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

OLGA LIDIA JACOBO CASANUEVA
DIRECTORA

RESOLUCIÓN No. 124 **/ 2024**

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

POR CUANTO: Por Resolución No. 165 de fecha 14 de abril del año 2014, emitida por el MINSAP, 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 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 Reguladora de Normas como una herramienta para la demostración de los principios esenciales de seguridad y desempeño de los dispositivos médicos.

POR CUANTO: Por Resolución No. 91 de fecha 14 de diciembre del año 2023, dispuesta por el CECMED, se aprobo y puso en vigor la edición 18 de la *Lista Regulatoria de Normas*, Lista de normas reconocidas por el CECMED para la demostración de los principios esenciales de seguridad y desempeño de los dispositivos médicos, incluyendo los dispositivos médicos para diagnóstico *in vitro*, correspondiente al año 2023.

POR CUANTO: Por Regulación ER 9-2012 *Empleo de las Normas en la Evaluación y Registro de los Equipos Médicos*, se establece que la Lista Regulatoria de Normas tenga una frecuencia de actualización anual. Por ello, se procede a su revisión y emisión de la actualización correspondiente al año 2024.

POR TANTO: En el ejercicio de todas las funciones y atribuciones inherentes que me están conferidas como Directora del CECMED, por Resolución No. 2 de fecha 6 de enero del año 2021, emitida por el MINSAP,

RESUELVO

PRIMERO: Aprobar y poner en vigor la Edición 19, correspondiente al año 2024 de la Regulación E 102-24 *Lista Regulatoria de Normas*, que se adjunta a la presente Resolución como Anexo Único y forma parte integrante de la misma.

SEGUNDO: Derogar la Resolución No. 91 de fecha 14 de diciembre del año 2023, dispuesta por el CECMED.

TERCERO: La presente Resolución será aprobada a partir de la fecha de su firma y entrará en vigor a partir de la fecha de su publicación en el Boletín Ámbito Regulador.

NOTIFÍQUESE al Departamento de Equipos y Dispositivos Médicos y a las demás estructuras correspondientes del CECMED.

COMUNÍQUESE a cuantos Titulares de Registros, empresas y compañías relacionadas con la fabricación, distribución, importación, suministros y distribución de equipos y dispositivos médicos proceda; al Grupo de las Industrias Biotecnológica y Farmacéutica, BioCubaFarma; a la Empresa MEDICuba S.A.; a la Empresa de Suministros Médicos, EMSUME; al Comité Técnico de Normalización No. 11 de Equipos Médicos; al Comité Técnico de Normalización No. 102 de Diagnosticadores, así como a cuantas personas naturales o jurídicas proceda.

DESE CUENTA a la Dirección de Ciencia y Tecnología, a la Dirección de Medicamentos y Tecnología Sanitaria y a la Dirección de Salud Ambiental del MINSAP.

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 sede del CECMED, en La Habana a los 26 días del mes de diciembre del año 2024. "Año 66 de la Revolución".

M. Sc. Olga Lidia Jacobo Casanueva
Directora

ANEXO ÚNICO

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CECMED

REGULACIÓN E 102-24

LISTA REGULATORIA DE NORMAS

Edición 19

(Lista de normas reconocidas por el CECMED para la demostración del cumplimiento de los principios esenciales de seguridad y desempeño de los dispositivos médicos, incluyendo dispositivos médicos para diagnóstico *in vitro*)

2024

Calle 5ta A, Número 6020, entre 60 y 62, Reparto Miramar, Municipio Playa, La Habana. CP 11300
Telef: (537) 2164100, 2164147, 2164148. E-mail: cecmed@cecmed.cu. Web: www.cecmed.cu

Notas a la presente edición

La Lista Regulatoria de Normas, en lo adelante LRN, es la lista de normas reconocidas por el CECMED para la demostración del cumplimiento de los principios esenciales de seguridad y desempeño de los dispositivos médicos, incluyendo a los dispositivos médicos para diagnóstico *in vitro*.

Las normas cumplen un papel fundamental en todo el ciclo de vida de los dispositivos médicos. Se utilizan para demostrar conformidad en los procesos regulatorios relacionados con el registro sanitario, la inscripción del fabricante, las investigaciones clínicas y con otras autorizaciones que emite la autoridad reguladora. Son la base para ejecutar los ensayos clínicos, técnicos, biológicos y la evaluación del desempeño a los dispositivos médicos. En cada uno de estos procesos se requiere y comprueba la conformidad con el cumplimiento de las normas.

Las organizaciones y organismos internacionales relacionados con la regulación de los dispositivos médicos recomiendan que las normas tengan propósitos reguladores, lo cual facilita el trabajo de las autoridades a partir de la exigencia de requisitos armonizados con dichas normas y del establecimiento de mecanismos de reconocimiento y confianza reguladora. Por ello, esta regulación toma como referencia los documentos:

- GHTF/SG1/N044:2008 *Role of Standards in the assessment of medical devices*
- IMDRF/Standards WG/N15 FINAL: 2014 *List of International standards recognized by IMDRF members*
- IMDRF/Standards WG/N51 FINAL: 2018 *Optimizing Standards for Regulatory Use*
- IMDRF/GRRP WG/N47: 2024 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.*

Esta 19na edición cumple los principios de las Buenas Prácticas Reguladoras del CECMED, fundamentalmente en lo que a legalidad, claridad, flexibilidad y transparencia se refiere.

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

Amd	*Amendment* /Enmienda
CLSI	*Clinical and Laboratory Standards Institute* /Instituto de Normas Clínicas y de Laboratorio
Cor	*Corrigendum* /Corrección
ed.	Edición
EN	*European Norm* /Norma europea
IEC	*International Electrotechnical Commission* /Comisión Electrotécnica Internacional
IEEE	*Institute of Electrical and Electronics Engineers* /Instituto de Ingenieros Electrónicos y Eléctricos
ISO	*International Organization for Standardization* /Organización Internacional de Normalización
NC	Norma Cubana
OIML	Organización Internacional de Metrología Legal

Las normas cubanas (NC) con alcance a los diagnosticadores, tal cual se refiere en su título, se aplican a los dispositivos médicos para diagnóstico *in vitro* que son reactivos, calibradores, y materiales de control.

Control de cambios

Se adicionan 11 normas, se eliminan 29 normas y se actualiza la edición de otras 31. Ninguna de las categorías tuvo un incremento significativo. Las normas incluidas, eliminadas y reemplazadas se relacionan en el acápite I de Cambios introducidos en la nueva edición 2024 de la Lista Regulatoria de Normas, páginas de la 7 a la 11, del cuerpo de esta disposición reguladora.

Se elimina el anexo referido a las normas que el CECMED reconoce en la declaración de conformidad con los principios esenciales para dispositivos médicos empleados en el enfrentamiento a la COVID-19, que se venía publicando desde la edición 15 (2020), toda vez que la OMS declaró, en mayo de 2023, el cese de la pandemia. Las normas que se incluían en dicho anexo aparecen listadas en el cuerpo principal de la Lista, en la categoría correspondiente.

