Essential Principles of Safety and Performance of Medical Devices and method used to demonstrate conformity (IVD LAMP method)

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
General requirements						
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	A	Horizontal standards: ISO 13485:2016: Medical device QMS CLSI EP12: User protocol for eval. quali. test performance ISO 14971:2019: Risk management CLSI EP18: Risk mgt. tech. to iden. and control lab. error source GHTF sg5n7:2012: Performance evaluation, stage 5, 6 Vertical standards: EN 13641:2002: Risk of infection related to IVD reagent	Yes	ISO 13485 Certificate no. ABC Analytical performance report, sensitivity and specificity Risk management file Clinical perform. eval. report cover clinical perform. study, literature, experience gained by routine diagnostic testing	CSDT file no. XYZ
2.	Product owners should establish, implement, document and maintain a risk management system to ensure the ongoing quality, safety and performance of the medical device. Risk management should be understood as a continuous iterative process throughout the entire lifecycle of a medical device, requiring regular systematic updating. In carrying out risk management, product owners should: a) establish and document a risk management plan for covering each medical device; b) identify and analyze the known and foreseeable hazards associated with each medical device; c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; d) eliminate or control the risks referred to in point (c) in accordance with the requirements of points 3 and 4 below; e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazardous situations and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk determination and risk acceptability; and f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of points 3 and 4 below. (additional)	A	Horizontal standards: ISO 14971:2019: Risk management CLSI EP18: Risk mgt. tech. to iden. and control lab. error source Vertical standards: EN 13641:2002: Risk of infection related to IVD reagent	Yes	Risk management file	CSDT file no. XYZ
3.	Risk control measures and outcomes adopted by the product owner for	A	Horizontal standards:	Yes		CSDT file no.

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the product owner should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. In selecting the most appropriate solutions, product owners should, in the following order of priority: a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, b) eliminate risks as far as reasonably practicable through inherently safe design and manufacture, c) reduce as low as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, d) inform users of any residual risks. e) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.		ISO 13485:2016: Medical device QMS ISO 14971:2019: Risk management CLSI EP18: Risk mgt. tech. to iden. and control lab. error source Vertical standards: EN 13641:2002: Risk of infection related to IVD reagent		ISO 13485 Certificate no. ABC Risk management file, part of FMEA table present risk control measures by 3 alts. 1. design 2. manu proc. 3. info.	XYZ
4.	In eliminating or reducing risks related to use, the Product owner should: a) reduce, as low as is reasonably practicable and appropriate, the risks related to the features of the medical device and the environment in which the medical devices are intended to be used (e.g. ergonomic features, tolerance to dust and humidity) and b) give consideration to the technical knowledge, experience, education, training and use environment and, where applicable, the medical and physical conditions of intended users. (additional)	A	Horizontal standards: ISO 14971:2019: Risk management CLSI EP18: Risk mgt. tech. to iden. and control lab. error source ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: EN 13641:2002: Risk of infection related to IVD reagent ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	Risk management file Label and instruction for use, IFU is evidence of risk cont. measure of risk & usability	CSDT file no. XYZ
5.	The characteristics and performances of a medical device should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the expected lifetime of the device, as indicated by the product owner, when the medical device is subjected to the stresses which can occur during intended conditions of use and has been properly maintained and calibrated (if applicable) in accordance with the product owner's instructions.	A	Horizontal standards: ISO 23640:2011: Stability IVD reagent CLSI EP25 Evaluation of stability IVD reagent EN 13640:2002: Stability testing of IVD reagent ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol	Yes	Real time stability report (shelf life, transport simulation) Accelerated stability report Label and instruction for use	CSDT file no. XYZ

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
			Vertical standards: ISO 18113-2:2009: Info. supply IVD reagent for professional use			
6.	Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances, including the integrity and cleanliness of the product and when used in accordance with the intended use, are not be adversely affected under transport and storage conditions (for example, through shock, vibrations and fluctuations of temperature and humidity) taking account of the instructions and information provided by the product owner. The performance, safety and sterility of the medical device should be maintained throughout any shelf-life specified by the product owner.	A	Horizontal standards: ISO 13485:2016: Medical device QMS ASTM D4169-22: Testing of shipping container and system GHTF sg3n99-10:2004: Process validation guidance ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	ISO 13485 Certificate no. ABC Transport model test report (container can protect product) Packaging validation report (tube and cap) Label and instruction for use	CSDT file no. XYZ
7.	Medical devices should have the stability necessary to maintain essential performance conditions in a period of time and conditions previously established during the shelf-life, during the time of use after being opened (for IVDs, including after being installed in the instrument), and during transportation or dispatch when under conditions other than storage conditions. (additional)	A	Horizontal standards: ISO 23640:2011: Stability IVD reagent CLSI EP25 Evaluation of stability IVD reagent EN 13640:2002: Stability testing of IVD reagent Vertical standards: -	Yes	Real time stability report (shelf life, transport simulation, in-use stability)	CSDT file no. XYZ
8.	All known and foreseeable risks, and any undesirable side-effects, should be minimized and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the medical device during intended conditions of use taking into account the generally acknowledged state of the art. (* For non-IVD, contact with body, may consider undesirable side-effect and control by risk and clinical evaluation. For IVD, not contact with body, may not consider undesirable side effect and control by risk only)	A	Horizontal standards: ISO 14971:2019: Risk management CLSI EP18: Risk mgt. tech. to iden. and control lab. error source Vertical standards: EN 13641:2002: Risk of infection related to IVD reagent	Yes	Risk management file	CSDT file no. XYZ
Essential Principles - Clinical Evaluation						
9. Clinical Evaluation						
9.1	Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies	A	Horizontal standards: GHTF sg5n7:2012: Performance	Yes	Perform. eval. report cover	CSDT file no. XYZ

