BSOL醫療器材資訊模組

選擇10項標準建立您的專屬模組
或從下列最常用的醫療器材標準中進行挑選:

通用標準		
1	EN ISO 13485	Medical devices. Quality management systems. Requirements for regulatory purposes
2	EN ISO 14155	Clinical investigation of medical devices for human subjects. Good clinical practice
3	EN 1401	Plastic piping systems for non-pressure underground drainage and sewerage. Unplasticized poly(vinyl chloride) (PVC-U)Specifications for pipes, fittings and the system
4	EN ISO 14971	Medical devices. Application of risk management to medical devices
5	PD CEN ISO/TR 14969	Medical devices. Quality management systems. Guidance on the application of ISO 13485:2003
6	BS EN ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labelling and information to be suppliedGeneral requirements
7	BS EN ISO 15223-2	Medical devices. Symbols to be used with medical device labels, labelling, and information to be suppliedSymbol development, selection and validation

生物相容性		
1	EN ISO 10993-1	Biological evaluation of medical devices Evaluation and testing within a risk management process
2	EN ISO 10993-3	Biological evaluation of medical devices Tests for genotoxicity, carcinogenicity and reproductive toxicity
3	EN ISO 10993-4	Biological evaluation of medical devices Selection of tests for interactions with blood
4	EN ISO 10993-5	Biological evaluation of medical devices Tests for in vitro cytotoxicity
5	EN ISO 10993-6	Biological evaluation of medical devices Tests for local effects after implantation
6	EN ISO 10993-7	Biological evaluation of medical devices Ethylene oxide sterilization residuals
7	EN ISO 10993-9	Biological evaluation of medical devices Framework for identification and quantification of potential degradation products
8	EN ISO 10993-11	Biological evaluation of medical devices Tests for systemic toxicity
9	EN ISO 10993-12	Biological evaluation of medical devices Sample preparation and reference materials
10	EN ISO 10993-13	Biological evaluation of medical devices Identification and quantification of degradation products from polymeric medical devices
11	EN ISO 10993-14	Biological evaluation of medical devices Identification and quantification of degradation products from ceramics
12	EN ISO 10993-15	Biological evaluation of medical devices Identification and quantification of degradation products from metals and alloys
13	EN ISO 10993-16	Biological evaluation of medical devices Toxicokinetic study design for degradation products and leachables
14	EN ISO 10993-17	Biological evaluation of medical devices Establishment of allowable limits for leachable substances
15	EN ISO 10993-18	Biological evaluation of medical devices Chemical characterization of materials

塑膠/橡膠類醫材		
1	EN 455-1	Medical gloves for single use. Requirements and testing for freedom from holes
2	EN 455-3	Medical gloves for single use. Requirements and testing for biological evaluation
3	EN 455-4	Medical gloves for single use. Requirements and testing for shelf life determination
4	EN 1282-2	Tracheostomy tubes. Paediatric tubes
5	EN 1618	Catheters other than intravascular catheters. Test methods for common properties
6	EN 1782	Tracheal tubes and connectors.
7	EN 1820	Anaesthetic reservoir bags.
8	EN 3826-2	Plastics collapsible containers for human blood and blood components. Graphical symbols for use on labels and instruction leaflets
9	EN 3826-3	Plastics collapsible containers for human blood and blood components. Blood bag systems with integrated features
10	EN ISO 4074	Natural latex rubber condoms. Requirements and test methods.
11	EN ISO 10555-1	Intravascular catheters. Sterile and single-use catheters. General requirements
12	EN ISO 7886-3	Sterile hypodermic syringes for single use. Auto-disable syringes for fixed-dose immunization
13	EN ISO 7886-4	Sterile hypodermic syringes for single use. Syringes with re-use prevention feature

牙科類醫材		
1	EN 1639	Dentistry. Medical devices for dentistry. Instruments.
2	EN 1640	Dentistry. Medical devices for dentistry. Equipment.
3	EN 1641	Dentistry. Medical devices for dentistry. Materials.
4	EN 1642	Dentistry. Medical devices for dentistry. Dental implants.