Tabla de contenido

I. Cambios introducidos en la nueva edición 2024 de la Lista Regulatoria de Normas

Normas adicionadas

NORMA	AÑO	TÍTULO
EN 556-1	2024	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 1: Requirements for terminally sterilized medical devices
IEC 61223-3-8	2024	Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests. Imaging performance of X-ray equipment for radiography and radioscopy
IEC 61674	2024	Medical electrical equipment. Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging
ISO 10555-7	2023	Intravascular catheters. Sterile and single-use catheters. Part 7: Peripherally inserted central catheters
ISO 17665	2024	Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 23217	2024	Injection systems for self-administration by paediatric patients. Requirements and guidelines for design
ISO/IEC 25059	2023	Software engineering. Systems and software Quality Requirements and Evaluation (SQuaRE). Quality model for AI systems
NC ISO 20658	2024	Requisitos para la Toma y el Transporte de Muestras para Análisis en el Laboratorio Clínico [ISO 20658: 2023, (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 20916	2023	Dispositivos Médicos para Diagnóstico *In Vitro*. Estudios de Desempeño Clínico con Muestras de Seres Humanos. Buenas Prácticas de Estudio (ISO 20916: 2019, IDT)
NC ISO 35001	2021	Gestión del Riesgo Biológico en Laboratorios y otras organizaciones relacionadas (ISO 35001:2019, IDT)
UNE-EN IEC 62471-6	2023	Seguridad fotobiológica de lámparas y de los aparatos que utilizan lámparas. Parte 6: Productos con lámparas de ultravioleta

Normas eliminadas

NORMA	AÑO	TÍTULO
IEC/TR 80001-2-1	2012	Application of risk management for IT-networks incorporating medical devices. Part 2-1: Step by step risk management of medical IT-networks. Practical applications and examples *Derogada por IEC*
IEC/TR 80001-2-3	2012	Application of risk management for IT-networks incorporating medical devices. Part 2-3: Guidance for wireless networks *Derogada por IEC*

NORMA	AÑO	TÍTULO
IEC/TR 80001-2-4	2012	Application of risk management for IT-networks incorporating medical devices. Part 2-4: Application guidance. General implementation guidance for healthcare delivery organizations *Derogada por IEC*
IEC/TR 80002-3	2014	Medical device software. Part 3: Process reference model of medical device software life cycle processes (IEC 62304) *Derogada por IEC*
ISO 14155	2020	Clinical investigation of medical devices for human subjects. Good clinical practice *Se incluye NC de adopción IDT a esta ISO vigente*
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 *Derogada por ISO*
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 *Derogada por ISO*
ISO 20658	2023	Requirements for the collection and transport of samples for medical laboratory examinations *Se incluye NC de adopción IDT a esta ISO vigente*
ISO 20916	2019	*In vitro* diagnostic medical devices. Clinical performance studies using specimens from human subjects. Good study practice *Se incluye NC de adopción IDT a esta ISO vigente*
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 *Sustituida por la ISO 17665: 2024*
NC 19-04-23	1985	Sistema de normas de protección e higiene del trabajo. Medios de protección dermatológica. Clasificación y requisitos generales *No aplica como dispositivo médico*
NC 20-27	1985	Armaduras metálicas de espejuelos. Especificaciones de calidad *Derogada por la ONN*
NC 887	2012	Aparatos de laboratorio. Baño termostático. Requisitos y especificaciones de calidad *No aplica como dispositivo médico*
NC 1400-2	2021	Industria del *software*. Modelo de la calidad para el desarrollo de aplicaciones informáticas (MCDAI). Parte 2: Requisitos *No aplica como dispositivo médico*
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)

NORMA	AÑO	TÍTULO
		La norma ISO por la que se adoptó idéntica fue derogada
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) *La norma ISO por la que se adoptó idéntica fue derogada*
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) *La norma ISO por la que se adoptó idéntica fue derogada*
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) *La norma ISO por la que se adoptó idéntica fue derogada*
NC ISO 10993-10	2020	Evaluación biológica de equipos médicos. Parte 10: Ensayos de irritación y de sensibilización cutánea (ISO 10993-10:2010, IDT) *La norma ISO por la que se adoptó idéntica fue derogada*
NC ISO 10993-11	2010	Evaluación biológica de equipos médicos. Parte 11: Ensayos de toxicidad sistémica (ISO 10993-11:2006, IDT) *La norma ISO por la que se adoptó idéntica fue derogada*
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) *La norma ISO por la que se adoptó idéntica fue derogada*
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) *La norma ISO por la que se adoptó idéntica fue derogada*
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) *La norma ISO por la que se adoptó idéntica fue derogada*
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) *La norma ISO por la que se adoptó idéntica fue derogada*
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) *La norma ISO por la que se adoptó idéntica fue derogada*
NC ISO 10993-18	2013	Evaluación biológica de equipos médicos. Parte 18: Caracterización química de materiales (ISO 10993-18:2005, IDT) *La norma ISO por la que se adoptó idéntica fue derogada*
NC ISO/IEC/IEEE 12207	2021	Ingeniería de *software* y sistemas. Procesos del ciclo de vida del *software* (ISO/IEC/IEEE 12207:2017, IDT)

NORMA	AÑO	TÍTULO
		Existen normas incluidas que son específicas para el ciclo de vida del software médico.
NC ISO/IEC/IEEE 15288	2020	Ingeniería de *software* y sistemas. Procesos del ciclo de vida del sistema (ISO/IEC/IEEE 15288:2015, IDT) *Existen normas incluidas que son específicas para el ciclo de vida del software médico*
UNE 0068	2020	Requisitos de seguridad para aparatos UV-C utilizados para la desinfección de aire de locales y superficies *Sustituida por la UNE-EN IEC 62471-6:2023*

Normas actualizadas (ediciones reemplazadas)

NORMA	AÑO	TÍTULO
CISPR 11	2024	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement *Anteriormente CISPR 11: 2015*
CLSI H21	2024	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assay *Anteriormente CLSI H21: 2008*
CLSI M02	2024	Performance Standards for Antimicrobial Disk Susceptibility Tests *Anteriormente CLSI M02: 2018*
CLSI M07	2024	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically *Anteriormente CLSI M02: 2018*
CLSI M100	2024	Performance Standards for Antimicrobial Susceptibility Testing *Anteriormente CLSI M100: 2023*
CLSI MM01	2023	Molecular Methods for Clinical Genetics and Oncology Testing *Anteriormente CLSI MM01: 2012*
IEC 61010-2-201	2024	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-201: Particular requirements for control equipment *Anteriormente IEC 61010-2-201: 2017*
IEC 80601-2-58	2024	Medical electrical equipment. Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery *Anteriormente IEC 80601-2-58: 2016*
IEC/TR 60601-4-2	2024	Medical electrical equipment. Part 4-2: Guidance and interpretation. Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems *Anteriormente IEC/TR 60601-4-2:2016*
ISO 37	2024	Rubber, vulcanized or thermoplastic. Determination of tensile stress-strain properties *Anteriormente ISO 37: 2017*

