

## Instructions for Completing the IMDRF Standards Checklist

- This checklist (see this document's second sheet 'Star complete answers for all. If you are unable to answer al choices or enter another response.
- The TC/SC (column B) lists the SDOs TC/SC based upo IEC 80369-5 is [IEC] SC62D.
- The Latest Publication listed may not account for rele includes the most recent such publications. If appropria
- 4. Please feel free to add other standards that are used,
- 5. Please see definitions for key terms below these instr
- When you have completed this document, please sav along with your completed 'Standards Survey' documen

## Column/question

- E. Recognized as part of a formal or informal recognition program?
- F. Not recognized but its use is allowed?
- G. Which version is recognized/allowed?
- H. Is its use mandatory?
- I. Recognized /allowed in full?
- J. Which part(s) are not recognized or allowed?
- K. Is this non-recognized or not-allowed part of the standard modified by your regulatory authority?

| modification?                     |
|-----------------------------------|
| M. Comments                       |
|                                   |
|                                   |
| DIRECT/FORMAL RECOGNITION PROGRAM |
| INFORMAL RECOGNITION PROGRAM      |
| FULLY RECOGNIZED STANDARD         |
| PARTIALLY RECOGNIZED STANDARD     |
| USE/ALLOW/ACCEPT                  |
| MANDATORY STANDARD                |
| VOLUNTARY STANDARD                |
| REGULATORY AUTHORITY (RA)         |
|                                   |

L. What is the reason for non-recognition or

CONFORMITY ASSESSMENT



ndards Checklist') features 1,126 standards used in medical device review. We ask that you provide I of them because of time constraints, please at least answer rows 2-293. Use the drop-down menu

n the ISO/IEC Document referenced (column A) as the lead SDO. For example, ISO 80369-1 is [ISO] TC210;

vant Amendments or Technical Corrigendum published; however, it is assumed that the use of standards te, please note this in Column M 'Comments.'

recognized by your Regulatory Authority (RA) after row 1,127. ructions.

re it as 'Standards Checklist [your regulatory authority name]' and email it to gail.rodriguez@fda.hhs.gov, it, no later than 7 December 2018. Thank you.

## Instructions

Please choose 'yes' or 'no' from the drop-down menu, or type in a response. If 'yes' skip to column G.

Please choose 'yes' 'no' or type in a response. If 'no' go to the next standard/row.

Please type the version/year of the standard your Regulatory Authority recognizes or allows the use of.

Please choose 'yes' or 'no, voluntary' from the drop-down menu, or type in a response.

Please choose 'yes' 'no, in part' 'no, modified by RA' or type in a response.

Please type in the part or parts of the standard that your Regulatory Authority does not recognize.

Please choose 'yes' if your RA has modified this part of the standard or 'no' or type in a response.

Please choose a reason from the drop-down menu, or type in the reason for the non-recognition or modification.

Please share any comments that provide clarification or useful information about your response.

## **DEFINITIONS**

A systematic and formal process for identifying and evaluating standards appropriate for manufacturers to use to meet a regulatory requirement. A formal program should feature a systematic evaluation process, and may also have other elements, e.g., a public process for nominating standards for recognition. A formal program often has a legal basis or authority to specify and/or support the standard recognition. Note: 'recognized' standards can be declared 'mandatory' or 'voluntary' in a standards recognition program. Both pre- and post-market standards can be a part of a recognition program.

An informal program, policy, or set of procedures that allows the use of certain standards in device submissions but does not feature a structured, routine or systematic approach to standards. For example, the RA's policies may affirm that certain standards can and/or should be used in the pre-market and post-market regulation of medical devices. However, an informal program often lacks of a legal basis or authority. Note: An informal recognition program may feature formal and informal elements, e.g., periodic publication of lists of standards appropriate for use in submissions.

The entire standard is recognized as appropriate to support regulatory requirements

Partial recognition refers to a standard in which only a part or parts are formally recognized.

A manufacturer is permitted to rely on/declare conformity with a consensus standard that may or may not be recognized or mandatory.

Standard the application of which is made compulsory by virtue of a general law or exclusive reference in a regulation (ISO/IEC Guide 2/2004)

Any standard, recognized or not, that is not mandatory.

A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (GHTF/SG1/N078:2012)

Demonstration that specified requirements...relating to a product... process, system, person or body are fulfilled (ISO/IEC 17000:2004 Conformity assessment: vocabulary and general principles)

| Recognized as part of a formal or informal recognition program? | Not recognized but its use is allowed? | Which version is recognized/all owed | Is its use<br>Mandatory ? |
|---|--|--------------------------------------|---------------------------|
| Yes   | yes                                    |                                      | yes                       |
| No  | no                                     |                                      | No, voluntary             |
|   |  |                                      |                           |
|   |  |                                      |                           |
|   |  |                                      |                           |
|   |  |                                      |                           |
|   |  |                                      |                           |
|   |  |                                      |                           |

| Recognized /allowed in full ? | which part(s)<br>are not<br>recognized or<br>allowed ? | is this non-<br>recognized or not<br>allowed parted<br>modified? | why is the reason for non-<br>recognition or modification?                                |
|-------------------------------|--|--|---|
| Yes                           |  | Yes  | Translated or transformed as MOD  |
| No, in part                   |  | No   | Does not have acceptance criteria   |
| No, modified by RA            |  |  | Not necessary for conformity assessment   |
|                               |  |  | Conflicts with an existing regulation   |
|                               |  |  | Conflicts with another recognized standard  |
|                               |  |  | Contains a test method or specification that is not scientifically acceptable or feasible |
|                               |  |  | Creates a barrier to trade, innovation or technological advancement                       |
|                               |  |  | Is not regulated as medical device  |
|                               |  |  | No or very few products in domestic market  |
|                               |  |  | Other (explain)   |

| 行标签            | 计数项:TC/SC |        |
|----------------|-----------|--------|
| ISO/TC172/SC7  | 79        | IS     |
| ISO/TC215      | 74        | IEC    |
| ISO/TC106/SC4  | 64        | ISC    |
| ISO/TC76       | 59        | ISO    |
| ISO/TC198      | 46        | ISO/   |
| IEC/TC62/SC62B | 42        | ISO/   |
| IEC/TC62/SC62D | 40        | ISO/   |
| ISO/TC150/SC1  | 39        | ISO/   |
| IEC/TC62/SC62A | 37        | ISO/1  |
| IEC/TC62/SC62C | 29        | ISO/T  |
| ISO/TC121/SC3  | 29        | ISO/TO |
| ISO/TC106/SC2  | 26        | ISO/TO |
| ISO/TC173/SC1  | 25        | ISO/TO |
| ISO/TC84       | 24        | IEC/TC |
| ISO/TC194      | 24        | ISO/TC |
| ISO/TC173/SC3  | 23        | ,      |
| ISO/TC212      | 22        |        |
| ISO/TC150/SC5  | 22        |        |
| ISO/TC168      | 21        |        |
| ISO/TC150/SC4  | 21        |        |
| ISO/TC106/SC1  | 20        |        |
| IEC/TC29       | 20        |        |
| ISO/TC210      | 18        |        |
| ISO/TC150/SC2  | 16        |        |
| ISO/TC121/SC6  | 15        |        |
| IEC/TC87       | 14        |        |
| ISO/TC150/SC6  | 14        |        |
| ISO/TC106/SC6  | 13        |        |
| ISO/TC173      | 13        |        |
| ISO/TC43       | 12        |        |
| ISO/TC121/SC2  | 12        |        |
| ISO/TC106/SC7  | 11        |        |
| ISO/TC121/SC1  | 11        |        |
| ISO/TC150      | 10        |        |
| ISO/TC172/SC5  | 10        |        |
| ISO/TC157      | 9         |        |
| ISO/TC6/SC2    | 9         |        |
| ISO/TC106/SC8  | 9         |        |
| IEC/TC66       | 7         |        |
| ISO/TC106/SC3  | 6         |        |
| ISO/TC194/SC1  | 5         |        |
| ISO/TC170      | 5         |        |
| ISO/TC159/SC5  | 3         |        |
| ISO/TC249      | 3         |        |
| ISO/TC217      | 3         |        |
| ISO/TC94/SC13  | 3         |        |
| ISO/TC45/SC4   | 3         |        |
| 130/1043/304   | 3         |        |

| IEC/TC76         | 3    |
|------------------|------|
| ISO/IECJTC1      | 3    |
| ISO/TC121/SC8    | 3    |
| ISO/TC122        | 2    |
| ISO/IECJTC1/SC35 | 2    |
| ISO/TC45/SC3     | 2    |
| ISO/TC178        | 2    |
| ISO/TC106/SC9    | 2    |
| IEC/TC100        | 1    |
| ISO/TC121/SC4    | 1    |
| ISO/TC85/SC2     | 1    |
| ISO/IECJTC1/SC28 | 1    |
| ISO/TC29/SC8     | 1    |
| ISO/TC58/SC4     | 1    |
| ISO/TC159/SC4    | 1    |
| ISO/TC106/SC5    | 1    |
| ISO/TC106        | 1    |
| ISO/TC159        | 1    |
| ISO/TC150/SC7    | 1    |
| ISO/TC173/SC2    | 1    |
| IEC/TC61         | 1    |
| IEC/TC65/SC65A   | 1    |
| ISO/TC229        | 1    |
| ISO/TC172        | 1    |
| 总计               | 1055 |

| Document<br>Reference | TC/SC     | Latest<br>Publication | Amendment or correction publication | English Title   |
|-----------------------|-----------|-----------------------|-------------------------------------|---|
| ISO 13485             | ISO/TC210 | 2016                  |                                     | Medical devices - Quality management systems - Requirements for regulatory purposes   |
| ISO 14971             | ISO/TC210 | 2019                  |                                     | Medical devices - Application of risk management to medical devices   |
| ISO 15223-1           | ISO/TC210 | 2016                  |                                     | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements  |
| ISO 15223-2           | ISO/TC210 | 2010                  |                                     | Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation   |
| ISO 16142-1           | ISO/TC210 | 2016                  |                                     | Medical devices - Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards |
| ISO 16142-2           | ISO/TC210 | 2017                  |                                     | Medical devices - Recognized essential principles of safety and performance of medical devices - Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards     |
| ISO 80369-1           | ISO/TC210 | 2018                  |                                     | Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements   |
| ISO 80369-3           | ISO/TC210 | 2016                  | A1:2019                             | Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications  |
| ISO 80369-6           | ISO/TC210 | 2016                  |                                     | Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications  |
| ISO 80369-7           | ISO/TC210 | 2016                  |                                     | Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications  |
| ISO 80369-20          | ISO/TC210 | 2015                  |                                     | Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods   |

| ISO/TR 24971     | ISO/TC210          | 2013 |         | Medical devices - Guidance on the application of ISO 14971   |
|------------------|--------------------|------|---------|--|
| ISO 18250-3      | ISO/TC210          | 2018 |         | Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 3: Enteral applications   |
| ISO 18250-8      | ISO/TC210          | 2018 |         | Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 8: Citrate-based anticoagulant solution for apheresis applications  |
| ISO/TS 19218-1   | ISO/TC210          | 2011 | A1:2013 | Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes  |
| ISO/TS 19218-2   | ISO/TC210          | 2012 |         | Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes  |
| ISO/TR 80002-2   | ISO/TC210          | 2017 |         | Medical device software - Part 2: Validation of software for medical device quality systems  |
| IEC/TR 60788     | ISO/TC210          | 2004 |         | Medical electrical equipment - Glossary of defined terms   |
| IEC 60601-1 ISH1 | IEC/TC62/SC62<br>A | 2008 |         | Interpretation sheet 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance  |
| IEC 60601-1 ISH2 | IEC/TC62/SC62<br>A | 2009 |         | Interpretation sheet 2 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance  |
| IEC 60601-1 ISH3 | IEC/TC62/SC62<br>A | 2013 |         | Interpretation sheet 3 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance  |
| IEC/TR 60513     | IEC/TC62/SC62<br>A | 1994 |         | Fundamental aspects of safety standards for medical electrical equipment   |
| IEC/TR 62366-2   | IEC/TC62/SC62<br>A | 2016 |         | Medical devices - Part 2: Guidance on the application of usability engineering to medical devices  |
| IEC 60601-1-10   | IEC/TC62/SC62<br>A | 2007 | A1:2013 | Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers |

