ÁMBITO REGULADOR

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

EDICIÓN ORDINARIA	**LA HABANA 07/12/2017**	**AÑO XVIII**	**NÚMERO: 00-305**
SUSCRIPCIÓN: ambitor@cecmed.cu			**ISSN 1684-1832**

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

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

RESOLUCIÓN No. 167/2017

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

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

POR CUANTO: Por Resolución No. 31 de fecha 19 de febrero del año 2013, dispuesta por el Director General del CECMED, se aprobó y puso en vigor la Regulación ER 9-2012 "Empleo de las Normas en la Evaluación y Registro de los Equipos Médicos", por la necesidad de actualizar la forma en que se emplean las Normas de Evaluación y Registro de los Equipos Médicos, sus prioridades y metodologías, de modo que estén acorde con el estado de la materia en el ámbito internacional y garantizar así la seguridad, eficacia y efectividad de los equipos médicos.

POR CUANTO: Por Resolución No. 178 de fecha 29 de diciembre del año 2016, dispuesta por el Director General del CECMED, se aprobó y puso en vigor la Lista Regulatoria de Normas (Lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos) de ese año.

POR CUANTO: La frecuencia de actualización de esta lista es anual, según lo establecido en la Regulación ER 9-2012, por lo que se hace necesario proceder a la revisión de la Lista mencionada en el POR CUANTO anterior y emitir la correspondiente al año 2017.

POR TANTO: En el ejercicio de las facultades y atribuciones que me están conferidas por Resolución No. 158 de fecha 24 de noviembre del año 2017, dispuesta por el Director General del CECMED,

RESUELVO

PRIMERO: Aprobar y poner en vigor la edición del año 2017 de la *Lista Regulatoria de Normas (Lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos)*, que se adjunta a la presente resolución y forma parte integrante de la misma.

SEGUNDO: Derogar la Resolución No. 178 de fecha 29 de diciembre del año 2016, dispuesta por el Director General del CECMED.

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

COMUNÍQUESE a cuantas empresas y compañías relacionadas con la fabricación, distribución, importación y suministros de equipos médicos proceda, al Director de Medicuba S.A., al Director de ENSUME; al Director Nacional de Medicamentos y Tecnologías del MINSAP; al Presidente del Comité Técnico de Normalización # 11 de Equipos Médicos (CTN11); a la Jefa del Departamento de Equipos y Dispositivos Médicos del CECMED; a los Jefes de Sección de Evaluación de Equipos y Dispositivos Médicos 1 y 2 del CECMED; a la Jefa de Sección de Radiofísica Médica del CECMED; a la Jefa de Sección de Recepción y Preevaluación de Trámites del CECMED; a la Jefa de Sección de Política y Asuntos Regulatorios del CECMED; a la Jefa del Laboratorio Nacional de Control del CECMED; y a cuantas personas naturales o jurídicas resulte necesario.

Regístrese y archívese un original en el protocolo de resoluciones de la Asesoría Jurídica del Centro, desde el que se emitirán las copias fieles que sean menester.

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

DADA en La Habana, a los 5 días del mes de diciembre del año 2017.
"Año 59 de la Revolución".

MsC. Yaquelín Rodríguez Valdés
Subdirectora

LISTA REGULATORIA DE NORMAS

(Lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos)

2017

I. Cambios introducidos en la nueva edición 2017 de la Lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos

Normas adicionadas

NORMA	AÑO	TÍTULO
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 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 ISO 10993-10	2016	Evaluación biológica de equipos médicos. Parte 10: Ensayos de irritación y de hipersensibilidad retardada (ISO 10993-10:2013, 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)
ISO 5361	2016	Anaesthetic and respiratory equipment. Tracheal tubes and connectors
ISO 7176-2	2017	Wheelchairs. Part 2: Determination of dynamic stability of electrically powered wheelchairs
ISO 10555-5	2013	Intravascular catheters. Sterile and single-use catheters. Part 5: Over-needle peripheral catheters
ISO 10993-11	2017	Biological evaluation of medical devices. Part 11: Tests for systemic toxicity
ISO/TR 10993-22	2017	Biological evaluation of medical devices. Part 22: Guidance on nanomaterials
ISO 11979-8	2017	Ophthalmic implants. Intraocular lenses. Part 8: Fundamental requirements
ISO/TR 13154	2017	Medical electrical equipment. Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph
ISO 14708-3	2017	Implants for surgery. Active implantable medical devices. Part 3: Implantable neurostimulators
ISO 16142-1	2016	Medical devices. Recognized essential principles of safety and performance of medical devices. Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories
ISO 17664	2017	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 18190	2016	Anaesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 18472	2006	Sterilization of health care products. Biological and chemical indicators. Test equipment
ISO 18562-1	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 1: Evaluation and testing within a risk management process
ISO 18562-2	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 2: Tests for emissions of particulate matter
ISO 25424	2009	Sterilization of medical devices. Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 25539-1	2017	Cardiovascular implants. Endovascular devices. Part 1: Endovascular prostheses
IEC 60601-2-75	2017	Medical electrical equipment. Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment
IEC 60731 (ed. consolidada)	2016	Medical electrical equipment. Dosimeters with ionization chambers as used in radiotherapy
IEC 60976	2007	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics
IEC 62563-1 (ed. consolidada)	2016	Medical electrical equipment. Medical image display systems. Part1: Evaluation methods
ISO/TR 80002-2	2017	Medical device software. Part 2: Validation of software for medical device quality systems
ISO 80369-3	2016	Small-bore connectors for liquids and gases in healthcare applications. Part 3: Connectors for enteral applications
ISO 80369-7	2016	Small-bore connectors for liquids and gases in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications
ISO 80601-2-74	2017	Medical electrical equipment. Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
IEC 82304-1	2016	Health software. Part 1: General requirements for product safety
OIML D 31	2008	Requisitos generales para los instrumentos de medida controlados por software