NORMA	AÑO	TÍTULO
ISO 5832-1	2024	Implants for surgery. Metallic materials. Part 1: Wrought stainless steel *Anteriormente ISO 5832-1:2016*
ISO 5832-4	2024	Implants for surgery. Metallic materials. Part 4: Cobalt-chromium-molybdenum casting alloy *Anteriormente ISO 5832-1:2014*
ISO 5832-11	2024	Implants for surgery. Metallic materials. Part 11: Wrought titanium 6-aluminium 7-niobium alloy *Anteriormente ISO 5832-11:2014*
ISO 8637-1	2024	Extracorporeal systems for blood purification. Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators *Anteriormente ISO 8637-1: 2017*
ISO 8637-2	2024	Extracorporeal systems for blood purification. Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters *Anteriormente ISO 8637-2: 2018*
ISO 10555-1	2023	Intravascular catheters. Sterile and single-use catheters. Part 1: General requirements *Anteriormente ISO 10555-1:2013*
ISO 10555-4	2023	Intravascular catheters. Sterile and single-use catheters. Part 4: Balloon dilatation catheters *Anteriormente ISO 10555-4:2013*
ISO 11979-7	2024	Ophthalmic implants. Intraocular lenses. Part 7: Clinical investigations of intraocular lenses for the correction of aphakia *Anteriormente ISO 11979-7:2018*
ISO 12417-1	2024	Cardiovascular implants and extracorporeal systems. Vascular device-drug combination products. Part 1: General requirements *Anteriormente ISO 12417-1:2015*
ISO 17665-1	2024	Sterilization of health care products. Moist heat. Part 1. Requirements for the development, validation and routine control of a sterilization process for medical devices *Anteriormente ISO 17665-1: 2006*
ISO 18562-1	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 1: Evaluation and testing within a risk management process *Anteriormente ISO 18562-1: 2017*
ISO 18562-2	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 2: Tests for emissions of particulate matter *Anteriormente ISO 18562-2: 2017*
ISO 23500-3	2024	Preparation and quality management of fluids for haemodialysis and related therapies. Part 3: Water for haemodialysis and related therapies *Anteriormente ISO 23500-3: 2019*

NORMA	AÑO	TÍTULO
ISO 23500-4	2024	Preparation and quality management of fluids for haemodialysis and related therapies. Part 4: Concentrates for haemodialysis and related therapies *Anteriormente ISO 23500-4: 2019*
ISO 23500-5	2024	Preparation and quality management of fluids for haemodialysis and related therapies. Part 5: Quality of dialysis fluid for haemodialysis and related therapies *Anteriormente ISO 23500-5: 2019*
ISO 80601-2-12	2023	Medical electrical equipment. Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators *Anteriormente IEC 80601-2-12:2020*
ISO 80601-2-84	2023	Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators *Anteriormente IEC 80601-2-84:2020*
NC 599	2023	Esfigmomanómetros. Métodos y equipos de verificación *Anteriormente NC 599: 2019*
NC ISO 14155	2024	Investigación clínica de equipos médicos en sujetos humanos. Parte 1: Requisitos generales (ISO 14155-1:2003, IDT) *Sustituye a la NC ISO 14155-1:2006 y a la NC ISO 14155-2:2006*
NC OIML D10	2024	Lineamientos para la Determinación de Intervalos de Calibración de Instrumentos de Medición (OIML D 10:2022, IDT) (ILAC G24/OIML D10) *Anteriormente NC OIML D10: 2021*
OIML D 31	2023	General requirements for software. Controlled measuring instruments *Anteriormente OIML D31: 2019*

II. Lista Regulatoria de Normas a partir de 2024

1. CALIDAD		
NORMA	**AÑO**	**TÍTULO**
IEC 62366-1+Amd 1: 2020 (ed consolidada)	2015	Medical devices. Part 1: Application of usability engineering to medical devices
IEC/TR 62366-2	2016	Medical devices. Part 2: Guidance on the application of usability engineering to medical devices
ISO 2859-2	2020	Sampling procedures for inspection by attributes. Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection

1. CALIDAD		
NORMA	**AÑO**	**TÍTULO**
ISO 2859-4	2020	Sampling procedures for inspection by attributes. Part 4: Procedures for assessment of declared quality levels
ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes
ISO 15223-1	2021	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 20417	2021	Medical devices. Information to be supplied by the manufacturer
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	2022	Quantities and units. Part 1: General
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/TR 20416	2020	Medical devices. Post-market surveillance for manufacturers
ISO/TR 24971	2020	Medical devices. Guidance on the application of ISO 14971
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 inspección 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 2859-5	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 9001	2015	Sistema de gestión de la calidad. Requisitos. [ISO 9001: 2015 (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	2023	Equipos Médicos. Aplicación de la gestión del riesgo a los equipos médicos (ISO 14971: 2019, 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]

1. CALIDAD		
NORMA	**AÑO**	**TÍTULO**
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/TS 19218-1	2020	Equipos y dispositivos médicos. Estructura jerárquica de codificación para eventos adversos. Parte 1: Códigos de tipo evento (ISO/TS 19218-1: 2011; AMD 1:2013, IDT)
NC ISO/TS 19218-2	2020	Equipos y dispositivos médicos. Estructura jerárquica de codificación para eventos adversos-parte 2: Códigos de evaluación (ISO/TS 19218-2:2012, IDT)

2. EVALUACIÓN BIOLÓGICA		
NORMA	**AÑO**	**TÍTULO**
ISO 10993-2	2022	Biological evaluation of medical devices. Part 2: Animal welfare requirements
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 devices. Part 4. Selection of tests for interactions with blood
ISO 10993-7+Cor 1: 2009+Amd 1:2019	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	2021	Biological evaluation of medical devices. 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	2021	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 10993-17	2023	Biological evaluation of medical devices. Part 17: Toxicological risk assessment of medical device constituents