| IEC 60601-1-2  | IEC/TC62/SC62<br>A | 2014 |           | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   |
|----------------|--------------------|------|-----------|---|
| IEC 60601-1-8  | IEC/TC62/SC62<br>A | 2006 | A1:2012   | 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 60601-1-9  | IEC/TC62/SC62<br>A | 2007 | A1:2013   | Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design   |
| IEC 62304      | IEC/TC62/SC62<br>A | 2006 | A1:2015   | Medical device software - Software life cycle processes   |
| IEC 62353      | IEC/TC62/SC62<br>A | 2014 |           | Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment   |
| IEC 62366-1    | IEC/TC62/SC62<br>A | 2015 | Cor1:2016 | Medical devices - Part 1: Application of usability engineering to medical devices   |
| IEC 80001-1    | IEC/TC62/SC62<br>A | 2010 |           | Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities   |
| IEC/TR 60930   | IEC/TC62/SC62<br>A | 2008 |           | Guidelines for administrative, medical and nursing staff concerned with the safe use of medical electrical equipment and medical electrical systems   |
| IEC/TR 61258   | IEC/TC62/SC62<br>A | 2008 |           | Guidelines for the development and use of medical electrical equipment educational materials  |
| IEC/TR 62296   | IEC/TC62/SC62<br>A | 2009 |           | Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements  |
| IEC/TR 80002-1 | IEC/TC62/SC62<br>A | 2009 |           | Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software   |
| IEC/TR 80002-3 | IEC/TC62/SC62<br>A | 2014 |           | Medical device software - Part 3: Process reference model of medical device software life cycle processes (IEC 62304)   |
| IEC 60601-1-11 | IEC/TC62/SC62<br>A | 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           | IEC/TC62/SC62<br>A | 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 service |
|--------------------------|--------------------|------|---------|---|
| IEC/TR 60878             | IEC/TC62/SC62<br>A | 2015 |         | Graphical symbols for electrical equipment in medical practice  |
| IEC/TR 62348             | IEC/TC62/SC62<br>A | 2012 |         | Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition  |
| IEC/TR 62354             | IEC/TC62/SC62<br>A | 2014 |         | General testing procedures for medical electrical equipment   |
| IEC 60601-1              | IEC/TC62/SC62<br>A | 2020 |         | Medical electrical equipment - All parts  |
| IEC 60601-1<br>ISH1:2008 | IEC/TC62/SC62<br>A |      |         | Interpretation sheet 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   |
| IEC 60601-1<br>ISH2:2008 | IEC/TC62/SC62<br>A |      |         | Interpretation sheet 2 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   |
| IEC 60601-1<br>ISH3:2008 | IEC/TC62/SC62<br>A | 2013 |         | Interpretation sheet 3 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   |
| IEC 60601-1-6            | IEC/TC62/SC62<br>A | 2010 | A1:2013 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability   |
| IEC/TR 60601-4-1         | IEC/TC62/SC62<br>A | 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         | IEC/TC62/SC62<br>A | 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 | IEC/TC62/SC62<br>A | 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 60601-4-4 | IEC/TC62/SC62<br>A | 2017 |           | Medical electrical equipment - Part 4-4: Guidance and interpretation - Guidance for writers of particular standards when creating alarm system-related requirements  |
| IEC/TR 80001-2-1 | IEC/TC62/SC62<br>A | 2012 |           | Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks - Pratical applications and examples  |
| IEC/TR 80001-2-2 | IEC/TC62/SC62<br>A | 2012 |           | Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls                                      |
| IEC/TR 80001-2-3 | IEC/TC62/SC62<br>A | 2012 |           | Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks  |
| IEC/TR 80001-2-4 | IEC/TC62/SC62<br>A | 2012 |           | Application of risk management for IT-networks incorporating medical devices - Part 2-4: Application guidance - General implementation guidance for healthcare delivery organizations  |
| IEC/TR 80001-2-5 | IEC/TC62/SC62<br>A | 2014 |           | Application of risk management for IT-networks incorporating medical devices - Part 2-5: Application guidance - Guidance on distributed alarm systems  |
| IEC/TR 80001-2-8 | IEC/TC62/SC62<br>A | 2016 |           | Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2                  |
| IEC/TR 80001-2-9 | IEC/TC62/SC62<br>A | 2017 |           | Application of risk management for IT-networks incorporating medical devices - Part 2-9: Application guidance - Guidance for use of security assurance cases to demonstrate confidence in IEC TR 80001-2-2 security capabilities |
| IEC 82304-1      | IEC/TC62/SC62<br>A | 2016 |           | Health software - Part 1: General requirements for product safety  |
| IEC TS 61223-1   | IEC/TC62/SC62<br>B | 1993 |           | Evaluation and routine testing in medical imaging departments - Part 1: General aspects  |
| IEC PAS 63077    | IEC/TC62/SC62<br>B | 2016 |           | Good refurbishment practices for medical imaging equipment   |
| IEC 60336        | IEC/TC62/SC62<br>B | 2005 | Cor1:2006 | Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots  |
| IEC 60522        | IEC/TC62/SC62<br>B | 1999 |           | Determination of the permanent filtration of X-ray tube assemblies   |

| IEC 60526      | IEC/TC62/SC62<br>B | 1978 |                          | High-voltage cable plug and socket connections for medical X-ray equipment   |
|----------------|--------------------|------|--------------------------|--|
| IEC 60601-1-3  | IEC/TC62/SC62<br>B | 2008 | A1:2013                  | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment   |
| IEC 60601-2-33 | IEC/TC62/SC62<br>B | 2010 | ,Cor1:2012,Cor2:<br>2016 | Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis               |
| IEC 60601-2-37 | IEC/TC62/SC62<br>B | 2007 |                          | Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment           |
| IEC 60601-2-43 | IEC/TC62/SC62<br>B | 2010 |                          | 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 | IEC/TC62/SC62<br>B | 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 | IEC/TC62/SC62<br>B | 2011 | A1:2015                  | Medical electrical equipment - Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammomagraphic stereotactic devices |
| IEC 60601-2-54 | IEC/TC62/SC62<br>B | 2009 | •                        | Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy                   |
| IEC 60613      | IEC/TC62/SC62<br>B | 2010 |                          | Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis  |
| IEC 60627      | IEC/TC62/SC62<br>B | 2013 |                          | Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids  |
| IEC 60806      | IEC/TC62/SC62<br>B | 1984 |                          | Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis  |
| IEC 61223-2-6  | IEC/TC62/SC62<br>B | 2006 |                          | Evaluation and routine testing in medical imaging departments 1 Part 216: Constancy tests 1 Imaging performance of computed tomography X-ray equipment                               |
| IEC 61223-3-2  | IEC/TC62/SC62<br>B | 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  | IEC/TC62/SC62<br>B | 2000 |                          | Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment   |

| IEC 64222 2 E | IEC/TC62/SC62      | 2004 | Cor1:2006 | Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests   |
|---------------|--------------------|------|-----------|--|
| IEC 61223-3-5 | B                  | 2004 | C011.2000 | - Imaging performance of computed tomography X-ray equipment   |
| IEC 61262-1   | IEC/TC62/SC62<br>B | 1994 |           | Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 1: Determination of the entrance field size  |
| IEC 61262-2   | IEC/TC62/SC62<br>B | 1994 |           | Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 2: Determination of the conversion factor  |
| IEC 61262-3   | IEC/TC62/SC62<br>B | 1994 |           | Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 3: Determination of the luminance distribution and luminance non-uniformity          |
| IEC 61262-4   | IEC/TC62/SC62<br>B | 1994 |           | Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 4: Determination of the image distortion   |
| IEC 61262-5   | IEC/TC62/SC62<br>B | 1994 |           | Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 5: Determination of the detective quantum efficiency                                 |
| IEC 61262-6   | IEC/TC62/SC62<br>B | 1994 |           | Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 6: Determination of the contrast ratio and veiling glare index                       |
| IEC 61262-7   | IEC/TC62/SC62<br>B | 1995 |           | Medical electrical equipment - Characteristics of electro-optical X-ray image intensifiers - Part 7: Determination of the modulation transfer function                                 |
| IEC 61331-1   | IEC/TC62/SC62<br>B | 2014 |           | Protective devices against diagnostic medical X-radiation - Part 1: Determination of attenuation properties of materials   |
| IEC 61331-2   | IEC/TC62/SC62<br>B | 2014 |           | Protective devices against diagnostic medical X-radiation - Part 2: Translucent protective plates  |
| IEC 61331-3   | IEC/TC62/SC62<br>B | 2014 |           | Protective devices against diagnostic medical X-radiation - Part 3: Protective clothing, eyewear and protective patient shields  |
| IEC 61910-1   | IEC/TC62/SC62<br>B | 2014 |           | Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy   |
| IEC 62220-1-1 | IEC/TC62/SC62<br>B | 2015 |           | Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging |
| IEC 62220-1-2 | IEC/TC62/SC62<br>B | 2007 |           | Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography          |
| IEC 62220-1-3 | IEC/TC62/SC62<br>B | 2008 |           | Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging      |

| IEC 62464-1      | IEC/TC62/SC62<br>B | 2018 |         | Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters  |
|------------------|--------------------|------|---------|---|
| IEC 62464-2      | IEC/TC62/SC62<br>B | 2010 |         | Magnetic resonance equipment for medical imaging - Part 2: Classification criteria for pulse sequences  |
| IEC 62494-1      | IEC/TC62/SC62<br>B | 2008 |         | Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography                                     |
| IEC 62563-1      | IEC/TC62/SC62<br>B | 2009 | A1:2016 | Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods   |
| IEC 60601-2-28   | IEC/TC62/SC62<br>B | 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 60601-2-63   | IEC/TC62/SC62<br>B | 2012 | A1:2017 | Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment                             |
| IEC 60601-2-65   | IEC/TC62/SC62<br>B | 2012 | A1:2017 | Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment                             |
| IEC TS 61223-2-1 | IEC/TC62/SC62<br>B | 1993 |         | Evaluation and routing testing in medical imaging departments - Part 2-1: Constancy tests - Film processors   |
| IEC 62570        | IEC/TC62/SC62<br>B | 2014 |         | Standard practice for marking medical devices and other items for safety in the magnetic resonance environment  |
| IEC TS 61170     | IEC/TC62/SC62<br>C | 1993 |         | Radiotherapy simulators - Guidelines for functional performance characteristics   |
| IEC TR 61852     | IEC/TC62/SC62<br>C | 1998 |         | Medical electrical equipment - Digital imaging and communications in medicine (DICOM) - Radiotherapy objects  |
| IEC 60580        | IEC/TC62/SC62<br>C | 2000 |         | Medical electrical equipment - Dose area product meters   |
| IEC 60601-2-1    | IEC/TC62/SC62<br>C | 2009 | A1:2014 | 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 60601-2-11   | IEC/TC62/SC62<br>C | 2013 |         | Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment                                  |
| IEC 60601-2-17   | IEC/TC62/SC62<br>C | 2013 |         | Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment |

| IEC 60601-2-29 | IEC/TC62/SC62<br>C | 2008 |           | Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators  |
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| IEC 60601-2-64 | IEC/TC62/SC62<br>C | 2014 |           | Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment  |
| IEC 60601-2-68 | IEC/TC62/SC62<br>C | 2014 |           | Electrical medical 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 |
| IEC 60601-2-8  | IEC/TC62/SC62<br>C | 2010 | A1:2015   | 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 60976      | IEC/TC62/SC62<br>C | 2007 |           | Medical electrical equipment - Medical electron accelerators - Functional performance characteristics  |
| IEC 61168      | IEC/TC62/SC62<br>C | 1993 |           | Radiotherapy simulators - Functional performance characteristics   |
| IEC 61217      | IEC/TC62/SC62<br>C | 2011 |           | Radiotherapy equipment - Coordinates, movements and scales   |
| IEC 61267      | IEC/TC62/SC62<br>C | 2005 |           | Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics  |
| IEC 61303      | IEC/TC62/SC62<br>C | 1994 | Cor1:2016 | Medical electrical equipment - Radionuclide calibrators - Particular methods for describing performance  |
| IEC 61674      | IEC/TC62/SC62<br>C | 2012 |           | Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging  |
| IEC 61675-2    | IEC/TC62/SC62<br>C | 2015 |           | Radionuclide imaging devices - Characteristics and test conditions - Part 2: Gamma cameras for planar, wholebody, and SPECT imaging  |
| IEC 61676      | IEC/TC62/SC62<br>C | 2002 | A1:2008   | Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology  |
| IEC 62083      | IEC/TC62/SC62<br>C | 2009 |           | Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems  |
| IEC 62274      | IEC/TC62/SC62<br>C | 2005 |           | Medical electrical equipment - Safety of radiotherapy record and verify systems  |