Normas eliminadas

NORMA	AÑO	TÍTULO
NC ISO 9000	2005	Sistema de gestión de la calidad. Fundamento y vocabulario. [ISO 9000:2005, (TRADUCCIÓN CERTIFICADA), IDT] *Certificaciones por esta norma sólo vigentes hasta marzo del 2017*
NC ISO 9001	2008	Sistema de gestión de la calidad. Requisitos. [ISO 9001:2008 (TRADUCCIÓN CERTIFICADA), IDT] *Certificaciones por esta norma sólo vigentes hasta marzo del 2017*
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Part 1: General requirements Revisada por ISO 80369-7: 2016
ISO 11137-1 / Amd 1:2013	2006	Sterilization of health care products. Radiation. Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices Publicada la NC ISO 11137-1:2017 (IDT)
ISO/TR 11175	1993	Dental implants. Guidelines for developing dental implants *Derogada por la ISO*
ISO/IEC 25010	2011	Systems and software engineering. Systems and software Quality Requirements and Evaluation (SQuaRE). System and software quality models *Publicada la NC ISO/IEC 25010:2017 (IDT)*
ISO/IEC 25020	2007	Software engineering. Software product Quality Requirements and Evaluation (SQuaRE). Measurement reference model and guide *Publicada la NC ISO/IEC 25020:2017(IDT)*
ISO/IEC 25040	2011	Systems and software engineering. Systems and software Quality Requirements and Evaluation (SQuaRE). Evaluation process *Publicada la NC ISO/IEC 25040:2017(IDT)*

Normas actualizadas (reemplazadas)

NORMA	AÑO	TÍTULO
ISO 5832-1	2016	Implants for surgery. Metallic materials. Part 1: Wrought stainless steel *Anteriormente ISO 5832-1:2007/Cor 1:2008*
ISO 7886-1	2017	Sterile hypodermic syringes for single use. Part 1: Syringes for manual use *Anteriormente ISO 7886-1:1993/Cor 1:1995*
ISO 10993-4	2017	Biological evaluation of medical device. Part 4. Selection of tests for interactions with blood *Anteriormente ISO 10993-4:2002/Amd 1:2006*
ISO 10993-16	2017	Biological evaluation of medical devices. Part 16: Toxicokinetic study design for degradation products and leachables *Anteriormente ISO 10993-16:2010*
ISO 11137-3	2017	Sterilization of health care products. Radiation. Part 3: Guidance on dosimetric aspects *Anteriormente ISO 11137-3:2006*
ISO 11138-1	2017	Sterilization of health care products. Biological indicators. Part 1: General requirements *Anteriormente ISO 11138-1:2006*
ISO 11138-2	2017	Sterilization of health care products. Biological indicators. Part 2: Biological indicators for ethylene oxide sterilization processes *Anteriormente ISO 11138-2:2006*
ISO 11138-3	2017	Sterilization of health care products. Biological indicators. Part 3: Biological indicators for moist heat sterilization processes *Anteriormente ISO 11138-3:2006*
ISO 15708-1	2017	Non-destructive testing. Radiation methods for computed tomography. Part 1: Terminology *Anteriormente ISO 15708-1:2002*
ISO 15708-2	2017	Non-destructive testing. Radiation methods for computed tomography. Part 2: Principles, equipment and samples *Anteriormente ISO 15708-2:2002*
ISO/TS 22911	2016	Dentistry. Preclinical evaluation of dental implant systems. Animal test methods *Anteriormente ISO/TS 22911:2005*
ISO 80601-2-56	2017	Medical electrical equipment. Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement *Anteriormente ISO 80601-2-56:2009*
IEC 60601-2-2	2017	Medical electrical equipment. Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories *Anteriormente IEC 60601-2-2:2009*
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 *Anteriormente IEC 60601-2-28:2010*

IEC 60601-2-43 (ed. consolidada)	2017	Medical electrical equipment. Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures *Edición consolidada de la IEC 60601-2-43:2010+AMD1:2017*
IEC 60601-2-63	2017	Medical electrical equipment. Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment *Edición consolidada de la IEC 60601-2-63:2012+AMD1:2017*
IEC 60601-2-65	2017	Medical electrical equipment. Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment *Edición consolidada de la IEC 60601-2-65:2012+AMD1:2017*
IEC 80601-2-59	2017	Medical electrical equipment. Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening *Anteriormente IEC 80601-2-59:2008*