2. EVALUACIÓN BIOLÓGICA		
NORMA	**AÑO**	**TÍTULO**
ISO 10993-18+Amd 1:2022	2020	Biological evaluation of medical devices. Part 18: Chemical characterization of medical device materials within a risk management process
ISO 10993-23	2021	Biological evaluation of medical devices. Part 23: Test for irritation
ISO 22442-1	2020	Medical devices utilizing animal tissues and their derivatives. Part 1: Application of risk management
ISO 22442-2	2020	Medical devices utilizing animal tissues and their derivatives. Part 2: Controls on sourcing, collection and handling
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 10993-55	2023	Biological evaluation of medical devices. Part 55: Interlaboratory study on cytotoxicity
ISO/TR 21582	2021	Pyrogenicity. Principles and methods for pyrogen testing of medical devices
ISO/TR 37137	2014	Cardiovascular biological evaluation of medical devices. Guidance for absorbable implants
ISO/TS 10993-19	2020	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 11796	2023	Biological evaluation of medical devices. Requirements for interlaboratory studies to demonstrate the applicability of validated *in vitro* methods to assess the skin sensitization 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
ISO/TS 37137-1	2021	Biological evaluation of absorbable medical devices. Part 1: General requirements
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	2023	Evaluación biológica de equipos médicos. Parte 1: Evaluación y ensayos mediante un proceso de gestión del riesgo (ISO 10993-1: 2018, IDT)
NC ISO 10993-5	2013	Evaluación biológica de equipos médicos. Parte 5: Ensayos de citotoxicidad *in vitro* (ISO 10993-5:2009, IDT)

2. EVALUACIÓN BIOLÓGICA		
NORMA	**AÑO**	**TÍTULO**
NC ISO 10993-6	2020	Evaluación biológica de equipos médicos. Parte 6: Ensayos relativos a los efectos locales después de la implantación (ISO 10993-6:2016, IDT)
NC ISO 10993-14	2020	Evaluación biológica de equipos médicos. Parte 14: Identificación y cuantificación de los productos de degradación de materiales (ISO 10993-14: 2001, IDT)
NC ISO 22442-1	2020	Equipos médicos que utilizan tejidos animales y sus derivados. Parte 1: Aplicación de la gestión de riesgos (ISO 22442-1: 2007, IDT)

3. INVESTIGACIONES CLÍNICAS		
NORMA	**AÑO**	**TÍTULO**
NC ISO 14155	2024	Investigación clínica de dispositivos médicos en seres humanos (ISO 14155: 2020, IDT)

4. EQUIPOS MÉDICOS CON FUNCIÓN DE MEDICIÓN		
NORMA	**AÑO**	**TÍTULO**
DG 01	2020	Instrumentos de medición sujetos a Control Metrológico Legal según los campos de aplicación donde serán utilizados
NC 599	2023	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 Guía 883	2020	Guía para la elaboración de normas de métodos y equipos para la verificación de instrumentos de medición
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 D10	2024	Lineamientos para la Determinación de Intervalos de Calibración de Instrumentos de Medición (OIML D 10:2022, IDT) (ILAC G24/OIML D10)
NC OIML D19	1994	Evaluación de modelos y aprobación de modelos
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)

4. EQUIPOS MÉDICOS CON FUNCIÓN DE MEDICIÓN		
NORMA	**AÑO**	**TÍTULO**
NC OIML R 76-1	2020	Instrumentos de pesar no automáticos. Parte 1: Requerimientos metrológicos y técnicos-Ensayo (OIML R 76-1: 2006, IDT)
OIML D 30	2020	Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology
OIML D 31	2023	General requirements for software. Controlled measuring instruments
OIML D 34	2019	Conformity to Type (CTT). Pre-market conformity assessment of measuring instruments
OIML G 19	2017	The role of measurement uncertainty in conformity assessment decisions in legal metrology
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
OIML R 148	2020	Non-invasive non-automated sphygmomanometers
OIML R 149	2020	Non-invasive automated sphygmomanometers

5. NORMAS ESPECÍFICAS DE PRODUCTO		
5.1 DE SIMPLE USO		
NORMA	**AÑO**	**TÍTULO**
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+Amd 1:2023	2019	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

5. NORMAS ESPECÍFICAS DE PRODUCTO		
5.1 DE SIMPLE USO		
NORMA	**AÑO**	**TÍTULO**
ISO 7439	2023	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 7886-2	2020	Sterile hypodermic syringes for single use. Part 2: Syringes for use with power-driven syringe pumps
ISO 7886-3	2020	Sterile hypodermic syringes for single use. Part 3: Auto-disabled syringes for fixed-dose immunization
ISO 8536-4	2019	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 8536-15	2022	Infusion equipment for medical use. Part 15: Light-protective infusion sets for single use
ISO 10282	2023	Single-use sterile rubber surgical gloves. Specification
ISO 10555-1	2023	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	2023	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+Amd 1: 2019	2015	Intravascular catheters. Sterile and single-use catheters. Part 6: Subcutaneous implanted ports
ISO 10555-7	2023	Intravascular catheters. Sterile and single-use catheters. Part 7: Peripherally inserted central catheters
ISO 11070+Amd 1:2018	2014	Sterile single-use intravascular introducers, dilators and guidewires
ISO 11193-1	2020	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 20698	2018	Catheter systems for neuraxial application. Sterile and single-use catheters and accessories

5. NORMAS ESPECÍFICAS DE PRODUCTO		
5.1 DE SIMPLE USO		
NORMA	**AÑO**	**TÍTULO**
ISO 23908	2011	Sharps injury protection. Requirements and tests methods. Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 25841+Amd 1: 2020	2017	Female condoms. Requirements and test methods
ISO 28620	2020	Medical devices. Non-electrically driven portable infusion devices
NC ISO 4074	2020	Condones Masculinos de Látex de Caucho Natural. Requisitos y Métodos de Ensayo (ISO 4074: 2015, IDT)
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 + Amd 1:2012 + Amd 2:2020 (ed. consolidada)	2005	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 + Amd 1:2020 (ed. consolidada)	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 + Amd 1:2013 + Amd 2:2021 (ed. consolidada)	2008	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 + Amd 1:2013 + Amd 2:2020 (ed. consolidada)	2010	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
IEC 60601-1-8 + Amd 1:2012 + Amd 2:2020 (ed. consolidada)	2006	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 60601-1-11 + Amd 1:2020 (ed. consolidada)	2015	Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12 + Amd 1:2020 (ed. consolidada)	2014	Medical electrical equipment. Part 1-12: General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical

5.2 ELECTROMECÁNICOS		
NORMA	**AÑO**	**TÍTULO**
		electrical systems intended for use in the emergency medical services environment
IEC 60601-2-1	2020	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 + Amd 1:2023 (ed. consolidada)	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 + Amd 1:2016 + Amd 2:2022 (ed. consolidada)	2012	Medical electrical equipment. Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
IEC 60601-2-4 + Amd 1:2018 (ed. consolidada)	2010	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 + Amd 1:2016 + Amd 2:2022 (ed. consolidada)	2012	Medical electrical equipment. Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
IEC 60601-2-8 + Amd 1:2015 (ed. consolidada)	2010	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 + Amd 1:2016 + Amd 2:2023 (ed. consolidada)	2012	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 + Amd 1:2023 (ed. consolidada)	2020	Medical electrical equipment. Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

5.2 ELECTROMECÁNICOS		
NORMA	**AÑO**	**TÍTULO**
IEC 60601-2-20 + Amd 1:2023 (ed. consolidada)	2020	Medical electrical equipment. Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
IEC 60601-2-21 + Amd 1:2023 (ed. consolidada)	2020	Medical electrical equipment. Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
IEC 60601-2-22	2019	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	2020	Medical electrical equipment. Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source
IEC 60601-2-33	2022	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 + Amd 1:2015 (ed. consolidada)	2007	Medical electrical equipment. Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