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滅菌標準		
1	EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE"Requirements for terminally sterilized medical devices
2	EN 556-2	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE"Requirements for aseptically processed medical devices
3	EN ISO 11135-1	Sterilization of health care products. Ethylene oxideRequirements for development, validation and routine control of a sterilization process for medical devices
4	EN ISO 11137-1	Sterilization of health care products. RadiationRequirements for development, validation and routine control of a sterilization process for medical devices
5	EN ISO 11137-2	Sterilization of health care products. RadiationEstablishing the sterilization dose
6	EN ISO 11138-2	Sterilization of health care products. Biological indicatorsBiological indicators for ethylene oxide sterilization processes
7	EN ISO 11138-3	Sterilization of health care products. Biological indicatorsBiological indicators for moist heat sterilization processes
8	EN ISO 11140-1	Sterilization of health care products. Chemical indicatorsGeneral requirements
9	EN ISO 11140-3	Sterilization of health care products. Chemical indicatorsClass 2 indicator systems for use in the Bowie and Dick-type steam penetration test
10	EN ISO 11607-1	Packaging for terminally sterilized medical devicesRequirements for materials, sterile barrier systems and packaging systems
11	EN ISO 11737-1	Sterilization of medical devices. Microbiological methodsDetermination of a population of microorganisms on products
12	EN ISO 11737-2	Sterilization of medical devices. Microbiological methodsTests of sterility performed in the definition, validation and maintenance of a sterilization process
13	EN ISO 13408-1	Aseptic processing of health care productsGeneral requirements
14	EN ISO 13408-2	Aseptic processing of health care productsFiltration
15	EN ISO 13408-3	Aseptic processing of health care productsLyophilization
16	EN ISO 13408-4	Aseptic processing of health care productsClean-in-place technologies
17	EN ISO 13408-5	Aseptic processing of health care productsSterilization in place
18	EN ISO 13408-6	Aseptic processing of health care productsIsolator systems
19	EN ISO 14937	Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
20	EN ISO 17665-1	Sterilization of health care products. Moist heatRequirements for the development, validation and routine control of a sterilization process for medical devices
21	EN 1422	Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods
22	EN 285	Sterilization. Steam sterilizers. Large sterilizers

機械/系統類醫材		
1	EN 794	Lung ventilators. Particular requirements for emergency and transport ventilators
2	EN 1060-3	Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems
3	EN 1060-4	Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
4	EN ISO 10651-4	Lung ventilators . Particular requirements for operator-powered resuscitators
5	EN ISO 10651-6	Lung ventilators for medical use. Particular requirements for basic safety and essential performance. Home-care ventilatory support devices
6	EN ISO 4135	Anaesthetic and respiratory equipment. Vocabulary.
7	EN ISO 5356-1	Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets
8	EN 1707	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings.
9	EN ISO 5356-2	Anaesthetic and respiratory equipment. Conical connectors. Screw-threaded weight-bearing connectors
10	EN ISO 7376	Anaesthetic and respiratory equipment. Laryngoscopes for tracheal intubation.
11	EN ISO 7396-1	Medical gas pipeline systems. Pipeline systems for compressed medical gases and vacuum
12	EN ISO 7396-2	Medical gas pipeline systems. Anaesthetic gas scavenging disposal systems
13	EN ISO 8835-2	Inhalational anaesthesia systems. Anaesthetic breathing systems (ISO 8835-2:2007)
14	EN ISO 8835-3	Inhalational anaesthesia systems. Transfer and receiving systems of active anaesthetic gas scavenging systems
15	EN ISO 8835-4	Inhalational anaesthesia systems. Anaesthetic vapour delivery devices
16	EN ISO 8835-5	Inhalational anaesthesia systems. Anaesthesia ventilators
17	EN ISO 8185	Respiratory tract humidifiers for medical use. Particular requirements for respiratory humidification systems.
18	EN ISO 9170-2	Oxygen concentrators for medical use. Safety requirements.
19	EN ISO 8359	Anaesthetic vaporizers. Agent-specific filling systems.
20	EN ISO 5360	Anaesthetic and respiratory equipment. Tracheostomy tubes. Tubes and connectors for use in adults
21	EN ISO 5366-1	Low-pressure hose assemblies for use with medical gases.
22	EN ISO 5359	Terminal units for medical gas pipeline systems. Terminal units for use with compressed medical gases and vacuum
23	EN ISO 9170-1	Terminal units for medical gas pipeline systems. Terminal units for anaesthetic gas scavenging systems
24	EN ISO 9360-1	Anaesthetic and respiratory equipment. Heat and moisture exchangers (HMEs) for humidifying respired gases in humans. HMEs for use with minimal tidal volumes of 250 ml
25	EN ISO 9360-2	Anaesthetic and respiratory equipment. Heat and moisture exchangers (HMEs) for humidifying respired gases in humans. HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml
26	EN ISO 10079-1	Medical suction equipment. Electrically powered suction equipment. Safety requirements
27	EN ISO 10079-2	Medical suction equipment. Electrically powered suction equipment. Safety requirements
28	EN ISO 10079-3	Medical suction equipment. Suction equipment powered from vacuum or pressure source
29	EN ISO 10524-1	Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow-metering devices
30	EN ISO 10524-2	Pressure regulators for use with medical gases. Manifold and line pressure regulators
31	EN ISO 10524-3	Pressure regulators for use with medical gases. Pressure regulators integrated with cylinder valves
32	EN ISO 10524-4	Pressure regulators for use with medical gases. Low-pressure regulators
33	EN ISO 10651-2	Lung ventilators for medical use. Particular requirements for basic safety and essential performance. Home care ventilators for ventilator-dependent patients