| IEC/TR 60977   | IEC/TC62/SC62<br>C | 2008 |                       | Medical electrical equipment - Medical electron accelerators - Guidelines for functional performance characteristics   |
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| IEC/TR 61948-2 | IEC/TC62/SC62<br>C | 2001 |                       | Nuclear medicine instrumentation - Routine tests - Part 2: Scintillation cameras and single photon emission computed tomography imaging                                    |
| IEC/TR 61948-4 | IEC/TC62/SC62<br>C | 2019 |                       | Nuclear medicine instrumentation - Routine tests - Part 4: Radionuclide calibrators  |
| IEC 61675-1    | IEC/TC62/SC62<br>C | 2013 |                       | Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs  |
| IEC/TR 61948-3 | IEC/TC62/SC62<br>C | 2018 |                       | Nuclear medicine instrumentation - Routine tests - Part 3: Positron emission tomographs  |
| IEC 60731      | IEC/TC62/SC62<br>C | 2011 | A1:2016               | Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy   |
| IEC 62467-1    | IEC/TC62/SC62<br>C | 2009 |                       | Medical electrical equipment - Dosimetric instruments as used in brachytherapy - Part 1: Instruments based on well-type ionization chambers                                |
| IEC 62667      | IEC/TC62/SC62<br>C | 2017 |                       | Medical electrical equipment - Medical light ion beam equipment - Performance characteristics  |
| IEC/TR 61948-1 | IEC/TC62/SC62<br>C | 2016 |                       | Nuclear medicine instrumentation - Routine tests - Part 1: Gamma radiation counting systems  |
| IEC/TR 61289   | IEC/TC62/SC62<br>D | 2011 |                       | High frequency surgical equipment - Operation and maintenance  |
| IEC 80601-2-71 | IEC/TC62/SC62<br>D | 2015 |                       | Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment |
| IEC 60601-2-18 | IEC/TC62/SC62<br>D | 2009 |                       | Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment                                   |
| IEC 60601-2-19 | IEC/TC62/SC62<br>D | 2009 |                       | Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators                                      |
| IEC 60601-2-20 | IEC/TC62/SC62<br>D | 2009 |                       | Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators                            |
| IEC 60601-2-21 | IEC/TC62/SC62<br>D | 2009 | Cor1:2013,A1:20<br>16 | Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers                                 |

| IEC 60601-2-23 | IEC/TC62/SC62<br>D | 2011 |         | Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment   |
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| IEC 60601-2-24 | IEC/TC62/SC62<br>D | 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 | IEC/TC62/SC62<br>D | 2011 |         | Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs                                    |
| IEC 60601-2-27 | IEC/TC62/SC62<br>D | 2011 |         | Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment              |
| IEC 60601-2-31 | IEC/TC62/SC62<br>D | 2008 | A1:2011 | Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source |
| IEC 60601-2-34 | IEC/TC62/SC62<br>D | 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 | IEC/TC62/SC62<br>D | 2014 |         | Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy     |
| IEC 60601-2-4  | IEC/TC62/SC62<br>D | 2010 | A1:2018 | Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators                                  |
| IEC 60601-2-40 | IEC/TC62/SC62<br>D | 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 | IEC/TC62/SC62<br>D | 2009 |         | Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis       |
| IEC 60601-2-46 | IEC/TC62/SC62<br>D | 2016 |         | Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables                                       |
| IEC 60601-2-47 | IEC/TC62/SC62<br>D | 2012 |         | Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems                |
| IEC 60601-2-5  | IEC/TC62/SC62<br>D | 2009 |         | Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment                      |
| IEC 60601-2-50 | IEC/TC62/SC62<br>D | 2009 |         | Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment                          |

| IEC 60601-2-52 | IEC/TC62/SC62<br>D | 2009 | Cor1:2010,A1:20<br>15 | Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds  |
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| IEC 60601-2-62 | IEC/TC62/SC62<br>D | 2013 |                       | Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment                                      |
| IEC 80369-5    | IEC/TC62/SC62<br>D | 2016 | Cor1:2017             | Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications  |
| IEC 80601-2-35 | IEC/TC62/SC62<br>D | 2009 | 2015,A1:2016          | Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use |
| IEC 80601-2-58 | IEC/TC62/SC62<br>D | 2014 | A1:2016               | Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery                          |
| IEC 80601-2-60 | IEC/TC62/SC62<br>D | 2019 |                       | Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment  |
| IEC 60601-2-10 | IEC/TC62/SC62<br>D | 2012 | A1:2016               | Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators  |
| IEC 60601-2-16 | IEC/TC62/SC62<br>D | 2018 |                       | Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment                                 |
| IEC 60601-2-2  | IEC/TC62/SC62<br>D | 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 60601-2-26 | IEC/TC62/SC62<br>D | 2012 |                       | Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs  |
| IEC 60601-2-3  | IEC/TC62/SC62<br>D | 2012 | A1:2016               | Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment   |
| IEC 60601-2-39 | IEC/TC62/SC62<br>D | 2018 |                       | Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment   |
| IEC 60601-2-6  | IEC/TC62/SC62<br>D | 2012 | A1:2016               | Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment  |
| IEC/TR 62653   | IEC/TC62/SC62<br>D | 2012 |                       | Guideline for safe operation of medical equipment used for haemodialysis treatments   |

| IEC 80601-2-30 | IEC/TC62/SC62<br>D | 2018 | Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers                       |
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| IEC 80601-2-59 | IEC/TC62/SC62<br>D | 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 60601-2-75 | IEC/TC62/SC62<br>D | 2017 | Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment      |
| IEC 60601-2-76 | IEC/TC62/SC62<br>D | 2018 | Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment                   |
| IEC PAS 63023  | IEC/TC62/SC62<br>D | 2016 | Medical electrical system - Input interface for haemodialysis equipment for use of external alarming device  |
| IEC 80601-2-49 | IEC/TC62/SC62<br>D | 2018 | Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors                                 |
| ISO/TR 15499   | ISO/TC194          | 2016 | Biological evaluation of medical devices Guidance on the conduct of biological evaluation within a risk management process   |
| ISO 10993-1    | ISO/TC194          | 2018 | Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process   |
| ISO 10993-10   | ISO/TC194          | 2010 | Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization  |
| ISO 10993-12   | ISO/TC194          | 2012 | Biological evaluation of medical devices Part 12: Sample preparation and reference materials   |
| ISO 10993-13   | ISO/TC194          | 2010 | Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices   |
| ISO 10993-14   | ISO/TC194          | 2001 | Biological evaluation of medical devices Part 14: Identification and quantification of degradation products from ceramics  |
| ISO 10993-15   | ISO/TC194          | 2000 | Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys   |
| ISO 10993-16   | ISO/TC194          | 2017 | Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables   |
| ISO 10993-17   | ISO/TC194          | 2002 | Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances   |

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| ISO 10993-2     | ISO/TC194 | 2006 |           | Biological evaluation of medical devices Part 2: Animal welfare requirements   |
| ISO 10993-3     | ISO/TC194 | 2014 |           | Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity                 |
| ISO 10993-4     | ISO/TC194 | 2017 |           | Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood                                    |
| ISO 10993-5     | ISO/TC194 | 2009 |           | Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity   |
| ISO 10993-6     | ISO/TC194 | 2016 |           | Biological evaluation of medical devices Part 6: Tests for local effects after implantation  |
| ISO 10993-7     | ISO/TC194 | 2008 | Cor1:2009 | Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals  |
| ISO 10993-9     | ISO/TC194 | 2009 |           | Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products |
| ISO/TR 10993-33 | ISO/TC194 | 2015 |           | Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3         |
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| ISO/TR 37137    | ISO/TC194 | 2014 |           | Cardiovascular biological evaluation of medical devices Guidance for absorbable implants   |
| ISO 10993-11    | ISO/TC194 | 2017 |           | Biological evaluation of medical devices - Part 11: Tests for systemic toxicity  |
| ISO/TS 10993-19 | ISO/TC194 | 2006 |           | Biological evaluation of medical devices Part 19: Physico-chemical, morphological and topographical characterization of materials  |
| ISO/TS 10993-20 | ISO/TC194 | 2006 |           | Biological evaluation of medical devices Part 20: Principles and methods for immunotoxicology testing of medical devices           |
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| ISO 22442-2    | ISO/TC194/SC1 | 2015 |                     | Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling  |
| ISO 22442-3    | ISO/TC194/SC1 | 2007 |                     | Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents                            |
| ISO/TR 22442-4 | ISO/TC194/SC1 | 2010 |                     | Medical devices utilizing animal tissues and their derivatives - Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes |
| ISO 11135      | ISO/TC198     | 2014 | A1:2018             | Sterilization of health-care products Ethylene oxide Requirements for the development, validation and routine control of a sterilization process for medical devices  |
| ISO 11137-1    | ISO/TC198     | 2006 | A1:2013,<br>A2:2018 | Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices   |
| ISO 11137-2    | ISO/TC198     | 2013 |                     | Sterilization of health care products Radiation Part 2: Establishing the sterilization dose   |
| ISO 11140-1    | ISO/TC198     | 2014 |                     | Sterilization of health care products Chemical indicators Part 1: General requirements  |
| ISO 11140-3    | ISO/TC198     | 2007 | Cor1:2007           | Sterilization of health care products Chemical indicators Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test   |
| ISO 11140-4    | ISO/TC198     | 2007 |                     | Sterilization of health care products Chemical indicators Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration   |
| ISO 11140-5    | ISO/TC198     | 2007 |                     | Sterilization of health care products Chemical indicators Part 5: Class 2 indicators for Bowie and Dick-type air removal tests  |
| ISO 11607-1    | ISO/TC198     | 2019 |                     | Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems   |
| ISO 11607-2    | ISO/TC198     | 2019 |                     | Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes   |

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| ISO 13004   | ISO/TC198 | 2013 |         | Sterilization of health care products Radiation Substantiation of selected sterilization dose: Method VDmaxSD  |
| ISO 13408-1 | ISO/TC198 | 2008 | A1:2013 | Aseptic processing of health care products Part 1: General requirements  |
| ISO 13408-3 | ISO/TC198 | 2006 |         | Aseptic processing of health care products Part 3: Lyophilization  |
| ISO 13408-4 | ISO/TC198 | 2005 |         | Aseptic processing of health care products Part 4: Clean-in-place technologies   |
| ISO 13408-5 | ISO/TC198 | 2006 |         | Aseptic processing of health care products Part 5: Sterilization in place  |
| ISO 13408-6 | ISO/TC198 | 2005 | A1:2013 | Aseptic processing of health care products Part 6: Isolator systems  |
| ISO 13408-7 | ISO/TC198 | 2012 |         | Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products  |
| ISO 14160   | ISO/TC198 | 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 |
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| ISO 15882   | ISO/TC198 | 2008 |         | Sterilization of health care products Chemical indicators Guidance for selection, use and interpretation of results  |
| ISO 15883-1 | ISO/TC198 | 2006 | A1:2014 | Washer-disinfectors - Part 1: General requirements, terms and definitions and tests  |
| ISO 15883-2 | ISO/TC198 | 2006 |         | Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.   |
| ISO 15883-3 | ISO/TC198 | 2006 |         | Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers   |

| ISO 15883-4    | ISO/TC198 | 2018 | Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes  |
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| ISO 15883-6    | ISO/TC198 | 2011 | Washer-disinfectors Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment               |
| ISO 15883-7    | ISO/TC198 | 2016 | Washer-disinfectors Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment |
| ISO 17665-1    | ISO/TC198 | 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 18362      | ISO/TC198 | 2016 | Manufacture of cell-based health care products Control of microbial risks during processing   |
| ISO 18472      | ISO/TC198 | 2018 | Sterilization of health care products - Biological and chemical indicators - Test equipment   |
| ISO 20857      | ISO/TC198 | 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      | ISO/TC198 | 2018 | Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices         |
| ISO/TS 17665-3 | ISO/TC198 | 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 11137-3    | ISO/TC198 | 2017 | Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control   |
| ISO 11138-1    | ISO/TC198 | 2017 | Sterilization of health care products Biological indicators Part 1: General requirements  |
| ISO 11138-2    | ISO/TC198 | 2017 | Sterilization of health care products Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes  |
| ISO 11138-3    | ISO/TC198 | 2017 | Sterilization of health care products Biological indicators Part 3: Biological indicators for moist heat sterilization processes  |
| ISO 11138-4    | ISO/TC198 | 2017 | Sterilization of health care products Biological indicators Part 4: Biological indicators for dry heat sterilization processes  |