Lista de Normas reconocidas a partir de esta edición

1. CALIDAD		
NORMA	**AÑO**	**TÍTULO**
NC GUIA 857-1	2011	Organización y ejecución de programas de aseguramiento metrológico. Parte 1: Diagnóstico metrológico a la documentación de proyectos de inversiones
NC GUIA 857-2	2013	Organización y ejecución de programas de aseguramiento metrológico. Parte 2: Elaboración y aprobación de los programas de aseguramiento metrológico
NC ISO 9000	2015	Sistema de gestión de la calidad. Fundamentos y vocabulario [ISO 9000:2015, (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 9001	2015	Sistema de gestión de la calidad. Requisitos. [ISO 9001: 2015 (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 9004	2009	Gestión para el éxito sostenido de una organización. Enfoque de gestión de la calidad [ISO 9004:2009 (TRADUCCIÓN CERTIFICADA, IDT)]
NC ISO 13485	2005	Equipos médicos. Sistemas de gestión de la calidad. Requisitos del sistema para propósitos reguladores (ISO 13485:2003, IDT)
NC ISO 14971	2012	Equipos médicos. Aplicación de la gestión de riesgos a los equipos médicos (ISO 14971:2007, IDT)
NC ISO/IEC 17025	2006	Requisitos generales para la competencia de los laboratorios de ensayo y de calibración [ISO/IEC 17025:2005 + Corrigendum Técnico 1:2006 (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO/IEC 17050-2	2005	Evaluación de la Conformidad. Declaración de Conformidad del Proveedor. Parte 2: Documentación de Apoyo [ISO/IEC 17050-2:2004 (TRADUCCIÓN CERTIFICADA), IDT]
NC ISO 19011	2012	Directrices para la auditoría de los sistemas de gestión. (ISO 19011: 2011, IDT)
ISO 9000	2015	Quality management systems. Fundamentals and vocabulary
ISO 9001	2015	Quality management systems. Requirements
ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes
ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
ISO 15223-2	2010	Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. Part 2: Symbol development, selection and validation
ISO 15225	2016	Medical devices. Quality management. Medical device nomenclature data structure
ISO 16142-1	2016	Medical devices. Recognized essential principles of safety and performance of medical devices. Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories
ISO/TS 19218-1 / Amd 1: 2013	2011	Medical devices. Hierarchical coding structure for adverse events. Part 1: Event-type codes
IEC 62366-1	2015	Medical devices. Part 1: Application of usability engineering to medical devices
2. EVALUACIÓN BIOLÓGICA		
NORMA	**AÑO**	**TÍTULO**
NC 305	2006	Biomateriales. Hidroxiapatita cerámica. Especificaciones y métodos de ensayo
NC 306	2006	Biomateriales. Adhesivo tisular de 2- cianoacrilato de n-butilo. Especificaciones y métodos de ensayo
NC ISO 10993-1	2013	Evaluación biológica de equipos médicos. Parte 1: Evaluación y ensayos mediante un proceso de gestión del riesgo (ISO 10993-1: 2009, IDT)
NC ISO 10993-2	2010	Evaluación biológica de equipos médicos. Parte 2: Requisitos relativos a la protección de los animales (ISO 10993-2:2006, IDT)
NC ISO 10993-3	2005	Evaluación biológica de equipos médicos. Parte 3: Ensayos relativos a la genotoxicidad, la carcinogenicidad y la toxicidad sobre la reproducción. (ISO 10993-3:2003, IDT)

NC ISO 10993-5	2013	Evaluación biológica de equipos médicos. Parte 5: Ensayos de citotoxicidad in vitro (ISO 10993-5:2009, IDT)
NC ISO 10993-6	2010	Evaluación biológica de equipos médicos. Parte 6: Ensayos relativos a los efectos locales después de la implantación (ISO 10993-6:2007, IDT)
NC ISO 10993-7	2005	Evaluación biológica de equipos médicos. Parte 7: Residuos de la esterilización por óxido de etileno (ISO 10993-7:1995, IDT)
NC ISO 10993-9	2012	Evaluación biológica de equipos médicos. Parte 9: Marco para la identificación y cuantificación de productos potenciales de degradación (ISO 10993-9: 2009, IDT)
NC ISO 10993-10	2016	Evaluación biológica de equipos médicos. Parte 10: Ensayos de irritación y de hipersensibilidad retardada (ISO 10993-10:2013, IDT)
NC ISO 10993-11	2010	Evaluación biológica de equipos médicos. Parte 11: Ensayos de toxicidad sistémica (ISO 10993-11:2006, IDT)
NC ISO 10993-12	2010	Evaluación biológica de equipos y dispositivos médicos. Parte 12: Preparación de muestras y materiales de referencia (ISO 10993-12:2007, IDT)
NC ISO 10993-13	2006	Evaluación biológica de equipos médicos. Parte 13: identificación y cuantificación de productos de degradación de equipos médicos poliméricos (ISO 10993-13:1998, IDT)
NC ISO 10993-14	2009	Evaluación biológica de equipos médicos. Parte 14: Identificación y cuantificación de los productos de degradación de materiales
NC ISO 10993-15	2009	Evaluación biológica de equipos médicos. Parte 15: Identificación y cuantificación de los productos de degradación de metales y aleaciones (ISO 10993-15:2000, IDT)
NC ISO 10993-16	2005	Evaluación biológica en equipos médicos. Parte 16: Diseño del estudio toxicocinético de productos de degradación lixiviables. (ISO 10993-16:1997, IDT)
NC ISO 10993-17	2009	Evaluación biológica de equipos y dispositivos médicos. Parte 17: Establecimiento de los límites permisibles para sustancias lixiviables (ISO 10993-17:2002, IDT)
NC ISO 10993-18	2013	Evaluación biológica de equipos médicos. Parte 18: Caracterización química de materiales (ISO 10993-18:2005, IDT)
ISO 10993-1 / Cor 1: 2010	2009	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
ISO 10993-3	2014	Biological evaluation of medical devices. Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4	2017	Biological evaluation of medical device. Part 4. Selection of tests for interactions with blood
ISO 10993-6	2016	Biological evaluation of medical devices. Part 6: Tests for local effects after implantation
ISO 10993-7 / Cor 1: 2009	2008	Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals
ISO 10993-10	2010	Biological evaluation of medical device. Part 10: Tests for irritation and skin sensitization
ISO 10993-11	2017	Biological evaluation of medical devices. Part 11: Tests for systemic toxicity
ISO 10993-12	2012	Biological evaluation of medical devices. Part 12: Sample preparation and reference materials
ISO 10993-13	2010	Biological evaluation of medical devices. Part 13: Identification and quantification of degradation products from polymeric medical devices
ISO 10993-16	2017	Biological evaluation of medical devices. Part 16: Toxicokinetic study design for degradation products and leachables
ISO/TS 10993-19	2006	Biological evaluation of medical devices. Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO/TS 10993-20	2006	Biological evaluation of medical devices. Part 20: Principles and methods for immunotoxicology testing of medical devices
ISO/TR 10993-22	2017	Biological evaluation of medical devices. Part 22: Guidance on nanomaterials
ISO/TR 10993-33	2015	Biological evaluation of medical devices. Part 33: Guidance on tests to evaluate genotoxicity. Supplement to ISO 10993-3
ISO/TR 15499	2016	Biological evaluation of medical devices. Guidance on the conduct of biological evaluation within a risk management process
ISO 22442-1	2015	Medical devices utilizing animal tissues and their derivatives. Part 1: Application of risk management
ISO/TR 37137	2014	Biological evaluation of medical devices. Guidance for absorbable implants
3. INVESTIGACIONES CLÍNICAS		
NORMA	**AÑO**	**TÍTULO**
NC ISO 14155-1	2006	Investigación clínica de equipos médicos en sujetos humanos. Parte 1: Requisitos generales (ISO 14155-1:2003, IDT)
NC ISO 14155-2	2006	Investigación clínica de equipos médicos en sujetos humanos. Parte 2: Planes de investigaciones clínicas (ISO 14155-2:2003, IDT)
ISO 14155 / Cor 1:2011	2011	Clinical investigation of medical devices for human subjects. Good clinical practice