IMD

1	**EN ISO 5840**	Cardiovascular implants. Cardiac valve prostheses
2	**EN ISO 7197**	Neurosurgical implants. Sterile, single-use hydrocephalus shunts and components
3	**EN ISO 9713**	Neurosurgical implants. Self-closing intracranial aneurysm clips
4	**EN 1642**	Dentistry. Medical devices for dentistry. Dental implants.

AIMD

1	**EN 45502-1**	Active implantable medical devicesGeneral requirements for safety, marking and information to be provided by the manufacturer
2	**EN 45502-2-1**	Active implantable medical devicesParticular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
3	**EN 45502-2-3**	Active implantable medical devicesParticular requirements for cochlear and auditory brainstem implant systems
4	**EN 45502-2-2**	Active implantable medical devicesParticular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)

電子類醫材

1	**EN 60601-1**	Medical electrical equipment. General requirements for safety. Collateral standard. General requirements for programmable electrical medical systems
2	**EN 60601-1-6**	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability

IVD

1	**EN 12322**	In vitro diagnostic medical devices. Culture media for microbiology. Performance criteria for culture media
2	**EN 13532**	General requirements for in vitro diagnostic medical devices for self-testing
3	**EN 13612**	Performance evaluation of in vitro diagnostic medical devices
4	**EN 13640**	Building construction. Jointing products. Specifications for test substrates
5	**EN 13641**	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
6	**EN13975**	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
7	**EN 14136**	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
8	**EN 14254**	In vitro diagnostic medical devices. Single-use receptacles for the collection of specimens, other than blood, from humans
9	**EN 14820**	Single-use containers for human venous blood specimen collection
10	**EN ISO 15193**	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for content and presentation of reference measurement procedures
11	**EN ISO 15194**	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for certified reference materials and the content of supporting documentation
12	**EN ISO 15197**	In vitro diagnostic test systems. Requirements for blood-glucosemonitoring systems for self-testing in managing diabetes mellitus
13	**EN ISO 17511**	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
14	**EN ISO 18113-1**	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling)Terms, definitions and general requirements
15	**EN ISO 18113-2**	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling)In vitro diagnostic reagents for professional use
16	**EN ISO 18113-3**	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling)In vitro diagnostic instruments for professional use
17	**EN ISO 18113-4**	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling)In vitro diagnostic reagents for self-testing
18	**EN ISO 18113-5**	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling)In vitro diagnostic instruments for self-testing
19	**EN ISO 18153**	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials
20	**EN ISO 20776-1**	Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devicesReference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases
21	**EN ISO 61010-2-101**	Safety requirements for electrical equipment for measurement, control and laboratory use.Particular requirements for in vitro diagnostic (IVD) medical equipment

輔具

1	**EN 1865-3**	Patient handling equipment used in road ambulances. Heavy duty stretcher
2	**EN 1865-4**	Patient handling equipment used in road ambulances. Foldable patient transfer chair
3	**EN 1865-5**	Patient handling equipment used in road ambulances. Stretcher support
4	**EN 1985**	Walking aids. General requirements and test methods.
5	**EN 1789**	Medical vehicles and their equipment. Road ambulances.
6	**EN ISO 10535**	Hoists for the transfer of disabled persons. Requirements and test methods.

軟體

1	**EN 62304**	Medical device software. Software life-cycle processes