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| ISO 11737-1        | ISO/TC198            | 2018 | Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products   |
| ISO 13408-2        | ISO/TC198            | 2018 | Aseptic processing of health care products Part 2: Sterilizing filtration   |
| ISO 17664          | ISO/TC198            | 2017 | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices  |
| ISO/TS 16775       | ISO/TC198            | 2014 | Packaging for terminally sterilized medical devices Guidance on the application of ISO 11607-1 and ISO 11607-2  |
| ISO 11139          | ISO/TC198            | 2018 | Sterilization of health care products Vocabulary of terms used in sterilization and related equipment and process standards   |
| ISO/TS 15883-5     | ISO/TC198            | 2005 | Washer-disinfectors Part 5: Test soils and methods for demonstrating cleaning efficacy  |
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| ISO/TS 19930       | ISO/TC198            | 2017 | Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6 |
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| ISO/IEC TR 29138-2 | ISO/IECJTC1          | 2009 | Information technology Accessibility considerations for people with disabilities Part 2: Standards inventory  |
| ISO/IEC TR 29138-3 | ISO/IECJTC1          | 2009 | Information technology Accessibility considerations for people with disabilities Part 3: Guidance on user needs mapping   |
| ISO/IEC 10779      | ISO/IECJTC1/S<br>C28 | 2008 | Information technology Office equipment accessibility guidelines for elderly persons and persons with disabilities  |
| ISO/IEC 13066-1    | ISO/IECJTC1/S<br>C35 | 2011 | Information technology Interoperability with assistive technology (AT) Part 1: Requirements and recommendations for interoperability  |
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| ISO80601-2-69 | ISO/TC121/SC3 | 2014 |         | Medical electrical equipment Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment |
| IEC 62127-1   | IEC/TC87      | 2007 | A1:2013 | Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz                              |
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| ISO 7405      | ISO/TC106     | 2018 |         | Dentistry Evaluation of biocompatibility of medical devices used in dentistry   |
| ISO 13116     | ISO/TC106/SC1 | 2014 |         | Dentistry Test Method for Determining Radio-Opacity of Materials  |
| ISO 15841     | ISO/TC106/SC1 | 2014 |         | Dentistry Wires for use in orthodontics   |
| ISO 17254     | ISO/TC106/SC1 | 2016 |         | Dentistry Coiled springs for use in orthodontics  |
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| ISO 13397-2 | ISO/TC106/SC4 | 2005 | Dentistry Periodontal curettes, dental scalers and excavators Part 2: Periodontal curettes of Gr-type                 |
| ISO 13397-3 | ISO/TC106/SC4 | 1996 | Periodontal curettes, dental scalers and excavators Part 3: Dental scalers H-type                                     |
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| ISO 16635-2 | ISO/TC106/SC4 | 2014 |         | Dentistry Dental rubber dam instruments Part 2: Clamp forceps                  |
| ISO 17509   | ISO/TC106/SC4 | 2016 |         | Dentistry Torque transmitter for handpieces                                    |
| ISO 17937   | ISO/TC106/SC4 | 2015 |         | Dentistry Osteotome  |
| ISO 1797    | ISO/TC106/SC4 | 2017 |         | Dentistry Shanks for rotary and oscillating instruments                        |
| ISO 18397   | ISO/TC106/SC4 | 2016 |         | Dentistry Powered scaler   |
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| ISO 3630-4  | ISO/TC106/SC4 | 2009 |         | Dentistry Root canal instruments Part 4: Auxiliary instruments                 |

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| ISO 7711-2 | ISO/TC106/SC4 | 2011 |         | Dentistry Rotary diamond instruments Part 2: Discs   |
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| ISO 9168   | ISO/TC106/SC4 | 2009 |         | Dentistry Hose connectors for air driven dental handpieces                      |
| ISO 9173-2 | ISO/TC106/SC4 | 2010 |         | Dentistry Extraction forceps Part 2: Designation                                |
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| ISO 3630-3 | ISO/TC106/SC4 | 2015 |         | Dentistry Endodontic instruments Part 3: Compactors: pluggers and spreaders     |
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| ISO 9680   | ISO/TC106/SC6 | 2014 | Dentistry Operating lights  |
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| ISO 10637  | ISO/TC106/SC6 | 2018 | Dentistry Central suction source equipment  |
| ISO 13897  | ISO/TC106/SC6 | 2018 | Dentistry Dental amalgam reusable mixing-capsules   |
| ISO 7488   | ISO/TC106/SC6 | 2018 | Dentistry Mixing machines for dental amalgam  |

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| ISO 17730  | ISO/TC106/SC7 | 2014 |         | Dentistry Fluoride varnishes   |
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| ISO 80601-2-13 | ISO/TC121/SC1 | 2011 | A1:2015,A2:2018                   | Medical electrical equipment Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation            |
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| ISO 8835-4     | ISO/TC121/SC1 | 2004 | revised by ISO<br>80601-2-13:2011 | Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices  |
| ISO 8835-5     | ISO/TC121/SC1 | 2004 | revised by ISO<br>80601-2-13:2011 |   |
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| ISO 10524-4    | ISO/TC121/SC6 | 2008 |         | Pressure regulators for use with medical gases Part 4: Low-pressure regulators   |
| ISO 11197      | ISO/TC121/SC6 | 2016 |         | Medical supply units   |
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| ISO 7396-2  | ISO/TC121/SC6 | 2007 |                                   | Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems  |
| ISO 9170-2  | ISO/TC121/SC6 | 2008 |                                   | Terminal units for medical gas pipeline systems Part 2: Terminal units for anaesthetic gas scavenging systems                 |
| ISO 10524-1 | ISO/TC121/SC6 | 2018 |                                   | Pressure regulators for use with medical gases Part 1: Pressure regulators and pressure regulators with flow-metering devices |
| ISO 10524-2 | ISO/TC121/SC6 | 2018 |                                   | Pressure regulators for use with medical gases Part 2: Manifold and line pressure regulators                                  |
| ISO 9170-1  | ISO/TC121/SC6 | 2017 |                                   | Terminal units for medical gas pipeline systems Part 1: Terminal units for use with compressed medical gases and vacuum       |
| ISO 10079-1 | ISO/TC121/SC8 | 2015 |                                   | Medical suction equipment Part 1: Electrically powered suction equipment  |
| ISO 10079-2 | ISO/TC121/SC8 | 2014 |                                   | Medical suction equipment Part 2: Manually powered suction equipment  |
| ISO 10079-3 | ISO/TC121/SC8 | 2014 |                                   | Medical suction equipment Part 3: Suction equipment powered from a vacuum or positive pressure gas source                     |
| ISO 11156   | ISO/TC122     | 2011 |                                   | Packaging Accessible design General requirements  |
| ISO 11683   | ISO/TC122     | 1997 |                                   | Packaging Tactile warnings of danger Requirements   |

| ISO 12891-1  | ISO/TC150     | 2015 |           | Retrieval and analysis of surgical implants Part 1: Retrieval and handling   |
|--------------|---------------|------|-----------|--|
| ISO 12891-2  | ISO/TC150     | 2014 |           | Retrieval and analysis of surgical implants Part 2: Analysis of retrieved surgical implants                                |
| ISO 14630    | ISO/TC150     | 2012 |           | Non-active surgical implants General requirements  |
| ISO 16054    | ISO/TC150     | 2000 |           | Implants for surgery Minimum data sets for surgical implants   |
| ISO 16061    | ISO/TC150     | 2015 |           | Instrumentation for use in association with non-active surgical implants General requirements                              |
| ISO 7197     | ISO/TC150     | 2006 | Cor1:2007 | Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components   |
| ISO 8828     | ISO/TC150     | 2014 |           | Implants for surgery Guidance on care and handling of orthopaedic implants   |
| ISO 9713     | ISO/TC150     | 2002 |           | Neurosurgical implants Self-closing intracranial aneurysm clips  |
| ISO 14607    | ISO/TC150     | 2018 |           | Non-active surgical implants Mammary implants Particular requirements  |
| ISO/TR 14283 | ISO/TC150     | 2018 |           | Implants for surgery Essential principles of safety and performance  |
| ISO 13175-3  | ISO/TC150/SC1 | 2012 |           | Implants for surgery Calcium phosphates Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes              |
| ISO 13179-1  | ISO/TC150/SC1 | 2014 |           | Implants for surgery Plasma-sprayed unalloyed titanium coatings on metallic surgical implants Part 1: General requirements |
| ISO 13356    | ISO/TC150/SC1 | 2015 |           | Implants for surgery Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)                              |
| ISO 13779-2  | ISO/TC150/SC1 | 2018 |           | Implants for surgery Hydroxyapatite Part 2: Coatings of hydroxyapatite   |
| ISO 13779-3  | ISO/TC150/SC1 | 2018 |           | Implants for surgery Hydroxyapatite Part 3: Chemical analysis and characterization of crystallinity and phase purity       |

| ISO 13779-4 | ISO/TC150/SC1 | 2018 | Implants for surgery Hydroxyapatite Part 4: Determination of coating adhesion strength   |
|-------------|---------------|------|--|
| ISO 13779-6 | ISO/TC150/SC1 | 2015 | Implants for surgery Hydroxyapatite Part 6: Powders  |
| ISO 13782   | ISO/TC150/SC1 | 1996 | Implants for surgery Metallic materials Unalloyed tantalum for surgical implant applications   |
| ISO 14949   | ISO/TC150/SC1 | 2001 | Implants for surgery Two-part addition-cure silicone elastomers  |
| ISO 15374   | ISO/TC150/SC1 | 1998 | Implants for surgery Requirements for production of forgings   |
| ISO 15309   | ISO/TC150/SC1 | 2013 | Implants for surgery Differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices                     |
| ISO 16402   | ISO/TC150/SC1 | 2008 | Implants for surgery Acrylic resin cement Flexural fatigue testing of acrylic resin cements used in orthopaedics   |
| ISO 16428   | ISO/TC150/SC1 | 2005 | Implants for surgery Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices                       |
| ISO 16429   | ISO/TC150/SC1 | 2004 | Implants for surgery Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods |
| ISO 20160   | ISO/TC150/SC1 | 2006 | Implants for surgery Metallic materials Classification of microstructures for alpha+beta titanium alloy bars   |
| ISO 23317   | ISO/TC150/SC1 | 2014 | Implants for surgery In vitro evaluation for apatite-forming ability of implant materials  |
| ISO 5832-1  | ISO/TC150/SC1 | 2016 | Implants for surgery Metallic materials Part 1: Wrought stainless steel  |
| ISO 5832-11 | ISO/TC150/SC1 | 2014 | Implants for surgery Metallic materials Part 11: Wrought titanium 6-aluminium 7-<br>niobium alloy  |
| ISO 5832-12 | ISO/TC150/SC1 | 2019 | Implants for surgery Metallic materials Part 12: Wrought cobalt-chromium-molybdenum alloy  |
| ISO 5832-14 | ISO/TC150/SC1 | 2019 | Implants for surgery Metallic materials Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy  |