4. EQUIPOS MÉDICOS CON FUNCIÓN DE MEDICIÓN

NORMA	AÑO	TÍTULO
DG 01	2015	Instrumentos de medición sujetos a la verificación obligatoria y a aprobación de modelo según los campos de aplicación donde serán utilizados (nueva revisión aprobada por Resolución de sep. 2014 - vigente desde 1 ene 2015)
NC 599	2014	Esfigmomanómetros. Métodos y equipos de verificación
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)
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)
OIML R 16-1	2002	Non-invasive mechanical sphygmomanometers
OIML R 16-2	2002	Non-invasive automated sphygmomanometers
OIML R 26	2002	Medical syringes
OIML D 31	2008	Requisitos generales para los instrumentos de medida controlados por software
OIML R 89	1990	Electroencephalographs. Metrological characteristics. Methods and equipment for verification
OIML R 90	1990	Electrocardiographs. Metrological characteristics. Methods and equipment for verification
OIML R 114	1995	Clinical electrical thermometers for continuous measurement
OIML R 115	1995	Clinical electrical thermometers with maximum device
OIML R 122	1996	Equipment for speech audiometry

5. NORMAS ESPECÍFICAS DE PRODUCTO

5.1 DE SIMPLE USO

NORMA	AÑO	TÍTULO
ISO 1135-3	2016	Transfusion equipment for medical use. Part 3: Blood-taking set
ISO 1135-4	2015	Transfusion equipment for medical use. Part 4: Transfusion sets for single use
ISO 1135-5	2015	Transfusion equipment for medical use. Part 5: Transfusion sets for single use with pressure infusion apparatus
ISO 3826-1	2013	Plastics collapsible containers for human blood and blood components. Part 1: Conventional containers
ISO 3826-2	2008	Plastics collapsible containers for human blood and blood components. Part 2: Graphical symbols for use on labels and instruction leaflets
ISO 3826-3	2006	Plastics collapsible containers for human blood and blood components. Part 3: Blood bag systems with integrated features
ISO 3826-4	2015	Plastics collapsible containers for human blood and blood components. Part 4: Aphaeresis blood bag systems with integrated features
ISO 4074	2015	Natural rubber latex male condoms. Requirements and test methods
ISO 7439	2015	Copper-bearing contraceptive intrauterine devices. Requirements and tests
ISO 7864	2016	Sterile hypodermic needles for single use. Requirements and test methods
ISO 7886-1	2017	Sterile hypodermic syringes for single use. Part 1: Syringes for manual use
ISO 7886-4	2006	Sterile hypodermic syringes for single use. Part 4: Syringes with re-use prevention feature
ISO 8536-4 / Amd 1:2013	2010	Infusion equipment for medical use. Part 4: Infusion sets for single use, gravity feed
ISO 8536-13	2016	Infusion equipment for medical use. Part 13: Graduated flow regulators for single use with infusion sets
ISO 10282	2014	Single-use sterile rubber surgical gloves. Specification
ISO 10555-1	2013	Intravascular catheters. Sterile and single-use catheters. Part 1: General requirements
ISO 10555-3	2013	Intravascular catheters. Sterile and single-use catheters. Part 3: Central venous catheters
ISO 10555-4	2013	Intravascular catheters. Sterile and single-use catheters. Part 4: Balloon dilatation catheters
ISO 10555-5	2013	Intravascular catheters. Sterile and single-use catheters. Part 5: Over-needle peripheral catheters
ISO 10555-6	2015	Intravascular catheters. Sterile and single-use catheters. Part 6: Subcutaneous implanted ports
ISO 11070	2014	Sterile single-use intravascular introducers, dilators and guidewires
ISO 11193-1 / Amd 1: 2012	2008	Single-use medical examination gloves. Part 1: Specification for gloves made from rubber latex or rubber solution
ISO 11193-2	2006	Single-use medical examination gloves. Part 2: Specification for gloves made from poly(vinyl chloride)
ISO 25841	2014	Female condoms. Requirements and test methods