5.2 ELECTROMECÁNICOS		
NORMA	**AÑO**	**TÍTULO**
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	2021	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	2022	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 + Amd 1:2012 + Amd 2:2016 (ed. consolidada)	2009	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 + Amd 1:2015 + Amd 2:2022 (ed. consolidada)	2011	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	2023	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 + Amd 1:2015 (ed. consolidada)	2009	Medical electrical equipment. Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
IEC 60601-2-54	2022	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 + Amd 1:2017 + Amd 2:2021 (ed. consolidada)	2012	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 + Amd 1:2017 + Amd 2:2021	2012	Medical electrical equipment. Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

5.2 ELECTROMECÁNICOS		
NORMA	**AÑO**	**TÍTULO**
(ed. consolidada)		
IEC 60601-2-66	2019	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 + Amd 1:2023	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	2024	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/TR 60601-4-5	2021	Medical electrical equipment. Part 4-5: Guidance and interpretation. Safety-related technical security specification
IEC 60731 + Amd 1:2016 (ed. consolidada)	2011	Medical electrical equipment. Dosimeters with ionization chambers as used in radiotherapy
IEC/TR 60878	2022	Graphical symbols for electrical equipment in medical practice
IEC 60976	2007	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics
IEC 61674	2024	Medical electrical equipment. Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging
IEC 62563-1 + Amd 1:2016 + Amd 2: 2021 (ed. consolidada)	2009	Medical electrical equipment. Medical image display systems. Part1: Evaluation methods
IEC 62563-2	2021	Medical electrical equipment. Medical image display systems. Part 2: Acceptance and constancy tests for medical image displays
IEC 80601-2-26 + Amd 1: 2024 (ed. consolidada)	2019	Medical electrical equipment. Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

5.2 ELECTROMECÁNICOS		
NORMA	**AÑO**	**TÍTULO**
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	2024	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 + Amd 1: 2023	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
IEC 80601-2-77	2019	Medical electrical equipment. Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
IEC 80601-2-78	2019	Medical electrical equipment. Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
IEC/IEEE 82079-1	2019	Preparation of information for use (instructions for use) of products. Part 1: Principles and general requirements.
IEC/TR 60513	1994	Fundamental aspects of safety standards for medical electrical equipment
ISO 80601-2-12	2023	Medical electrical equipment. Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-13	2022	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 + Amd 1:2018	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

5.2 ELECTROMECÁNICOS		
NORMA	**AÑO**	**TÍTULO**
ISO 80601-2-67	2020	Medical electrical equipment. Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment
ISO 80601-2-69	2020	Medical electrical equipment. Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
ISO 80601-2-70	2020	Medical Electrical Equipment. Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
ISO 80601-2-72	2023	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	2021	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 80601-2-84	2023	Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators
ISO 80601-2-85	2021	Medical electrical equipment. Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment
ISO 80601-2-87	2021	Medical electrical equipment. Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators
ISO 80601-2-90	2021	Medical electrical equipment. Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
ISO 81060-1	2007	Non-invasive sphygmomanometers. Part 1: Requirements and test methods for non-automated measurement type
ISO 81060-2 + Amd 1: 2020 + Amd 2: 2024	2018	Non-invasive sphygmomanometers. Part 2: Clinical validation of intermittent measurement type
ISO 81060-3	2022	Non-invasive sphygmomanometers. Part 3: Clinical investigation of continuous automated measurement type
ISO/TS 81060-5	2020	Non-invasive sphygmomanometers. Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers

5.2 ELECTROMECÁNICOS		
NORMA	**AÑO**	**TÍTULO**
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 9999	2022	Assistive products. Classification and terminology
ISO 11199-1	2021	Walking aids manipulated by both arms. Requirements and test methods. Part 1: Walking frames
ISO 11199-2	2021	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
ISO 21856	2022	Assistive products. General requirements and test methods
NC 214	2002	Silla de ruedas de propulsión manual. Requisitos y métodos de ensayo

5.4 RADIOLÓGICOS PARA DIAGNÓSTICO Y TERAPIA		
NORMA	**AÑO**	**TÍTULO**
CISPR 11	2024	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 + Cor 1:2022	2019	Evaluation and routine testing in medical imaging departments. Part 3-5: Acceptance tests. Imaging performance of computed tomography X-ray equipment

5.4 RADIOLÓGICOS PARA DIAGNÓSTICO Y TERAPIA		
NORMA	**AÑO**	**TÍTULO**
IEC 61223-3-6	2020	Evaluation and routine testing in medical imaging departments. Part 3-6: Acceptance and constancy tests. Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation
IEC 61223-3-7	2021	Evaluation and routine testing in medical imaging departments. Part 3-7: Acceptance and constancy tests. Imaging performance of X-ray equipment for dental cone beam computed tomography
IEC 61223-3-8	2024	Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging performance of X-ray equipment for radiography and radioscopy
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 61675-1	2022	Radionuclide imaging devices. Characteristics and test conditions. Part 1: Positron emission tomographs
IEC 62464-1	2018	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/ASTM TR 52916	2022	Additive manufacturing for medical. Data. Optimized medical image data
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

5.4 RADIOLÓGICOS PARA DIAGNÓSTICO Y TERAPIA		
NORMA	**AÑO**	**TÍTULO**
ISO 15382	2015	Radiological protection. Procedures for monitoring the dose to the lens of the eye, the skin and the extremities
ISO 15708-2	2017	Non-destructive testing. Radiation methods for computed tomography. Part 2: Principles, equipment and samples
ISO 15708-3	2017	Non-destructive testing. Radiation methods for computed tomography. Part 2: Operation and interpretation
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	2020	Dentistry. Corrosion test methods for metallic materials
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

5.6 HOSPITAL GENERAL		
NORMA	**AÑO**	**TÍTULO**
BP	2022	Farmacopea Británica
FEUM	2023	Farmacopea de los Estados Unidos Mexicanos. Suplemento para Dispositivos Médicos. 5ta ed.
ISO 37	2024	Rubber, vulcanized or thermoplastic. Determination of tensile stress-strain properties
ISO 188	2023	Rubber vulcanized or thermoplastic. Accelerated ageing and heat resistance tests