| ISO 5832-3 | ISO/TC150/SC1 | 2016 | Implants for surgery Metallic materials Part 3: Wrought titanium 6-aluminium 4-vanadium alloy  |
|------------|---------------|------|--|
| ISO 5832-4 | ISO/TC150/SC1 | 2014 | Implants for surgery Metallic materials Part 4: Cobalt-chromium-molybdenum casting alloy   |
| ISO 5832-5 | ISO/TC150/SC1 | 2005 | Implants for surgery Metallic materials Part 5: Wrought cobalt-chromium-tungsten-<br>nickel alloy  |
| ISO 5832-6 | ISO/TC150/SC1 | 1997 | Implants for surgery Metallic materials Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy  |
| ISO 5832-7 | ISO/TC150/SC1 | 2016 | Implants for surgery Metallic materials Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy                   |
| ISO 5832-8 | ISO/TC150/SC1 | 1997 | Implants for surgery Metallic materials Part 8: Wrought cobalt-nickel-chromium-molybdenum- tungsten-iron alloy                           |
| ISO 5832-9 | ISO/TC150/SC1 | 2019 | Implants for surgery Metallic materials Part 9: Wrought high nitrogen stainless steel  |
| ISO 5833   | ISO/TC150/SC1 | 2002 | Implants for surgery Acrylic resin cements   |
| ISO 5834-1 | ISO/TC150/SC1 | 2019 | Implants for surgery Ultra-high-molecular-weight polyethylene Part 1: Powder form  |
| ISO 5834-2 | ISO/TC150/SC1 | 2019 | Implants for surgery Ultra-high-molecular-weight polyethylene Part 2: Moulded forms  |
| ISO 5834-3 | ISO/TC150/SC1 | 2019 | Implants for surgery Ultra-high-molecular-weight polyethylene Part 3: Accelerated ageing methods   |
| ISO 5834-4 | ISO/TC150/SC1 | 2019 | Implants for surgery Ultra-high-molecular-weight polyethylene Part 4: Oxidation index measurement method                                 |
| ISO 5834-5 | ISO/TC150/SC1 | 2019 | Implants for surgery Ultra-high-molecular-weight polyethylene Part 5: Morphology assessment method                                       |
| ISO 6474-1 | ISO/TC150/SC1 | 2019 | Implants for surgery Ceramic materials Part 1: Ceramic materials based on high purity alumina  |
| ISO 6474-2 | ISO/TC150/SC1 | 2019 | Implants for surgery Ceramic materials Part 2: Composite materials based on a high-<br>purity alumina matrix with zirconia reinforcement |

| ISO 9583     | ISO/TC150/SC1 | 1993 | Implants for surgery Non-destructive testing Liquid penetrant inspection of metallic surgical implants   |
|--------------|---------------|------|--|
| ISO 9584     | ISO/TC150/SC1 | 1993 | Implants for surgery Non-destructive testing Radiographic examination of cast metallic surgical implants   |
| ISO 13781    | ISO/TC150/SC1 | 2017 | Implants for surgery - Homopolymers, copolymers and blends on poly(lactide) - In vitro degradation testing   |
| ISO 5832-2   | ISO/TC150/SC1 | 2018 | Implants for surgery - Metallic materials - Part 2: Unalloyed titanium   |
| ISO 11658    | ISO/TC150/SC2 | 2012 | Cardiovascular implants and extracorporeal systems - Blood/tissue contact surface modifications for extracorporeal perfusion systems                               |
| ISO 12417-1  | ISO/TC150/SC2 | 2015 | Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements                                      |
| ISO 15674    | ISO/TC150/SC2 | 2016 | Cardiovascular implants and artificial organs - Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags                |
| ISO 15675    | ISO/TC150/SC2 | 2016 | Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters   |
| ISO 15676    | ISO/TC150/SC2 | 2016 | Cardiovascular implants and artificial organs - Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) |
| ISO/TS 17137 | ISO/TC150/SC2 | 2014 | Cardiovascular implants and extracorporeal systems - Cardiovascular absorbable implants  |
| ISO 18242    | ISO/TC150/SC2 | 2016 | Cardiovascular implants and extracorporeal systems Centrifugal blood pumps   |
| ISO 25539-1  | ISO/TC150/SC2 | 2017 | Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses   |
| ISO 25539-2  | ISO/TC150/SC2 | 2012 | Cardiovascular implants - Endovascular devices Part 2: Vascular stents   |
| ISO 25539-3  | ISO/TC150/SC2 | 2011 | Cardiovascular implants - Endovascular devices Part 3: Vena cava filters   |

| ISO 5840-1   | ISO/TC150/SC2 | 2015 |         | Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements  |
|--------------|---------------|------|---------|--|
|              |               |      |         |  |
| ISO 5840-2   | ISO/TC150/SC2 | 2015 |         | Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes  |
| ISO 5840-3   | ISO/TC150/SC2 | 2013 |         | Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques   |
| ISO 7198     | ISO/TC150/SC2 | 2016 |         | Cardiovascular implants and extracorporeal systems Vascular prostheses Tubular vascular grafts and vascular patches  |
| ISO 7199     | ISO/TC150/SC2 | 2016 |         | Cardiovascular implants and artificial organs Blood-gas exchangers (oxygenators)   |
| ISO/TS 23810 | ISO/TC150/SC2 | 2018 |         | Cardiovascular implants and artificial organs Checklist for preoperative extracorporeal circulation equipment setup  |
| ISO 14242-1  | ISO/TC150/SC4 | 2014 | A1:2018 | Implants for surgery Wear of total hip-joint prostheses Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test                      |
| ISO 14242-2  | ISO/TC150/SC4 | 2016 |         | Implants for surgery Wear of total hip-joint prostheses Part 2: Methods of measurement   |
| ISO 14242-3  | ISO/TC150/SC4 | 2009 | A1:2019 | Implants for surgery Wear of total hip-joint prostheses Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test |
| ISO 14243-1  | ISO/TC150/SC4 | 2009 |         | Implants for surgery Wear of total knee-joint prostheses Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test   |
| ISO 14243-2  | ISO/TC150/SC4 | 2016 |         | Implants for surgery Wear of total knee-joint prostheses Part 2: Methods of measurement  |
| ISO 14879-1  | ISO/TC150/SC4 | 2000 |         | Implants for surgery Total knee-joint prostheses Part 1: Determination of endurance properties of knee tibial trays  |
| ISO 16087    | ISO/TC150/SC4 | 2013 |         | Implants for surgery Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants   |
| ISO 17853    | ISO/TC150/SC4 | 2011 |         | Wear of implant materials Polymer and metal wear particles Isolation and characterization  |
| ISO 21534    | ISO/TC150/SC4 | 2007 |         | Non-active surgical implants Joint replacement implants Particular requirements  |

| ISO 21535   | ISO/TC150/SC4 | 2007 | A1:2016 | Non-active surgical implants Joint replacement implants Specific requirements for hip-<br>joint replacement implants   |
|-------------|---------------|------|---------|--|
| ISO 21536   | ISO/TC150/SC4 | 2007 | A1:2014 | Non-active surgical implants Joint replacement implants Specific requirements for knee-joint replacement implants  |
| ISO 7206-1  | ISO/TC150/SC4 | 2008 |         | Implants for surgery Partial and total hip joint prostheses Part 1: Classification and designation of dimensions   |
| ISO 7206-10 | ISO/TC150/SC4 | 2018 |         | Implants for surgery Partial and total hip-joint prostheses Part 10: Determination of resistance to static load of modular femoral heads   |
| ISO 7206-12 | ISO/TC150/SC4 | 2016 |         | Implants for surgery Partial and total hip joint prostheses Part 12: Deformation test method for acetabular shells   |
| ISO 7206-13 | ISO/TC150/SC4 | 2016 |         | Implants for surgery Partial and total hip joint prostheses Part 13: Determination of resistance to torque of head fixation of stemmed femoral components  |
| ISO 7206-2  | ISO/TC150/SC4 | 2011 | A1:2016 | Implants for surgery Partial and total hip joint prostheses Part 2: Articulating surfaces made of metallic, ceramic and plastics materials   |
| ISO 7206-4  | ISO/TC150/SC4 | 2010 | A1:2016 | Implants for surgery Partial and total hip joint prostheses Part 4: Determination of endurance properties and performance of stemmed femoral components  |
| ISO 7206-6  | ISO/TC150/SC4 | 2013 |         | Implants for surgery Partial and total hip joint prostheses Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components                                   |
| ISO 7207-1  | ISO/TC150/SC4 | 2007 |         | Implants for surgery Components for partial and total knee joint prostheses Part 1: Classification, definitions and designation of dimensions  |
| ISO 7207-2  | ISO/TC150/SC4 | 2011 | A1:2016 | Implants for surgery Components for partial and total knee joint prostheses Part 2: Articulating surfaces made of metal, ceramic and plastics materials  |
| ISO 14243-3 | ISO/TC150/SC4 | 2014 |         | Implants for surgery Wear of total knee-joint prostheses Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test |
| ISO 10334   | ISO/TC150/SC5 | 1994 |         | Implants for surgery Malleable wires for use as sutures and other surgical applications  |
| ISO 12189   | ISO/TC150/SC5 | 2008 |         | Implants for surgery Mechanical testing of implantable spinal devices Fatigue test method for spinal implant assemblies using an anterior support  |

| ISO 14602   | ISO/TC150/SC5 | 2010 |         | Non-active surgical implants Implants for osteosynthesis Particular requirements  |
|-------------|---------------|------|---------|---|
| ISO 15142-1 | ISO/TC150/SC5 | 2003 |         | Implants for surgery Metal intramedullary nailing systems Part 1: Intramedullary nails  |
| ISO 15142-2 | ISO/TC150/SC5 | 2003 |         | Implants for surgery Metal intramedullary nailing systems Part 2: Locking components  |
| ISO 15142-3 | ISO/TC150/SC5 | 2003 |         | Implants for surgery Metal intramedullary nailing systems Part 3: Connection devices and reamer diameter measurements   |
| ISO 18192-1 | ISO/TC150/SC5 | 2011 | A1:2018 | Implants for surgery Wear of total intervertebral spinal disc prostheses Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test |
| ISO 18192-2 | ISO/TC150/SC5 | 2010 |         | Implants for surgery Wear of total intervertebral spinal disc prostheses Part 2: Nucleus replacements   |
| ISO 5835    | ISO/TC150/SC5 | 1991 |         | Implants for surgery Metal bone screws with hexagonal drive connection, spherical under-<br>surface of head, asymmetrical thread Dimensions   |
| ISO 5836    | ISO/TC150/SC5 | 1988 |         | Implants for surgery Metal bone plates Holes corresponding to screws with asymmetrical thread and spherical under-surface   |
| ISO 5837-1  | ISO/TC150/SC5 | 1985 |         | Implants for surgery Intramedullary nailing systems Part 1: Intramedullary nails with cloverleaf or V-shaped cross-section  |
| ISO 5838-1  | ISO/TC150/SC5 | 2013 |         | Implants for surgery Metallic skeletal pins and wires Part 1: General requirements  |
| ISO 5838-2  | ISO/TC150/SC5 | 1991 |         | Implants for surgery Skeletal pins and wires Part 2: Steinmann skeletal pins Dimensions   |
| ISO 5838-3  | ISO/TC150/SC5 | 1993 |         | Implants for surgery Skeletal pins and wires Part 3: Kirschner skeletal wires   |
| ISO 6475    | ISO/TC150/SC5 | 1989 |         | Implants for surgery Metal bone screws with asymmetrical thread and spherical under-<br>surface Mechanical requirements and test methods  |
| ISO 8319-1  | ISO/TC150/SC5 | 1996 |         | Orthopaedic instruments Drive connections Part 1: Keys for use with screws with hexagon socket heads  |
| ISO 8319-2  | ISO/TC150/SC5 | 1986 |         | Orthopaedic instruments Drive connections Part 2: Screwdrivers for single slot head screws, screws with cruciate slot and cross-recessed head screws                                      |