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
IEC/TR 60513	1994	Fundamental aspects of safety standards for medical electrical equipment
IEC 60601-1	2005	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance

IEC 60601-1 (ed. consolidada)	2012	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	2014	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
IEC 60601-1-3 (ed. consolidada)	2013	Medical electrical equipment. Part 1-3: General requirements for basic safety and essential performance. Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6 (ed. consolidada)	2013	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
IEC 60601-1-8 (ed. consolidada)	2012	Medical electrical equipment. Part 1-8: General requirements for basic safety and essential performance. Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-12	2014	Medical electrical equipment. Part 1-12: General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 60601-2-1 (ed. consolidada)	2014	Medical electrical equipment. Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
IEC 60601-2-2	2017	Medical electrical equipment. Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-2-3 (ed. consolidada)	2016	Medical electrical equipment. Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment
IEC 60601-2-4	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 (ed. consolidada)	2016	Medical electrical equipment. Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
IEC 60601-2-8 (ed. consolidada)	2015	Medical electrical equipment. Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
IEC 60601-2-10 (ed. consolidada)	2016	Medical electrical equipment. Part 2-10. Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-2-11	2013	Medical electrical equipment. Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment
IEC 60601-2-16	2012	Medical electrical equipment. Part 2-16. Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
IEC 60601-2-17	2013	Medical electrical equipment. Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment
IEC 60601-2-18	2009	Medical electrical equipment. Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-19 (ed. consolidada)	2016	Medical electrical equipment. Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
IEC 60601-2-20 (ed. consolidada)	2016	Medical electrical equipment. Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
IEC 60601-2-21 (ed. consolidada)	2016	Medical electrical equipment. Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
IEC 60601-2-22 (ed. consolidada)	2012	Medical electrical equipment. Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-23	2011	Medical electrical equipment. Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
IEC 60601-2-24	2012	Medical electrical equipment. Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
IEC 60601-2-25	2011	Medical electrical equipment. Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-26	2012	Medical electrical equipment. Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-27	2011	Medical electrical equipment. Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-2-28	2017	Medical electrical equipment. Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-29	2008	Medical electrical equipment. Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators
IEC 60601-2-31 (ed. consolidada)	2011	Medical electrical equipment. Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source
IEC 60601-2-33 (ed. consolidada)	2015	Medical electrical equipment. Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC 60601-2-34	2011	Medical electrical equipment. Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

IEC 60601-2-36	2014	Medical electrical equipment. Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
IEC 60601-2-37 (ed. consolidada)	2015	Medical electrical equipment. Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-39	2007	Medical electrical equipment. Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
IEC 60601-2-40	2016	Medical electrical equipment. Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
IEC 60601-2-41 (ed. consolidada)	2013	Medical electrical equipment. Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
IEC 60601-2-43 (ed. consolidada)	2017	Medical electrical equipment. Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-44 (ed. consolidada)	2016	Medical electrical equipment. Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
IEC 60601-2-45 (ed. consolidada)	2015	Medical electrical equipment - Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-46	2016	Medical electrical equipment. Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
IEC 60601-2-47	2012	Medical electrical equipment. Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 60601-2-49	2011	Medical electrical equipment. Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 60601-2-52 ed. consolidada)	2015	Medical electrical equipment. Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
IEC 60601-2-54 (ed. consolidada)	2015	Medical electrical equipment. Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-2-62	2013	Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
IEC 60601-2-63	2017	Medical electrical equipment. Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60601-2-64	2014	Medical electrical equipment. Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment
IEC 60601-2-65	2017	Medical electrical equipment. Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 60601-2-66	2015	Medical electrical equipment. Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
IEC 60601-2-68	2014	Medical electrical equipment. Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
IEC 60601-2-75	2017	Medical electrical equipment. Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment
IEC TR 60601-4-2	2016	Medical electrical equipment. Part 4-2: Guidance and interpretation. Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC TR 60601-4-3	2015	Medical electrical equipment. Part 4-3: Guidance and interpretation. Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements
IEC 60731 (ed. consolidada)	2016	Medical electrical equipment. Dosimeters with ionization chambers as used in radiotherapy
IEC 60976	2007	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics
IEC 62563-1 (ed. consolidada)	2016	Medical electrical equipment. Medical image display systems. Part1: Evaluation methods
ISO 80601-2-12	2011	Medical electrical equipment. Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-13 / Amd 1: 2015	2011	Medical electrical equipment. Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
IEC 80601-2-30 (ed. consolidada)	2013	Medical electrical equipment. Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 80601-2-55	2011	Medical electrical equipment. Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56	2017	Medical electrical equipment. Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
IEC 80601-2-58 (ed. consolidada)	2016	Medical electrical equipment. Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
IEC 80601-2-59	2017	Medical electrical equipment. Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