5.6 HOSPITAL GENERAL		
NORMA	**AÑO**	**TÍTULO**
ISO 1658	2022	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 8637-1	2024	Extracorporeal systems for blood purification. Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
ISO 8637-2	2024	Extracorporeal systems for blood purification. Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
ISO 8871-2	2020	Elastomeric parts for parenterals and for devices for pharmaceutical use. Part 2: Identification and characterization
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 + Amd 2023	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 + Amd 2: 2021	2013	Mechanical vibration and shock. Hand-arm vibration. Measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand
ISO 11608-1	2022	Needle-based injection systems for medical use. Requirements and test methods. Part 1: Needle-based injection systems
ISO 12891-1	2015	Retrieval and analysis of surgical implants. Part 1: Retrieval and handling
ISO 12891-2	2020	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 13688 + Amd 1:2021	2013	Protective clothing. General requirements
ISO 14698-1	2003	Cleanrooms and associated controlled environments. Biocontamination control. Part 1: General principles and methods
ISO 14698-2 + Cor 1:2004	2003	Cleanrooms and associated controlled environments. Biocontamination control. Part 2: Evaluation and interpretation of biocontamination data
ISO 15621	2017	Absorbent incontinence aids for urine and/or faeces. General guidelines on evaluation
ISO 15714	2019	Method of evaluating the UV dose to airbone microorganisms transiting in-duct ultraviolet germicidal irradiation device

5.6 HOSPITAL GENERAL		
NORMA	**AÑO**	**TÍTULO**
ISO 15727	2020	UV-C devices. Measurement of the output of UV-C lamp
ISO 15858	2016	UV-C devices. Safety information. Permissible human exposure
ISO 16054	2019	Implants for surgery. Minimum data sets for surgical implants
ISO 18250-1	2018	Medical devices. Connectors for reservoir delivery systems for healthcare applications. Part 1: General requirements and common test methods
ISO 18250-3	2018	Medical devices. Connectors for reservoir delivery systems for healthcare applications. Part 3: Enteral applications
ISO 18250-6	2019	Medical devices. Connectors for reservoir delivery systems for healthcare applications. Part 6: Neural applications
ISO 18250-7	2018	Medical devices. Connectors for reservoir delivery systems for healthcare applications. Part 7: Connectors for intravascular infusion
ISO 18250-8	2018	Medical devices. Connectors for reservoir delivery systems for healthcare applications. Part 8: Citrate-based anticoagulant solution for apheresis applications
ISO 21171	2006	Medical gloves. Determination of removable surface powder
ISO 22609	2004	Clothing for protection against infectious agents. Medical face masks. Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
ISO 23217	2024	Injection systems for self-administration by paediatric patients. Requirements and guidelines for design
ISO 23500-1	2019	Preparation and quality management of fluids for haemodialysis and related therapies. Part 1: General requirements
ISO 23500-2	2019	Preparation and quality management of fluids for haemodialysis and related therapies. Part 2: Water treatment equipment for haemodialysis applications and related therapies
ISO 23500-3	2024	Preparation and quality management of fluids for haemodialysis and related therapies. Part 3: Water for haemodialysis and related therapies
ISO 23500-4	2024	Preparation and quality management of fluids for haemodialysis and related therapies. Part 4: Concentrates for haemodialysis and related therapies
ISO 23500-5	2024	Preparation and quality management of fluids for haemodialysis and related therapies. Part 5: Quality of dialysis fluid for haemodialysis and related therapies
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	2021	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

5.6 HOSPITAL GENERAL		
NORMA	**AÑO**	**TÍTULO**
NC 20-13	1986	Materiales y curación. Piezas, bastones y rollos de gasa. Especificaciones de calidad
NC 20-28	1988	Ciencias médicas. Instrumentos médicos metálicos. Especificaciones generales de calidad
NC 146	2017	Almohadillas sanitarias. Requisitos y métodos de ensayo
NC 963	2020	Kit de colecta de sangre arterial. Requisitos
NC 964	2020	Capilares de vidrio. Requisitos
NC 1039	2014	Equipos de protección personal de los trabajadores. Requisitos generales y clasificación
NC ISO 6710	2020	Recipientes de un solo uso para la recogida de muestras de sangre venosa (ISO 6710: 2017, IDT)
Ph. Eur.	2023	European Pharmacopoeia 11th ed.
Ph. Int.	2023	The international pharmacopoeia 11th ed.
UNE-EN IEC 62471-6	2023	Seguridad fotobiológica de lámparas y de los aparatos que utilizan lámparas. Parte 6: Productos con lámparas de ultravioleta
UNE EN 149 + A1:2010	2001	Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado
UNE EN 405 + A1:2010	2002	Equipos de protección respiratoria. Medias máscaras filtrantes con válvulas para la protección contra gases o contra gases y partículas. Requisitos, ensayos, marcado
UNE EN 14126	2004	Ropa de protección. Requisitos y métodos de ensayo para la ropa de protección contra agentes biológicos
UNE EN 14255-1	2007	Medición y evaluación de la exposición de las personas a la radiación óptica incoherente. Parte 1: Radiación ultravioleta emitida por fuentes artificiales en el lugar de trabajo
UNE EN 14255-4	2007	Medición y evaluación de la exposición de las personas a la radiación óptica incoherente. Parte 4: Terminología y magnitudes usadas en mediciones de exposición a radiación ultravioleta, visible e infrarroja
UNE EN 14683 + AC:2019	2019	Mascarillas quirúrgicas. Requisitos y métodos de ensayo
USP 44–NF 39	2021	Farmacopea de los Estados Unidos de América

5.6.1 ESTERILIZACIÓN		
NORMA	**AÑO**	**TÍTULO**
EN 556-1	2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 556-2	2015	Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Part 2: Requirements for aseptically processed medical devices

5.6.1 ESTERILIZACIÓN		
NORMA	**AÑO**	**TÍTULO**
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 + Amd 1:2022	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 11138-8	2021	Sterilization of health care products. Biological indicators. Part 8: Method for validation of a reduced incubation time for a biological indicator
ISO 11607-1 + Amd 1:2023	2019	Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2 + Amd 1:2023	2019	Packaging for terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-1 + Amd 1:2021	2018	Sterilization of medical devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products
ISO 11737-2	2019	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	2023	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

5.6.1 ESTERILIZACIÓN		
NORMA	**AÑO**	**TÍTULO**
ISO 14160	2020	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 14644-1	2015	Cleanrooms and associated controlled environments. Part 1: Classification of air cleanliness by particle concentration
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 14644-3	2019	Cleanrooms and associated controlled environments. Part 3: Test methods
ISO 14644-4	2022	Cleanrooms and associated controlled environments. Part 4: Design, construction and start-up
ISO 14644-5	2004	Cleanrooms and associated controlled environments. Part 5: Operations
ISO 14644-7	2004	Cleanrooms and associated controlled environments. Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
ISO 14644-8	2022	Cleanrooms and associated controlled environments. Part 8: Assessment of air cleanliness by chemical concentration (ACC)
ISO 14644-9	2022	Cleanrooms and associated controlled environments. Part 9: Assessment of surface cleanliness for particle concentration
ISO 14644-10	2022	Cleanrooms and associated controlled environments. Part 10: Assessment of surface cleanliness for chemical contamination
ISO 14644-12	2018	Cleanrooms and associated controlled environments. Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration
ISO 14644-13	2017	Cleanrooms and associated controlled environments. Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications
ISO 14644-14	2016	Cleanrooms and associated controlled environments. Part 14: Assessment of suitability for use of equipment by airborne particle concentration
ISO 14644-15	2017	Cleanrooms and associated controlled environments. Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration
ISO 14644-16	2019	Cleanrooms and associated controlled environments. Part 16: Energy efficiency in cleanrooms and separative devices
ISO 14644-17	2021	Cleanrooms and associated controlled environments. Part 17: Particle deposition rate applications
ISO 14937	2009	Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development,

