: 2008, IDT)
NC ISO/IEC 25020	2016	Ingeniería de software. Requisitos de la calidad y evaluación del producto de software (SQuaRE). Modelo de referencia y guía para las mediciones (ISO/IEC 25020:2007, IDT)
NC ISO/IEC 25022	2018	Ingeniería de software y sistemas. Requisitos de la calidad y evaluación de software y sistemas (SQuaRE). Medición de la calidad en el uso. (ISO/IEC 25022: 2016, IDT)
NC ISO/IEC 25030	2017	Ingeniería de software. Requisitos de la calidad y evaluación de productos de software (SQUARE). Requisitos de la calidad (ISO/IEC 25030: 2007, IDT)
NC ISO/IEC 25040	2016	Ingeniería de software y sistemas. Requisitos de la calidad y evaluación de software y sistemas (SQuaRE). Proceso de evaluación (ISO/IEC 25040:2011, IDT)

7. **ENSAYOS DE LABORATORIO**

NORMA	**AÑO**	**TÍTULO**
IEC 60068-1	2013	Environmental testing. Part 1: General and guidance
IEC 60068-3-1	2011	Environmental testing. Part 3-1: Supporting documentation and guidance. Cold and dry heat tests
IEC 60721-1 (ed. consolidada)	1995	Classification of environmental conditions. Part 1: Environmental parameters and their severities
IEC 60721-2-1	2013	Classification of environmental conditions. Part 2-1: Environmental conditions appearing in nature. Temperature and humidity
IEC 61010-1 (ed. consolidada)	2016	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements
IEC 61010-2-010	2019	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-040	2015	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
IEC 61010-2-051	2018	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
IEC 61010-2-101	2018	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-201	2017	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-201: Particular requirements for control equipment
IEC 61326-2-6	2012	Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 2-6: Particular requirements. In vitro diagnostic (IVD) medical equipment
IEC/TR 62354	2014	General testing procedures for medical electrical equipment
ISO 23529	2016	Rubber. General procedures for preparing and conditioning test pieces for physical test method

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