| ISO 8615    | ISO/TC150/SC5 | 1991 | Implants for surgery Fixation devices for use in the ends of the femur in adults  |
|-------------|---------------|------|---|
| ISO 8827    | ISO/TC150/SC5 | 1988 | Implants for surgery Staples with parallel legs for orthopaedic use General requirements  |
| ISO 9268    | ISO/TC150/SC5 | 1988 | Implants for surgery Metal bone screws with conical under-surface of head Dimensions  |
| ISO 9269    | ISO/TC150/SC5 | 1988 | Implants for surgery Metal bone plates Holes and slots corresponding to screws with conical under-surface   |
| ISO 9585    | ISO/TC150/SC5 | 1990 | Implants for surgery Determination of bending strength and stiffness of bone plates   |
| ISO 11318   | ISO/TC150/SC6 | 2002 | Cardiac defibrillators Connector assembly DF-1 for implantable defibrillators Dimensions and test requirements  |
| ISO 14117   | ISO/TC150/SC6 | 2012 | Active implantable medical devices Electromagnetic compatibility EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices   |
| ISO 14708-1 | ISO/TC150/SC6 | 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 14708-2 | ISO/TC150/SC6 | 2012 | Implants for surgery Active implantable medical devices Part 2: Cardiac pacemakers  |
| ISO 14708-4 | ISO/TC150/SC6 | 2008 | Implants for surgery Active implantable medical devices Part 4: Implantable infusion pumps  |
| ISO 14708-5 | ISO/TC150/SC6 | 2010 | Implants for surgery Active implantable medical devices Part 5: Circulatory support devices   |
| ISO 14708-6 | ISO/TC150/SC6 | 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 14708-7 | ISO/TC150/SC6 | 2013 | Implants for surgery Active implantable medical devices Part 7: Particular requirements for cochlear implant systems  |
| ISO 27185   | ISO/TC150/SC6 | 2012 | Cardiac rhythm management devices Symbols to be used with cardiac rhythm management device labels, and information to be supplied General requirements  |
| ISO 27186   | ISO/TC150/SC6 | 2010 | Active implantable medical devices Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements   |

| ISO 5841-2   | ISO/TC150/SC6 | 2014 |         | Implants for surgery Cardiac pacemakers Part 2: Reporting of clinical performance of populations of pulse generators or leads                                       |
|--------------|---------------|------|---------|---|
| ISO 5841-3   | ISO/TC150/SC6 | 2013 |         | Implants for surgery Cardiac pacemakers Part 3: Low-profile connectors (IS-1) for implantable pacemakers  |
| ISO/TS 10974 | ISO/TC150/SC6 | 2018 |         | Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device   |
| ISO 14708-3  | ISO/TC150/SC6 | 2017 |         | Implants for surgery Active implantable medical devices Part 3: Implantable neurostimulators  |
| ISO/TR 16379 | ISO/TC150/SC7 | 2014 |         | Tissue-engineered medical products Evaluation of anisotropic structure of articular cartilage using DT (Diffusion Tensor)-MR Imaging                                |
| ISO 16037    | ISO/TC157     | 2002 | A1:2011 | Rubber condoms for clinical trials Measurement of physical properties   |
| ISO 23409    | ISO/TC157     | 2011 |         | Male condoms Requirements and test methods for condoms made from synthetic materials  |
| ISO 29941    | ISO/TC157     | 2010 |         | Condoms Determination of nitrosamines migrating from natural rubber latex condoms   |
| ISO 29942    | ISO/TC157     | 2011 |         | Prophylactic dams Requirements and test methods   |
| ISO 4074     | ISO/TC157     | 2015 |         | Natural rubber latex male condoms - Requirements and test methods   |
| ISO 7439     | ISO/TC157     | 2015 |         | Copper-bearing contraceptive intrauterine devices Requirements and tests  |
| ISO 8009     | ISO/TC157     | 2014 |         | Mechanical contraceptives Reusable natural and silicone rubber contraceptive diaphragms Requirements and tests  |
| ISO 16038    | ISO/TC157     | 2017 |         | Male condoms Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms   |
| ISO 25841    | ISO/TC157     | 2017 |         | Female condoms Requirements and test methods  |
| ISO/TR 22411 | ISO/TC159     | 2008 |         | Ergonomics data and guidelines for the application of ISO/IEC Guide 71 to products and services to address the needs of older persons and persons with disabilities |

| ISO 24503   | ISO/TC159/SC4 | 2011 | Ergonomics Accessible designTactile dots and bars on consumer products  |
|-------------|---------------|------|---|
| ISO 24500   | ISO/TC159/SC5 | 2010 | Ergonomics Accessible design Auditory signals for consumer products   |
| ISO 24501   | ISO/TC159/SC5 | 2010 | Ergonomics Accessible design Sound pressure levels of auditory signals for consumer products  |
| ISO 24502   | ISO/TC159/SC5 | 2010 | Ergonomics Accessible design Sound pressure levels of auditory signals for consumer products  |
| ISO 13404   | ISO/TC168     | 2007 | Prosthetics and orthotics Categorization and description of external orthoses and orthotic components   |
| ISO 15032   | ISO/TC168     | 2000 | Prostheses Structural testing of hip units  |
| ISO 22523   | ISO/TC168     | 2006 | External limb prostheses and external orthoses - Requirements and test methods  |
| ISO 29781   | ISO/TC168     | 2008 | Prostheses and orthoses Factors to be included when describing physical activity of a person who has had a lower limb amputation(s) or who has a deficiency of a lower limb segment(s) present at birth |
| ISO 29782   | ISO/TC168     | 2008 | Prostheses and orthoses Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation  |
| ISO 29783-1 | ISO/TC168     | 2008 | Prosthetics and orthotics Vocabulary Part 1: Normal gait  |
| ISO 8548-1  | ISO/TC168     | 1989 | Prosthetics and orthotics Limb deficiencies Part 1: Method of describing limb deficiencies present at birth   |
| ISO 8548-2  | ISO/TC168     | 1993 | Prosthetics and orthotics Limb deficiencies Part 2: Method of describing lower limb amputation stumps   |
| ISO 8548-3  | ISO/TC168     | 1993 | Prosthetics and orthotics Limb deficiencies Part 3: Method of describing upper limb amputation stumps   |
| ISO 8548-4  | ISO/TC168     | 1998 | Prosthetics and orthotics Limb deficiencies Part 4: Description of causal conditions leading to amputation  |
| ISO 8548-5  | ISO/TC168     | 2003 | Prosthetics and orthotics Limb deficiencies Part 5: Description of the clinical condition of the person who has had an amputation   |

| ISO 8549-1   | ISO/TC168 | 1989 | Prosthetics and orthotics Vocabulary Part 1: General terms for external limb prostheses and external orthoses   |
|--------------|-----------|------|---|
| ISO 8549-2   | ISO/TC168 | 1989 | Prosthetics and orthotics Vocabulary Part 2: Terms relating to external limb prostheses and wearers of these prostheses   |
| ISO 8549-3   | ISO/TC168 | 1989 | Prosthetics and orthotics Vocabulary Part 3: Terms relating to external orthoses  |
| ISO 8551     | ISO/TC168 | 2003 | Prosthetics and orthotics Functional deficiencies Description of the person to be treated with an orthosis, clinical objectives of treatment, and functional requirements of the orthosis |
| ISO/TR 22676 | ISO/TC168 | 2006 | Prosthetics Testing of ankle-foot devices and foot units Guidance on the application of the test loading conditions of ISO 22675 and on the design of appropriate test equipment          |
| ISO 10328    | ISO/TC168 | 2016 | Prosthetics Structural testing of lower-limb prostheses Requirements and test methods   |
| ISO 13405-1  | ISO/TC168 | 2015 | Prosthetics and orthotics Classification and description of prosthetic components Part 1: Classification of prosthetic components   |
| ISO 13405-2  | ISO/TC168 | 2015 | Prosthetics and orthotics Classification and description of prosthetic components Part 2: Description of lower limb prosthetic components   |
| ISO 13405-3  | ISO/TC168 | 2015 | Prosthetics and orthotics Classification and description of prosthetic components Part 3: Description of upper limb prosthetic components   |
| ISO 22675    | ISO/TC168 | 2016 | Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods  |
| ISO 13402    | ISO/TC170 | 1995 | Surgical and dental hand instruments Determination of resistance against autoclaving, corrosion and thermal exposure  |
| ISO 7151     | ISO/TC170 | 1988 | Surgical instruments Non-cutting, articulated instruments General requirements and test methods   |
| ISO 7740     | ISO/TC170 | 1985 | Instruments for surgery Scalpels with detachable blades Fitting dimensions  |
| ISO 7741     | ISO/TC170 | 1986 | Instruments for surgery Scissors and shears General requirements and test methods   |

| ISO 7153-1   | ISO/TC170     | 2016 |           | Surgical instruments Materials Part 1: Metals   |
|--------------|---------------|------|-----------|---|
| ISO 7944     | ISO/TC172     | 1998 | Cor: 2009 | Optics and optical instruments Reference wavelengths  |
| ISO 11990    | ISO/TC172     | 2018 |           | Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs   |
| ISO 11948-1  | ISO/TC173/SC3 | 1996 |           | Urine-absorbing aids Part 1: Whole-product testing  |
| ISO 8600-1   | ISO/TC172/SC5 | 2015 |           | Endoscopes Medical endoscopes and endotherapy devices Part 1: General requirements  |
| ISO 8600-2   | ISO/TC172/SC5 | 2015 |           | Endoscopes - Medical endoscopes and endotherapy devices Part 2: Particular requirements for rigid bronchoscopes   |
| ISO 8600-3   | ISO/TC172/SC5 | 1997 | A1:2003   | Optics and optical instruments Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics |
| ISO 8600-4   | ISO/TC172/SC5 | 2014 |           | Endoscopes Medical endoscopes and endotherapy devices Part 4: Determination of maximum width of insertion portion   |
| ISO 8600-5   | ISO/TC172/SC5 | 2005 |           | Optics and photonics Medical endoscopes and endotherapy devices Part 5: Determination of optical resolution of rigid endoscopes with optics                         |
| ISO 8600-6   | ISO/TC172/SC5 | 2005 |           | Optics and photonics Medical endoscopes and endotherapy devices Part 6: Vocabulary  |
| ISO 8600-7   | ISO/TC172/SC5 | 2012 |           | Endoscopes Medical endoscopes and endotherapy devices Part 7: Basic requirements for medical endoscopes of water-resistant type                                     |
| ISO/TS 18339 | ISO/TC172/SC5 | 2015 |           | Endotherapy devices Eyepiece cap and light guide connector  |
| ISO/TS 18340 | ISO/TC172/SC5 | 2015 |           | Endoscopes Trocar pins, trocar sleeves and endotherapy devices for use with trocar sleeves  |
| ISO 10936-1  | ISO/TC172/SC5 | 2017 |           | Optics and photonics Operation microscopes Part 1: Requirements and test methods  |
| ISO 10341    | ISO/TC172/SC7 | 2012 |           | Ophthalmic instruments Refractor heads  |