5.6.1 ESTERILIZACIÓN		
NORMA	**AÑO**	**TÍTULO**
		validation and routine control of a sterilization process for medical devices
ISO 17664-1	2021	Processing of health care products. Information to be provider by the medical device manufacturer for the processing of medical devices. Part 1: Critical and semi-critical medical devices
ISO 17664-2	2021	Processing of health care products. Information to be provider by the medical device manufacturer for the processing of medical devices. Part 2: Non-critical medical devices
ISO 17665-1	2024	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 22441	2022	Sterilization of health care products. Low temperature vaporized hydrogen peroxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 25424 + Amd 1:2022	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 11137-4	2020	Sterilization of health care products. Radiation. Part 4: Guidance on process control
ISO/TS 16775	2021	Packaging for terminally sterilized medical devices. Guidance on the application of ISO 11607-1 and ISO 11607-2
ISO 17665	2024	Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO/TS 21387	2020	Sterilization of medical devices. Guidance on the requirement for the validation and routine control of a sterilization process for medical devices
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)

5.6.1 ESTERILIZACIÓN		
NORMA	**AÑO**	**TÍTULO**
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	2022	Implants for surgery. Active implantable medical devices. Part 4: Implantable infusion pumps
ISO 14708-5	2020	Implants for surgery. Active implantable medical devices. Part 5: Circulatory support devices
ISO 14708-7	2019	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 25539-2	2020	Cardiovascular implants. Endovascular devices. Part 2: Vascular stents

5.8 IMPLANTES NO ACTIVOS		
NORMA	**AÑO**	**TÍTULO**
ISO 5832-1	2024	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	2021	Implants for surgery. Metallic materials. Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 5832-4	2024	Implants for surgery. Metallic materials. Part 4: Cobalt-chromium-molybdenum casting alloy
ISO 5832-6	2022	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	2024	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	2021	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
ISO/TR 17327-2	2021	Non-active surgical implants. Implant coating. Part 2: Reference standards related to coating
NC ISO 5832-3	2020	Implantes quirúrgicos. Materiales metálicos. Parte 3: Aleación forjada a base de titanio, aluminio 6 y vanadio 4 (ISO 5832-3:2016, IDT)

5.8.1 ORTOPEDIA		
NORMA	**AÑO**	**TÍTULO**
ISO 643	2019	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

5.8.1 ORTOPEDIA		
NORMA	**AÑO**	**TÍTULO**
ISO 6475	1989	Implants for surgery. Metal bone screws with asymmetrical thread and spherical under-surface. Mechanical requirements and test methods
ISO 6892-1	2019	Metallic materials. Tensile testing. Part 1: Method of test at room temperature
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 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 21534	2007	Non-active surgical implants. Joint replacement implants. Particular requirements
ISO/TS 21560	2020	General requirements of tissue-engineered medical products
NC 298	2012	Vendas enyesadas. Especificaciones
NC 20-02	1984	Artificios ortopédicos. Términos y definiciones

5.8.2 CARDIOLOGÍA		
NORMA	**AÑO**	**TÍTULO**
ISO 5840-1	2021	Cardiovascular implants. Cardiac valve prostheses. Part 1: General requirements
ISO 5840-2	2021	Cardiovascular implants. Cardiac valve prostheses. Part 2: Surgically implanted heart valve substitutes
ISO 5840-3	2021	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 + Amd 1: 2020	2016	Cardiovascular implants and artificial organs. Blood-gas exchangers (oxygenators)
ISO 12417-1	2024	Cardiovascular implants and extracorporeal systems. Vascular device-drug combination products. Part 1: General requirements
ISO 12417-2	2022	Cardiovascular implants and extracorporeal systems. Vascular device-drug combination products. Part 2: Local regulatory information

5.8.2 CARDIOLOGÍA		
NORMA	**AÑO**	**TÍTULO**
ISO 15674 + Amd 1: 2020	2016	Cardiovascular implants and artificial organs. Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags
ISO 15675 + Amd 1: 2020	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	2022	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	2024	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 + Amd 1: 2017	2013	Ophthalmic optics. Spectacle lenses. Fundamental requirements for uncut finished lenses
ISO 15004-1	2020	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/TR 28980	2007	Ophthalmic optics. Spectacle lenses. Parameters affecting lens power measurement

5.10. EQUIPOS DE ANESTESIA Y RESPIRACIÓN		
NORMA	**AÑO**	**TÍTULO**
ISO 5356-1	2015	Anaesthetic and respiratory equipment. Conical connectors. Part 1: Cones and sockets
ISO 5366	2016	Anaesthetic and respiratory equipment. Tracheostomy tubes and connector
ISO 16900-7	2020	Respiratory protective devices. Methods of test and test equipment. Part 7: Practical performance test methods
ISO 18190	2016	Anaesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 18562-1	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 1: Evaluation and testing within a risk management process
ISO 18562-2	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 2: Tests for emissions of particulate matter

5.11. DISPOSITIVOS MÉDICOS PARA DIAGNÓSTICO *IN VITRO*		
NORMA	**AÑO**	**TÍTULO**
CLSI EP05	2014	Evaluation of Precision of Quantitative Measurement Procedures In Vitro
CLSI EP06	2020	Evaluation of the Linearity of Quantitative Measurement Procedures
CLSI EP07	2018	Interference Testing in Clinical Chemistry
CLSI EP09	2018	Measurement Procedure Comparison and Bias Estimation Using Patient Samples
CLSI EP10	2014	Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures
CLSI EP12	2023	User Protocol for Evaluation of Qualitative Test Performance
CLSI EP14	2022	Evaluation of Commutability of Processed Samples
CLSI EP15	2014	User Verification of Precision and Estimation of Bias
CLSI EP17/A2:2020	2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedure
CLSI EP18	2009	Risk Management Techniques to Identify and Control Laboratory Error Sources
CLSI EP24	2011	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves
CLSI EP25	2023	Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
CLSI EP32	2006	Metrological Traceability and Its Implementation
CLSI EP37/Cor 1: 2019/Cor 2: 2021	2018	Supplemental Tables for Interference Testing in Clinical Chemistry
CLSI GP16	2009	Urinalysis