IEC 80601-2-60	2012	Medical electrical equipment. Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
ISO 80601-2-61	2011	Medical electrical equipment. Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-69	2014	Medical electrical equipment. Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
ISO 80601-2-70	2015	Medical Electrical Equipment. Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
IEC 80601-2-71	2015	Medical electrical equipment. Part 2-71: Particular requirements for the basic safety and essential performance of functional Near-Infrared Spectroscopy (NIRS) equipment
ISO 80601-2-72	2015	Medical electrical equipment. Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
ISO 80601-2-74	2017	Medical electrical equipment. Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
ISO 81060-1	2011	Non-invasive sphygmomanometers. Part 1: Requirements and test methods for non-automated measurement type
ISO 81060-2	2013	Non-invasive sphygmomanometers. Part 2: Clinical validation of automated measurement type
5.3 PARA PERSONAS CON DISCAPACIDAD		
NORMA	**AÑO**	**TÍTULO**
NC 214	2002	Silla de ruedas de propulsión manual. Requisitos y métodos de ensayo. (Obligatoria)
ISO 7176-2	2017	Wheelchairs. Part 2: Determination of dynamic stability of electrically powered wheelchairs
5.4 RADIOLÓGICOS PARA DIAGNÓSTICO Y TERAPIA		
NORMA	**AÑO**	**TÍTULO**
NC 352	2005	Dosímetros clínicos de referencia con cámaras de ionización utilizados en radioterapia. Métodos de verificación
ISO 3665	2011	Photography. Intra-oral dental radiographic film and film packets. Manufacturer specifications
ISO 4090	2001	Photography. Medical radiographic cassettes/screens/films and hard-copy imaging films. Dimensions and specifications
ISO 9236-1	2004	Photography. Sensitometry of screen/film systems for medical radiography. Part 1: Determination of sensitometric curve shape, speed and average gradient
ISO 9236-3	1999	Photography. Sensitometry of screen/film systems for medical radiography. Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography
ISO 15708-1	2017	Non-destructive testing. Radiation methods for computed tomography. Part 1: Terminology
ISO 15708-2	2017	Non-destructive testing. Radiation methods for computed tomography. Part 2: Principles, equipment and samples
IEC CISPR 11 (ed. consolidada)	2016	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 61223-3-4	2000	Evaluation and routine testing in medical imaging departments. Part 3-4: Acceptance tests. Imaging performance of dental X-ray equipment
IEC 61331-1	2014	Protective devices against diagnostic medical X-radiation. Part 1: Determination of attenuation properties of materials
IEC 61331-2	2014	Protective devices against diagnostic medical X-radiation. Part 2: Translucent protective plates
IEC 61331-3	2014	Protective devices against diagnostic medical X-radiation. Part 3: Protective clothing, eyewear and protective patient shields
5.5 ESTOMATOLOGÍA		
NORMA	**AÑO**	**TÍTULO**
ISO 6872	2015	Dentistry. Ceramic materials
ISO 7405 / Amd 1: 2013	2008	Dentistry. Evaluation of biocompatibility of medical devices used in dentistry
ISO 7885	2010	Dentistry. Sterile injection needles for single use
ISO 10271	2011	Dental metallic materials. Corrosion test methods
ISO 10451	2010	Dentistry. Contents of technical file for dental implant systems
ISO/TS 11405	2015	Dentistry. Testing of adhesion to tooth structure
ISO 14801	2016	Dentistry. Implants. Dynamic loading test for endosseous dental implants
ISO 22794	2007	Dentistry. Implantable materials for bone filling and augmentation in oral and maxillofacial surgery. Contents of a technical file
ISO 22803	2004	Dentistry. Membrane materials for guided tissue regeneration in oral and maxillofacial surgery. Contents of a technical file
ISO/TS 22911	2016	Dentistry. Preclinical evaluation of dental implant systems. Animal test methods
5.6 HOSPITAL GENERAL		
NORMA	**AÑO**	**TÍTULO**
NC 20-13	1985	Materiales y curación. Piezas, bastones y rollos de gasa. Especificaciones de calidad
NC 20-28	1987	Ciencias médicas. Instrumentos médicos metálicos. Especificaciones generales de calidad
NC 146	2005	Almohadillas sanitarias. Requisitos y métodos de ensayo. (Obligatoria)
NC 887	2012	Aparatos de laboratorio. Baño termostático. Requisitos y especificaciones de calidad