| ISO 10342   | ISO/TC172/SC7 | 2010 |         | Ophthalmic instruments Eye refractometers   |
|-------------|---------------|------|---------|---|
| ISO 10343   | ISO/TC172/SC7 | 2014 |         | Ophthalmic instruments Ophthalmometers  |
| ISO 10685-1 | ISO/TC172/SC7 | 2011 |         | Ophthalmic optics Spectacle frames and sunglasses electronic catalogue and identification Part 1: Product identification and electronic catalogue product hierarchy |
| ISO 10936-2 | ISO/TC172/SC7 | 2010 |         | Optics and photonics Operation microscopes Part 2: Light hazard from operation microscopes used in ocular surgery   |
| ISO 10938   | ISO/TC172/SC7 | 2016 |         | Ophthalmic optics Chart displays for visual acuity measurement Printed, projected and electronic  |
| ISO 10940   | ISO/TC172/SC7 | 2009 |         | Ophthalmic instruments Fundus cameras   |
| ISO 10942   | ISO/TC172/SC7 | 2006 |         | Ophthalmic instruments Direct ophthalmoscopes   |
| ISO 10943   | ISO/TC172/SC7 | 2011 |         | Ophthalmic instruments Indirect ophthalmoscopes   |
| ISO 10944   | ISO/TC172/SC7 | 2009 |         | Ophthalmic instruments Synoptophores  |
| ISO 11380   | ISO/TC172/SC7 | 1994 |         | Optics and optical instruments Ophthalmic optics Formers  |
| ISO 11979-1 | ISO/TC172/SC7 | 2018 |         | Ophthalmic implants Intraocular lenses Part 1: Vocabulary   |
| ISO 11979-2 | ISO/TC172/SC7 | 2014 |         | Ophthalmic implants Intraocular lenses Part 2: Optical properties and test methods  |
| ISO 11979-3 | ISO/TC172/SC7 | 2012 |         | Ophthalmic implants Intraocular lenses Part 3: Mechanical properties and test methods   |
| ISO 11979-4 | ISO/TC172/SC7 | 2008 | A1:2012 | Ophthalmic implants Intraocular lenses Part 4: Labelling and information  |
| ISO 11979-5 | ISO/TC172/SC7 | 2006 |         | Ophthalmic implants Intraocular lenses Part 5: Biocompatibility   |

| ISO 11979-6 | ISO/TC172/SC7 | 2014 |         | Ophthalmic implants Intraocular lenses Part 6: Shelf-life and transport stability testing  |
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| ISO 11980   | ISO/TC172/SC7 | 2012 |         | Ophthalmic optics Contact lenses and contact lens care products Guidance for clinical investigations   |
| ISO 11987   | ISO/TC172/SC7 | 2012 |         | Ophthalmic optics Contact lenses Determination of shelf-life   |
| ISO 12865   | ISO/TC172/SC7 | 2006 |         | Ophthalmic instruments Retinoscopes  |
| ISO 12866   | ISO/TC172/SC7 | 1999 | A1:2008 | Ophthalmic instruments Perimeters  |
| ISO 12867   | ISO/TC172/SC7 | 2010 |         | Ophthalmic instruments Trial frames  |
| ISO 13212   | ISO/TC172/SC7 | 2014 |         | Ophthalmic optics Contact lens care products Guidelines for determination of shelf-life  |
| ISO 14534   | ISO/TC172/SC7 | 2011 |         | Ophthalmic optics Contact lenses and contact lens care products Fundamental requirements   |
| ISO 14729   | ISO/TC172/SC7 | 2001 | A1:2010 | Ophthalmic optics Contact lens care products Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses |
| ISO 14730   | ISO/TC172/SC7 | 2014 |         | Ophthalmic optics Contact lens care products Antimicrobial preservative efficacy testing and guidance on determining discard date                              |
| ISO 15004-1 | ISO/TC172/SC7 | 2006 |         | Ophthalmic instruments Fundamental requirements and test methods Part 1: General requirements applicable to all ophthalmic instruments                         |
| ISO 15004-2 | ISO/TC172/SC7 | 2007 |         | Ophthalmic instruments Fundamental requirements and test methods Part 2: Light hazard protection   |
| ISO 15253   | ISO/TC172/SC7 | 2000 |         | Ophthalmic optics and instruments Optical devices for enhancing low vision   |
| ISO 15254   | ISO/TC172/SC7 | 2009 |         | Ophthalmic optics and instruments Electro-optical devices for enhancing low vision   |
| ISO 15752   | ISO/TC172/SC7 | 2010 |         | Ophthalmic instruments Endoilluminators Fundamental requirements and test methods for optical radiation safety   |

| ISO 15798  | ISO/TC172/SC7 | 2013 | A1:2017   | Ophthalmic implants Ophthalmic viscosurgical devices  |
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| ISO 16034  | ISO/TC172/SC7 | 2002 | Cor1:2006 | Ophthalmic optics Specifications for single-vision ready-to-wear near- vision spectacles  |
| ISO 16284  | ISO/TC172/SC7 | 2006 |           | Ophthalmic optics Information interchange for ophthalmic optical equipment  |
| ISO 16671  | ISO/TC172/SC7 | 2015 | A1:2017   | Ophthalmic implants Irrigating solutions for ophthalmic surgery   |
| ISO 16672  | ISO/TC172/SC7 | 2015 |           | Ophthalmic implants Ocular endotamponades   |
| ISO 16971  | ISO/TC172/SC7 | 2015 |           | Ophthalmic instruments Optical coherence tomograph for the posterior segment of the human eye   |
| ISO 18259  | ISO/TC172/SC7 | 2014 |           | Ophthalmic optics Contact lens care products Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms |
| ISO 19045  | ISO/TC172/SC7 | 2015 |           | Ophthalmic optics Contact lens care products Method for evaluating Acanthamoeba encystment by contact lens care products  |
| ISO 19980  | ISO/TC172/SC7 | 2012 |           | Ophthalmic instruments Corneal topographers   |
| ISO 22665  | ISO/TC172/SC7 | 2012 |           | Ophthalmic optics and instruments - Instruments to measure axial distances in the eye   |
| ISO 24157  | ISO/TC172/SC7 | 2008 |           | Ophthalmic optics and instruments Reporting aberrations of the human eye  |
| ISO 7998   | ISO/TC172/SC7 | 2005 |           | Ophthalmic optics Spectacle frames Lists of equivalent terms and vocabulary   |
| ISO 8429   | ISO/TC172/SC7 | 1986 |           | Optics and optical instruments Ophthalmology Graduated dial scale   |
| ISO 8598-1 | ISO/TC172/SC7 | 2014 |           | Optics and optical instruments Focimeters Part 1: General purpose instruments   |
| ISO 8612   | ISO/TC172/SC7 | 2009 |           | Ophthalmic instruments Tonometers   |

| ISO 8624     | ISO/TC172/SC7 | 2011 | A1:2015 | Ophthalmic optics Spectacle frames Measuring system and terminology   |
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| ISO 8980-4   | ISO/TC172/SC7 | 2006 |         | Ophthalmic optics Uncut finished spectacle lenses Part 4: Specifications and test methods for anti-reflective coatings  |
| ISO 8980-5   | ISO/TC172/SC7 | 2005 |         | Ophthalmic optics Uncut finished spectacle lenses Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant   |
| ISO 9342-1   | ISO/TC172/SC7 | 2005 |         | Optics and optical instruments Test lenses for calibration of focimeters Part 1: Test lenses for focimeters used for measuring spectacle lenses   |
| ISO 9342-2   | ISO/TC172/SC7 | 2005 |         | Optics and optical instruments Test lenses for calibration of focimeters Part 2: Test lenses for focimeters used for measuring contact lenses   |
| ISO 9801     | ISO/TC172/SC7 | 2009 |         | Ophthalmic instruments Trial case lenses  |
| ISO/TR 20824 | ISO/TC172/SC7 | 2007 |         | Ophthalmic instruments Background for light hazard specification in ophthalmic instrument standards   |
| ISO/TR 28980 | ISO/TC172/SC7 | 2007 |         | Ophthalmic optics - Spectacle lenses - Parameters affecting lens power measurement  |
| ISO 10322-1  | ISO/TC172/SC7 | 2016 |         | Ophthalmic optics Semi-finished spectacle lens blanks Part 1: Specifications for single-vision and multifocal lens blanks   |
| ISO 10322-2  | ISO/TC172/SC7 | 2016 |         | Ophthalmic optics Semi-finished spectacle lens blanks Part 2: Specifications for progressive-power and degressive-power lens blanks   |
| ISO 10939    | ISO/TC172/SC7 | 2017 |         | Ophthalmic instruments Slit-lamp microscopes  |
| ISO 11381    | ISO/TC172/SC7 | 2016 |         | Ophthalmic optics Spectacle frames Screw threads  |
| ISO 11810    | ISO/TC172/SC9 | 2015 |         | Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Primary ignition, penetration, flame spread and secondary ignition |
| ISO 11978    | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Contact lenses and contact lens care products Labelling   |
| ISO 11979-10 | ISO/TC172/SC7 | 2018 |         | Ophthalmic implants Intraocular lenses Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes  |

| ISO 11979-7 | ISO/TC172/SC7 | 2018 |         | Ophthalmic implants Intraocular lenses Part 7: Clinical investigations of intraocular lenses for the correction of aphakia                                |
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| ISO 11979-8 | ISO/TC172/SC7 | 2017 |         | Ophthalmic implants Intraocular lenses Part 8: Fundamental requirements   |
| ISO 11981   | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Contact lenses and contact lens care products Determination of physical compatibility of contact lens care products with contact lenses |
| ISO 11986   | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Contact lenses and contact lens care products Determination of preservative uptake and release  |
| ISO 12870   | ISO/TC172/SC7 | 2016 |         | Ophthalmic optics - Spectacle frames - Requirements and test methods  |
| ISO 13666   | ISO/TC172/SC7 | 2019 |         | Ophthalmic optics Spectacle lenses Vocabulary   |
| ISO 14889   | ISO/TC172/SC7 | 2013 | A1:2017 | Ophthalmic optics Spectacle lenses Fundamental requirements for uncut finished lenses   |
| ISO 18369-1 | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Contact lenses Part 1: Vocabulary, classification system and recommendations for labelling specifications                               |
| ISO 18369-2 | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Contact lenses Part 2: Tolerances   |
| ISO 18369-3 | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Contact lenses Part 3: Measurement methods  |
| ISO 18369-4 | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Contact lenses Part 4: Physicochemical properties of contact lens materials   |
| ISO 19979   | ISO/TC172/SC7 | 2018 |         | Ophthalmic optics Contact lenses Hygienic management of multipatient use trial contact lenses   |
| ISO 21987   | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics - Mounted spectacle lenses  |
| ISO 8596    | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Visual acuity testing Standard and clinical optotypes and their presentation  |
| ISO 8980-1  | ISO/TC172/SC7 | 2017 |         | Ophthalmic optics Uncut finished spectacle lenses Part 1: Specifications for single-vision and multifocal lenses  |

| ISO 8980-2   | ISO/TC172/SC7 | 2017 | Ophthalmic optics Uncut finished spectacle lenses Part 2: Specifications for power-variation lenses   |
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| ISO 8980-3   | ISO/TC172/SC7 | 2013 | Ophthalmic optics Uncut finished spectacle lenses Part 3: Transmittance specifications and test methods   |
| ISO 9394     | ISO/TC172/SC7 | 2012 | Ophthalmic optics Contact lenses and contact lens care products Determination of biocompatibility by ocular study with rabbit eyes                                |
| ISO/TR 22979 | ISO/TC172/SC7 | 2017 | Ophthalmic implants Intraocular lenses Guidance on assessment of the need for clinical investigation of intraocular lens design modifications                     |
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| ISO 11199-1  | ISO/TC173     | 1999 | Walking aids manipulated by both arms Requirements and test methods Part 1: Walking frames  |
| ISO 11199-2  | ISO/TC173     | 2005 | Walking aids manipulated by both arms Requirements and test methods Part 2: Rollators   |
| ISO 11199-3  | ISO/TC173     | 2005 | Walking aids manipulated by both arms Requirements and test methods Part 3: Walking tables  |
| ISO 11334-1  | ISO/TC173     | 2007 | Assistive products for walking manipulated by one arm Requirements and test methods Part 1: Elbow crutches  |
| ISO 11334-4  | ISO/TC173     | 1999 | Walking aids manipulated by one arm Requirements and test methods Part 4: Walking sticks with three or more legs  |
| ISO 16201    | ISO/TC173     | 2006 | Technical aids for persons with disability Environmental control systems for daily living   |
| ISO 23599    | ISO/TC173     | 2019 | Assistive products for blind and vision-impaired persons Tactile walking surface indicators   |
| ISO 23600    | ISO/TC173     | 2007 | Assistive products for persons with vision impairments and persons with vision and hearing impairments Acoustic and tactile signals for pedestrian traffic lights |
| ISO 24415-1  | ISO/TC173     | 2009 | Tips for assistive products for walking Requirements and test methods Part 1: Friction of tips  |
| ISO 24415-2  | ISO/TC173     | 2011 | Tips for assistive products for walking Requirements and test methods Part 2:  Durability of tips for crutches  |