5.11. DISPOSITIVOS MÉDICOS PARA DIAGNÓSTICO *IN VITRO*		
NORMA	**AÑO**	**TÍTULO**
CLSI H21	2024	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	2023	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	2024	Performance Standards for Antimicrobial Disk Susceptibility Tests
CLSI M07	2024	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically
CLSI M100	2024	Performance Standards for Antimicrobial Susceptibility Testing
CLSI M23	2023	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters
CLSI M43	2011	Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas
CLSI M60	2020	Performance Standards for Antifungal Susceptibility Testing of Yeasts
CLSI M61	2020	Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi
CLSI MM01	2023	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	2023	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine
CLSI MM12	2006	Diagnostic Nucleic Acid Microarrays
CLSI MM13	2020	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	2018	Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing
CLSI NBS01	2021	Dried Blood Spot Specimen Collection for Newborn Screening
CLSI POCT14	2020	Point-of-Care Monitoring of Anticoagulation Therapy
EN 12322 + Amd 1:2001	1999	Productos sanitarios para diagnóstico *in vitro*. Medios de cultivo para microbiología. Criterios para las características funcionales de los medios de cultivo
ISO 6717	2021	*In vitro* diagnostic medical devices. Single-use containers for the collection of specimens from humans other than blood

5.11. DISPOSITIVOS MÉDICOS PARA DIAGNÓSTICO *IN VITRO*		
NORMA	**AÑO**	**TÍTULO**
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	2021	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	2020	*In vitro* diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
ISO 17593	2022	Clinical laboratory testing and *in vitro* medical devices. Requirements for *in vitro* monitoring systems for self-testing of oral anticoagulant therapy
ISO 17822	2020	*In vitro* diagnostic test systems. Nucleic acid amplification-based examination procedure for detection and identification of microbial pathogens. Laboratory quality practice guide
ISO 18113-1	2022	*In vitro* diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements
ISO 18113-2	2022	*In vitro* diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 2: *In vitro* diagnostic reagents for professional use
ISO 18113-3	2022	*In vitro* diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 3: *In vitro* diagnostic instruments for professional use
ISO 18113-4	2022	*In vitro* diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 4: *In vitro* diagnostic reagents for self-testing
ISO 18113-5	2022	*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

5.11. DISPOSITIVOS MÉDICOS PARA DIAGNÓSTICO *IN VITRO*		
NORMA	**AÑO**	**TÍTULO**
ISO 20776-1	2019	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	2021	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 21151	2020	*In vitro* diagnostic medical devices. Requirements for international harmonisation protocols establishing metrological traceability of values assigned to calibrators and human samples
ISO 21474-2	2022	*In vitro* diagnostic medical devices. Multiplex molecular testing for nucleic acids. Part 2: Validation and verification
ISO 22367	2020	Medical laboratories. Application of risk management to medical laboratories
NC 376	2021	Terminología sobre laboratorios clínicos y diagnosticadores
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	2023	Laboratorios Clínicos. Requisitos para la Calidad y la Competencia [ISO 15189: 2022, (TRADUCCIÓN CERTIFICADA), 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

5.11. DISPOSITIVOS MÉDICOS PARA DIAGNÓSTICO *IN VITRO*		
NORMA	**AÑO**	**TÍTULO**
		diagnóstico *in vitro* utilizados para tinción en biología (ISO 19001:2013, IDT)
NC ISO 20658	2024	Requisitos para la Toma y el Transporte de Muestras para Análisis en el Laboratorio Clínico [ISO 20658: 2023, (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 20916	2023	Dispositivos Médicos para Diagnóstico *In Vitro*. Estudios de Desempeño Clínico con Muestras de Seres Humanos. Buenas Prácticas de Estudio (ISO 20916: 2019, 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)
UNE EN 12322 / Amd1:2002	1999	Productos sanitarios para diagnóstico *in vitro*. Medios de cultivo para microbiología. Criterios para las características funcionales de los medios de cultivo

6. SOFTWARE MÉDICO		
NORMA	**AÑO**	**TÍTULO**
IEC 82304-1	2016	Health software. Part 1: General requirements for product safety
IEC 80001-1	2021	Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software. Part 1: Application of risk management
IEC/TR 80002-1	2009	Medical device software. Part 1: Guidance on the application of ISO 14971 to medical device software
ISO/IEC 25021	2012	Systems and software engineering. Systems and software quality requirements and evaluation (SQuaRE). Quality measurement
ISO/IEC 25030	2019	Systems and software engineering. Systems and software quality requirements and evaluation (SQuaRE). Quality requirements framework
ISO/IEC 25059	2023	Software engineering. Systems and software Quality Requirements and Evaluation (SQuaRE). Quality model for AI systems
ISO/IEC/IEEE 29119-1	2022	Software and systems engineering. Software testing. Part 1: General concepts
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 IEC 62304	2021	S*oftware* médico. Procesos del ciclo de vida del *software* (IEC 62304:2006+Amd1:2015, IDT)

6. SOFTWARE MÉDICO		
NORMA	**AÑO**	**TÍTULO**
NC ISO/IEC 25000	2020	Ingeniería de *software* y sistemas. Requisitos de la calidad y evaluación de *software* y de sistemas (SQuaRE). Guía para SQuaRE (ISO/IEC 25000: 2014, 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 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	2021	Ingeniería de *software* y sistemas. Requisitos de la calidad y evaluación de *software* y sistemas (SQuaRE). Marco de medición de la calidad. (ISO/IEC 25020:2019, 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 25023	2018	Ingeniería de *software* y sistemas. Requisitos de la calidad y evaluación de *software* y sistemas (SQuaRE). Medición de la calidad del producto de *software*. (ISO/IEC 25023: 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)
NC ISO/IEC 25041	2018	Ingeniería de *software* y sistemas. Requisitos de la calidad y evaluación de *software* y sistemas (SQuaRE). Guía de evaluación para desarrolladores, adquirientes y evaluadores independientes (ISO/IEC 25041:2011, 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)
7. ENSAYOS DE LABORATORIO		
NORMA	**AÑO**	**TÍTULO**
IEC 60068-1	2013	Environmental testing. Part 1: General and guidance
IEC 60068-3-1	2023	Environmental testing. Part 3-1: Supporting documentation and guidance. Cold and dry heat tests
IEC 60721-1 + Amd 1:1992 + Amd 2: 1995 (ed. consolidada)	1990	Classification of environmental conditions. Part 1: Environmental parameters and their severities

6. SOFTWARE MÉDICO		
NORMA	**AÑO**	**TÍTULO**
IEC 60721-2-1	2013	Classification of environmental conditions. Part 2-1: Environmental conditions appearing in nature. Temperature and humidity
IEC 61010-1 + Amd 1:2016 (ed. consolidada)	2010	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	2020	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	2024	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-201: Particular requirements for control equipment
IEC 61326-2-6	2020	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
NC ISO 15190	2023	Laboratorios Clínicos. Requisitos de Seguridad (ISO 15190: 2020, IDT)
NC ISO 35001	2021	Gestión del Riesgo Biológico en Laboratorios y otras organizaciones relacionadas (ISO 35001:2019, IDT)