NC 963	2013	Colectores de sangre arterial. Requisitos
NC 964	2013	Capilares de vidrio. Requisitos
ISO 37	2011	Rubber, vulcanized or thermoplastic. Determination of tensile stress-strain properties
ISO 188	2011	Rubber, vulcanized or thermoplastic- Accelerated ageing and heat resistance tests
ISO 1658	2015	Natural rubber (NR). Evaluation procedure
ISO 7153-1	2016	Surgical instruments. Materials. Part 1: Metals
ISO 8600-1	2015	Endoscopes. Medical endoscopes and endotherapy devices. Part 1: General requirements
ISO 9626	2016	Stainless steel needle tubing for the manufacture of medical devices. Requirements and test methods
ISO 10334	1994	Implants for surgery. Malleable wires for use as sutures and other surgical applications
ISO 10819	2013	Mechanical vibration and shock. Hand-arm vibration. Measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand
ISO 12891-1	2015	Retrieval and analysis of surgical implants. Part 1: Retrieval and handling
ISO 12891-2	2014	Retrieval and analysis of surgical implants. Part 2: Analysis of retrieved surgical implants
ISO 13402	1995	Surgical and dental hand instruments. Determination of resistance against autoclaving, corrosion and thermal exposure
ISO/TR 14283	2004	Implants for surgery. Fundamental principles
ISO 14644-1	2015	Cleanrooms and associated controlled environments. Part 1: Classification of air cleanliness
ISO 14644-2	2015	Cleanrooms and associated controlled environments. Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 16054	2000	Implants for surgery. Minimum data sets for surgical implants
ISO 21171	2006	Medical gloves. Determination of removable surface powder
ISO 80369-3	2016	Small-bore connectors for liquids and gases in healthcare applications. Part 3: Connectors for enteral applications
ISO 80369-7	2016	Small-bore connectors for liquids and gases in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications
Ph Eur	2014	Farmacopea Europea, 8va ed.
USP 38– NF 33	2015	Farmacopea de los Estados Unidos de América
BP	2015	Farmacopea Británica
Ph. Int.	2015	The international pharmacopoeia. 5th ed.
FEUM	2014	Farmacopea de los Estados Unidos Mexicanos. Suplemento para Dispositivos Médicos. 3ra ed.
5.6.1 ESTERILIZACIÓN		
NORMA	**AÑO**	**TÍTULO**
NC EN 556-1	2007	Esterilización de equipos y dispositivos médicos. Requisitos de los equipos y dispositivos médicos para ser designados "estéril". Parte 1: Requisitos de los equipos y dispositivos médicos esterilizados en su estado final (EN 556-1:2001, IDT)
NC EN 556-2	2007	Esterilización de equipos y dispositivos médicos. Requisitos de los equipos y dispositivos médicos para ser designados "estéril". Parte 2: Requisitos de los equipos y dispositivos médicos procesados asépticamente (EN 556-2: 2003, IDT)
NC ISO 11135	2004	Equipos Médicos. Validación y control de rutina de la esterilización por óxido de etileno (ISO 11135:1994, IDT)
NC ISO 11137-1	2017	Esterilización de productos para uso médico. Radiación. Parte 1: Requisitos para el desarrollo, la validación y el control de rutina de un proceso de esterilización para equipos médicos (ISO 11137-1:2006, IDT)
NC ISO 11137-2	2016	Esterilización de productos para uso médico. Radiación. Parte 2: Establecimiento de la dosis de esterilización (ISO 11137-2: 2006, IDT)
NC ISO 11137-3	2016	Esterilización de productos para uso médico. Radiación. Parte 3: Recomendaciones sobre los aspectos dosimétricos (ISO 11137-3: 2006, IDT)
NC ISO 17664	2010	Evaluación de equipos médicos. Información a proporcionar por el fabricante para el procesamiento de equipos médicos reesterilizables (ISO 17664:2004, IDT)
EN 556-2	2015	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 2: Requirements for aseptically processed medical devices
ISO 11135	2014	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11137-2	2013	Sterilization of health care products. Radiation. Part 2: Establishing the sterilization dose
ISO 11137-3	2017	Sterilization of health care products. Radiation. Part 3: Guidance on dosimetric aspects
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 11607-1 / Amd 1: 2014	2006	Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2 / Amd 1: 2014	2006	Packaging for terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing and assembly processes

ISO 11737-1 / Cor 1: 2007	2006	Sterilization of medical devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products
ISO 11737-2	2009	Sterilization of medical devices. Microbiological methods. Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 13408-1 / Amd 1:2013	2008	Aseptic processing of health care products. Part 1: General requirements
ISO 13408-7	2012	Aseptic processing of health care products. Part 7: Alternative processes for medical devices and combination products
ISO 14160	2011	Sterilization of health care products. Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives. Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
ISO 14161	2009	Sterilization of health care products. Biological indicators. Guidance for the selection, use and interpretation of results
ISO 14937	2009	Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO/TS 16775	2014	Packaging for terminally sterilized medical devices. Guidance on the application of ISO 11607-1 and ISO 11607-2
ISO 17664	2017	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17665-1	2006	Sterilization of health care products. Moist heat. Part 1. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO/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
ISO 18472	2006	Sterilization of health care products. Biological and chemical indicators. Test equipment
ISO 20857	2010	Sterilization of health care products. Dry heat. Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 25424	2009	Sterilization of medical devices. Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical devices
5.7 IMPLANTES ACTIVOS		
NORMA	**AÑO**	**TÍTULO**
ISO 14708-1	2014	Implants for surgery. Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-4	2008	Implants for surgery. Active implantable medical devices. Part 4: Implantable infusion pumps
ISO 14708-7	2013	Implants for surgery. Active implantable medical devices. Part 7: Particular requirements for cochlear implant systems
5.7.1 CARDIOLOGÍA		
NORMA	**AÑO**	**TÍTULO**
ISO 14708-2	2012	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	2010	Implants for surgery. Active implantable medical devices. Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
ISO 25539-1	2017	Cardiovascular implants. Endovascular devices. Part 1: Endovascular prostheses
ISO 25539-2	2012	Cardiovascular implants. Endovascular devices. Part 2: Vascular stents
5.8 IMPLANTES NO ACTIVOS		
NORMA	**AÑO**	**TÍTULO**
ISO 5832-1	2016	Implants for surgery. Metallic materials. Part 1: Wrought stainless steel
ISO 5832-2	1999	Implants for surgery. Metallic materials. Part 2: Unalloyed titanium
ISO 5832-3	2016	Implants for surgery. Metallic materials. Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 5832-4	2014	Implants for surgery. Metallic materials. Part 4: Cobalt-chromium-molybdenum casting alloy
ISO 5832-6	1997	Implants for surgery. Metallic materials. Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy
ISO 5832-11	2014	Implants for surgery. Metallic materials. Part 11: Wrought titanium 6-aluminium 7-niobium alloy
ISO 5832-12 / Cor 1:2008	2007	Implants for surgery. Metallic materials. Part 12: Cobalt-chromium-molybdenum alloy
ISO 14602	2010	Non-active surgical implants. Implants for osteosynthesis. Particular requirements
ISO 14607	2007	Non-active surgical implants. Mammary implants. Particular requirements
ISO 14630	2012	Non active surgical implants. General requirements
ISO 16061	2015	Instrumentation for use in association with non-active surgical implants. General requirements
5.8.1 ORTOPEDIA		
NORMA	**AÑO**	**TÍTULO**
NC 20-02	1983	Artificios ortopédicos. Términos y definiciones
NC 20-05	1984	Juego ortopédico para fijaciones externas. Tipo RALCA
NC 298	2012	Vendas enyesadas. Especificaciones