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| ISO/TR 11548-2 | ISO/TC173     | 2001 |         | Communication aids for blind persons Identifiers, names and assignation to coded character sets for 8-dot Braille characters Part 2: Latin alphabet based character sets                        |
| ISO 16840-1    | ISO/TC173/SC1 | 2006 |         | Wheelchair seating Part 1: Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces  |
| ISO 16840-4    | ISO/TC173/SC1 | 2009 |         | Wheelchair seating Part 4: Seating systems for use in motor vehicles  |
| ISO 7176-10    | ISO/TC173/SC1 | 2008 |         | Wheelchairs Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs   |
| ISO 7176-13    | ISO/TC173/SC1 | 1989 |         | Wheelchairs Part 13: Determination of coefficient of friction of test surfaces  |
| ISO 7176-14    | ISO/TC173/SC1 | 2008 |         | Wheelchairs Part 14: Power and control systems for electrically powered wheelchairs and scooters Requirements and test methods  |
| ISO 7176-15    | ISO/TC173/SC1 | 1996 |         | Wheelchairs Part 15: Requirements for information disclosure, documentation and labelling   |
| ISO 7176-19    | ISO/TC173/SC1 | 2008 | A1:2015 | Wheelchairs Part 19: Wheeled mobility devices for use as seats in motor vehicles  |
| ISO 7176-21    | ISO/TC173/SC1 | 2009 |         | Wheelchairs Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers                                     |
| ISO 7176-26    | ISO/TC173/SC1 | 2007 |         | Wheelchairs Part 26: Vocabulary   |
| ISO 7176-4     | ISO/TC173/SC1 | 2008 |         | Wheelchairs Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range   |
| ISO 7176-5     | ISO/TC173/SC1 | 2008 |         | Wheelchairs Part 5: Determination of dimensions, mass and manoeuvring space   |
| ISO 7176-7     | ISO/TC173/SC1 | 1998 |         | Wheelchairs Part 7: Measurement of seating and wheel dimensions   |
| ISO 7176-9     | ISO/TC173/SC1 | 2009 |         | Wheelchairs Part 9: Climatic tests for electric wheelchairs   |
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| ISO 10542-1    | ISO/TC173/SC1    | 2012 | Cor1:2013,A1:20<br>16 | Technical systems and aids for disabled or handicapped persons Wheelchair tiedown and occupant-restraint systems Part 1: Requirements and test methods for all systems |
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| ISO 16840-3    | ISO/TC173/SC1    | 2014 |                       | Wheelchair seating Part 3: Determination of static, impact and repetitive load strengths for postural support devices  |
| ISO 7176-1     | ISO/TC173/SC1    | 2014 |                       | Wheelchairs Part 1: Determination of static stability  |
| ISO 7176-11    | ISO/TC173/SC1    | 2012 |                       | Wheelchairs Part 11: Test dummies  |
| ISO 7176-16    | ISO/TC173/SC1    | 2012 |                       | Wheelchairs Part 16: Resistance to ignition of postural support devices  |
| ISO 7176-2     | ISO/TC173/SC1    | 2017 |                       | Wheelchairs Part 2: Determination of dynamic stability of electrically powered wheelchairs   |
| ISO 7176-22    | ISO/TC173/SC1    | 2014 |                       | Wheelchairs Part 22: Set-up procedures   |
| ISO 7176-3     | ISO/TC173/SC1    | 2012 |                       | Wheelchairs Part 3: Determination of effectiveness of brakes   |
| ISO 7176-6     | ISO/TC173/SC1    | 2018 |                       | Wheelchairs Part 6: Determination of maximum speed of electrically powered wheelchairs   |
| ISO 7176-8     | ISO/TC173/SC1    | 2014 |                       | Wheelchairs Part 8: Requirements and test methods for static, impact and fatigue strengths   |
| ISO 9999       | ISO/TC173/SC2    | 2016 |                       | Assistive products for persons with disability Classification and terminology  |
| ISO 16021      | ISO/TC173/SC3    | 2000 |                       | Urine-absorbing aids Basic principles for evaluation of single-use adult-incontinence-<br>absorbing aids from the perspective of users and caregivers                  |
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| ISO 17190-10 | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 10: Determination of extractable polymer content by  |
| ISO 17190-11 | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 11: Determination of content of respirable particles   |
| ISO 17190-2  | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 2: Determination of amount of residual monomers  |
| ISO 17190-3  | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 3: Determination of particle size distribution by sieve fractionation                            |
| ISO 17190-4  | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 4: Determination of moisture content by mass loss upon heating                                   |
| ISO 17190-5  | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 5: Gravimetric determination of free swell capacity in saline solution                           |
| ISO 17190-6  | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 6: Gravimetric determination of fluid retention capacity in saline solution after centrifugation |
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| ISO 17190-8  | ISO/TC173/SC3 | 2001 |           | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 8: Gravimetric determination of flowrate   |
| ISO 17190-9  | ISO/TC173/SC3 | 2001 | Cor1:2002 | Urine-absorbing aids for incontinence Test methods for characterizing polymer-based absorbent materials Part 9: Gravimetric determination of density  |
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| ISO 8670-2 | ISO/TC173/SC3 | 1996 | Ostomy collection bags Part 2: Requirements and test methods   |
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| ISO 9949-2 | ISO/TC173/SC3 | 1993 | Urine absorbing aids Vocabulary Part 2: Products   |
| ISO 9949-3 | ISO/TC173/SC3 | 1993 | Urine absorbing aids Vocabulary Part 3: Identification of product types  |
| ISO 15621  | ISO/TC173/SC3 | 2017 | Absorbent incontinence aids for urine and/or faeces General guidelines on evaluation   |
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| ISO 9386-2 | ISO/TC178     | 2000 | Power-operated lifting platforms for persons with impaired mobility Rules for safety, dimensions and functional operation Part 2: Powered stairlifts for seated, standing and wheelchair users moving in an inclined plane |
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| ISO 15193  | ISO/TC212     | 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  | ISO/TC212     | 2009 | In vitro diagnostic medical devices Measurement of quantities in samples of biological origin Requirements for certified reference materials and the content of supporting   |
| ISO 15197  | ISO/TC212     | 2013 | In vitro diagnostic test systems Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus  |
| ISO 15198  | ISO/TC212     | 2004 | Clinical laboratory medicine In vitro diagnostic medical devices Validation of user quality control procedures by the manufacturer   |
| ISO 16256  | ISO/TC212     | 2012 | Clinical laboratory testing and in vitro diagnostic test systems Reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases                            |

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| ISO 18113-1    | ISO/TC212 | 2009 | In vitro diagnostic medical devices Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements   |
| ISO 18113-2    | ISO/TC212 | 2009 | In vitro diagnostic medical devices Information supplied by the manufacturer (labelling) Part 2: In vitro diagnostic reagents for professional use   |
| ISO 18113-3    | ISO/TC212 | 2009 | In vitro diagnostic medical devices Information supplied by the manufacturer (labelling) Part 3: In vitro diagnostic instruments for professional use  |
| ISO 18113-4    | ISO/TC212 | 2009 | In vitro diagnostic medical devices Information supplied by the manufacturer (labelling) Part 4: In vitro diagnostic reagents for self-testing   |
| ISO 18113-5    | ISO/TC212 | 2009 | In vitro diagnostic medical devices Information supplied by the manufacturer (labelling) Part 5: In vitro diagnostic instruments for self-testing  |
| ISO 18153      | ISO/TC212 | 2003 | In vitro diagnostic medical devices Measurement of quantities in biological samples Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials  |
| ISO 19001      | ISO/TC212 | 2013 | In vitro diagnostic medical devices Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology   |
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| ISO/TS 17518    | ISO/TC212 | 2015 | Medical laboratories Reagents for staining biological material Guidance for users   |
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| ISO 11073-91064 | ISO/TC215 | 2009 | Health informatics Standard communication protocol Part 91064: Computer-assisted electrocardiography  |
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| ISO 12967-2     | ISO/TC215 | 2009 | Health informatics Service architecture Part 2: Information viewpoint   |
| ISO 12967-3     | ISO/TC215 | 2009 | Health informatics Service architecture Part 3: Computational viewpoint   |
| ISO 13606-1     | ISO/TC215 | 2008 | Health informatics Electronic health record communication Part 1: Reference model   |
| ISO 13606-2     | ISO/TC215 | 2008 | Health informatics Electronic health record communication Part 2: Archetype interchange specification   |
| ISO 13606-3     | ISO/TC215 | 2009 | Health informatics Electronic health record communication Part 3: Reference archetypes and term lists   |
| ISO 13606-5     | ISO/TC215 | 2010 | Health informatics Electronic health record communication Part 5: Interface specification   |
| ISO 17090-3     | ISO/TC215 | 2008 | Health informatics Public key infrastructure Part 3: Policy management of certification authority   |
| ISO 17115       | ISO/TC215 | 2007 | Health informatics Vocabulary of compositional terminological systems   |
| ISO 17432       | ISO/TC215 | 2004 | Health informatics Messages and communication Web access to DICOM persistent objects  |

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| ISO 18308                | ISO/TC215 | 2011 |         | Health informatics Requirements for an electronic health record architecture  |
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| ISO 21090                | ISO/TC215 | 2011 |         | Health informatics Harmonized data types for information interchange  |
| ISO 21549-6              | ISO/TC215 | 2008 |         | Health informatics Patient healthcard data Part 6: Administrative data  |
| ISO 21549-8              | ISO/TC215 | 2010 |         | Health informatics Patient healthcard data Part 8: Links  |
| ISO 21667                | ISO/TC215 | 2010 |         | Health informatics Health indicators conceptual framework   |
| ISO 25720                | ISO/TC215 | 2009 |         | Health informatics Genomic Sequence Variation Markup Language (GSVML)   |
| ISO/HL7 27931            | ISO/TC215 | 2009 |         | Data Exchange Standards Health Level Seven Version 2.5 An application protocol for electronic data exchange in healthcare environments      |
| ISO/HL7 27932            | ISO/TC215 | 2009 |         | Data Exchange Standards HL7 Clinical Document Architecture, Release 2   |
| ISO/HL7 27951            | ISO/TC215 | 2009 |         | Health informatics Common terminology services, release 1   |
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| ISO/HL7 27953-2          | ISO/TC215 | 2011 |         | Health informatics Individual case safety reports (ICSRs) in pharmacovigilance Part 2: Human pharmaceutical reporting requirements for ICSR |
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| ISO/IEEE 11073-<br>10408 | ISO/TC215 | 2010 |         | Health informatics Personal health device communication Part 10408: Device specialization Thermometer   |
| ISO/IEEE 11073-<br>10415 | ISO/TC215 | 2010 |         | Health informatics Personal health device communication Part 10415: Device specialization Weighing scale  |
| ISO/IEEE 11073-<br>10471 | ISO/TC215 | 2010 |         | Health informatics Personal health device communication Part 10471: Device specialization - Independent living activity hub   |
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| ISO/IEEE 11073-<br>30300 | ISO/TC215 | 2004 |         | Health informatics Point-of-care medical device communication Part 30300: Transport profile Infrared wireless   |
| ISO/TR 11487             | ISO/TC215 | 2008 |         | Health informatics Clinical stakeholder participation in the work of ISO TC 215   |
| ISO/TR 11633-1           | ISO/TC215 | 2009 |         | Health informatics Information security management for remote maintenance of medical devices and medical information systems Part 1: Requirements and risk analysis                                     |
| ISO/TR 11633-2           | ISO/TC215 | 2009 |         | Health informatics Information security management for remote maintenance of medical devices and medical information systems Part 2: Implementation of an information security management system (ISMS) |
| ISO/TR 11636             | ISO/TC215 | 2009 |         | Health Informatics Dynamic on-demand virtual private network for health information infrastructure  |
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| ISO 21549-3              | ISO/TC215 | 2014 |           | Health informatics Patient healthcard data Part 3: Limited clinical data   |
| ISO 21549-4              | ISO/TC215 | 2014 |           | Health informatics Patient healthcard data Part 4: Extended clinical data  |
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