ISO 8828	2014	Implants for surgery. Guidance on care and handling of orthopaedic implant
ISO 21534	2007	Non-active surgical implants. Joint replacement implants. Particular requirements
5.8.2 CARDIOLOGÍA		
NORMA	**AÑO**	**TÍTULO**
ISO 5840-1	2015	Cardiovascular implants. Cardiac valve prostheses. Part 1: General requirements
ISO 5840-2	2015	Cardiovascular implants. Cardiac valve prostheses. Part 2: Surgically implanted heart valve substitutes
ISO 5840-3	2013	Cardiovascular implants. Cardiac valve prostheses. Part 3: Heart valve substitutes implanted by transcatheter techniques
ISO 7198	2016	Cardiovascular implants and extracorporeal systems. Vascular prostheses. Tubular vascular grafts and vascular patches
ISO 8637 / Amd 1: 2013	2010	Cardiovascular implants and extracorporeal systems. Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators
ISO 8638	2010	Cardiovascular implants and extracorporeal systems. Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
ISO 12417-1	2015	Cardiovascular implants and extracorporeal systems. Vascular device-drug combination products. Part 1: General requirements
5.9 OFTALMOLOGÍA Y EQUIPOS ÓPTICOS		
NORMA	**AÑO**	**TÍTULO**
NC 20-27	1983	Armaduras metálicas de espejuelos. Especificaciones de calidad
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 11979-8	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 15004-1	2006	Ophthalmic instruments. Fundamental requirements and test methods. Part 1: General requirements applicable to all ophthalmic instruments
5.10 EQUIPOS DE ANESTESIA Y RESPIRACIÓN		
NORMA	**AÑO**	**TÍTULO**
ISO 5361	2016	Anaesthetic and respiratory equipment. Tracheal tubes and connectors
ISO 5366	2016	Anaesthetic and respiratory equipment. Tracheostomy tubes and connector.
ISO 18190	2016	Anaesthetic and respiratory equipment. General requirements for airways and related equipment
ISO 18562-1	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 1: Evaluation and testing within a risk management process
ISO 18562-2	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 2: Tests for emissions of particulate matter
6. SOFTWARE MÉDICO		
NORMA	**AÑO**	**TÍTULO**
NC ISO/IEC 12119	2005	Tecnología de la información. Paquetes de software. Requisitos de calidad y ensayos/pruebas (ISO/IEC 12119: 1994, IDT)
NC ISO/IEC 25010	2016	Ingeniería de software y sistemas. Requisitos de la calidad y evaluación de software (SQuaRE). Modelos de la calidad de software y sistemas (ISO/IEC 25010:2011, IDT)
NC ISO/IEC 25020	2016	Ingeniería de software. Requisitos de la calidad y evaluación del producto de software (SQuaRE). Modelo de referencia y guía para las mediciones (ISO/IEC 25020:2007, IDT)
NC ISO IEC 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 90003	2006	Ingeniería de software. Directivas para la aplicación de la NC ISO 9001:2001 al software de computación (ISO/IEC 90003:2004, IDT)
ISO/IEC 12207	2008	Systems and software engineering. Software life cycle processes
ISO/IEC/IEEE 15288:2015	2015	Systems and software engineering. System life cycle processes
ISO/IEC 25000	2014	Systems and software engineering. Systems and software Quality Requirements and Evaluation (SQuaRE). Guide to SQuaRE
IEC 62304 (ed. consolidada)	2015	Medical device software. Software life cycle processes
IEC/TR 80002-1	2009	Medical device software. Part 1: Guidance on the application of ISO 14971 to medical device software
ISO/TR 80002-2	2017	Medical device software. Part 2: Validation of software for medical device quality systems
IEC/TR 80002-3	2014	Medical device software. Part 3: Process reference model of medical device software life cycle processes (IEC 62304)
IEC 82304-1	2016	Health software. Part 1: General requirements for product safety
ISO/IEC 90003	2014	Software engineering. Guidelines for the application of ISO 9001:2008 to computer software

7. ENSAYOS DE LABORATORIO		
NORMA	**AÑO**	**TÍTULO**
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
ISO 23529	2016	Rubber. General procedures for preparing and conditioning test pieces for physical test method
IEC 60068-1	2013	Environmental testing. Part 1: General and guidance
IEC 60068-3-1	2011	Environmental testing. Part 3-1: Supporting documentation and guidance. Cold and dry heat tests
IEC 60721-1 (ed. consolidada)	1995	Classification of environmental conditions. Part 1: Environmental parameters and their severities
IEC 60721-2-1	2013	Classification of environmental conditions. Part 2-1: Environmental conditions appearing in nature. Temperature and humidity
IEC 61010-1	2010	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements
IEC 61010-2-010	2014	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-040	2015	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
IEC 61010-2-051	2015	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	2015	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

El contenido y la edición de este número estuvo a cargo de un grupo de trabajo coordinado por la Sección de Políticas y Asuntos Reguladores del CECMED integrado por:

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