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	with the applicable provisions of the essential principles. A clinical evaluation should be conducted.		evaluation Vertical standards: -		scientific validity, analytical performance, clinical performance	
9.2	A clinical evaluation should assess clinical data to establish that a favorable benefit-risk determination exists for the medical device in the form of one or more of the following: a) clinical investigation reports (for IVDs, clinical performance evaluation reports) b) published scientific literature reports/ reviews c) clinical experience (additional)	A	Horizontal standards: GHTF sg5n7:2012: Performance evaluation, stage 5, 6 Vertical standards: -	Yes	Clinical perform. eval. report cover clinical perform. study, literature, experience gained by routine diagnostic testing	CSDT file no. XYZ
9.3	Clinical investigations should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. These principles protect the rights, safety and well-being of human subjects, which are the most important considerations and shall prevail over interests of science and society. These principles shall be understood, observed, and applied at every step in the clinical investigation.	A	Horizontal standards: ISO 20916:2019: Clinical performance study (interventional study) EN 13612:2002: Performance eval. study (non-interventional study) Vertical standards: -	Yes	Clinical perform. study protocol and report	CSDT file no. XYZ
Essential Principles - Chemical, physical and biological properties						
10. Chemical, physical and biological properties						
10.1	The medical devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 8 of the 'General Requirements'. Particular attention should be paid to: a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, b) the impact of processes on material properties; c) where appropriate, the results of biophysical or modelling research whose validity of which has been demonstrated beforehand; d) the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device, e) the choice of materials used should reflect, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance. f) surface properties; and g) the confirmation that the device meets any defined chemical and/or physical specifications.	A	Horizontal standards: ISO 13485:2016: Medical device QMS Spec. of mat. ISO 10993-1:2018: Biological evaluation of med. device, cl. 5.2.2 Vertical standards: -	Yes	ISO 13485 Certificate no. ABC COA Biological evaluation report	CSDT file no. XYZ
10.2	The medical device should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices	A	Horizontal standards: ISO 13485:2016: Medical device QMS	Yes	ISO 13485 Certificate no. ABC	CSDT file no. XYZ

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.		ASTM D4169-22: Testing of shipping container and system GHTF sg3n99-10:2004: Process validation guidance Vertical standards: -		Transport model test report (container can protect product) Packaging validation report (tube and cap)	
10.3	The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.	NA (external use, IVD device)				
10.4	The medical device should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress into the device taking into account the device and the nature of the environment in which it is intended to be used.	A	Horizontal standards: ISO 13485:2016: Medical device QMS GHTF sg3n99-10:2004: Process validation guidance Vertical standards: -	Yes	ISO 13485 Certificate no. ABC Packaging validation report (tube and cap)	CSDT file no. XYZ
Essential Principles - Sterility, Packaging and Microbial contamination						
11. Sterility, Packaging and Microbial contamination		NA (it's for non-IVD, non-act. dev.)				
11.1	Medical devices and their manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, all other persons who may come in contact with the medical device. The design should allow easy and safe handling, and, where necessary: a) reduce as far as reasonably practicable and appropriate any microbial leakage from the medical device and/or microbial exposure during use; b) prevent microbial contamination of the medical device, or its content (e.g. specimens); and c) reduce as low as reasonably practicable and appropriate the risks from unintended exposure (e.g. cuts and pricks (such as needle stick injuries), eye splashes, etc.).					
11.2	Medical devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the product owner.					
11.3	Medical devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions					

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	indicated by the product owner, until the protective packaging is damaged or opened.					
11.4	Medical devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods. The shelf-life of these medical devices should be determined by validated methods.					
11.5	Medical devices intended to be sterilized, either by product owner or user, should be manufactured and packaged in appropriate and controlled (e.g. environmental) conditions and facilities.					
11.6	Packaging systems for non-sterile medical devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the product owner.					
11.7	The packaging and/or label of the medical device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.					
11.8	Medical devices meant by the product owner to be reusable, must be designed and manufactured in a way to facilitate appropriate processes to allow reuse, including cleaning, disinfection, packaging and where appropriate, the method of re-sterilization. The instructions for use should provide information to identify when the device should no longer be reused (e.g. when there are signs of material degradation or the maximum number of allowed reuses). (additional)					
Essential Principles - Considerations of Environment and Conditions of Use						
12. Considerations of Environment and Conditions of Use						
12.1	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the:	A (some items)	Horizontal standards: ISO 13485:2016: Medical device QMS ISO 14971:2019: Risk management CLSI EP18: Risk mgt. tech. to iden. and control lab. error source Vertical standards: EN 13641:2002: Risk of infection related to IVD reagent	Yes	ISO 13485 Certificate no. ABC Risk management file, part of FMEA table present risk control measures by 3 alts. 1. design 2. manu proc. 3. info.	CSDT file no. XYZ
	a) risks of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	A	Horizontal standards: ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: ISO 18113-2:2009: Info. supply IVD	Yes	Label and instruction for use, IFU is evidence of risk cont. measure of risk & usability	

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
			reagent for professional use			
	b) risks of user error due to the design of the medical device user interface, ergonomic features, and the environment in which the medical device is intended to be used; (additional)	A	Horizontal standards: ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	Label and instruction for use, IFU is evidence of risk cont. measure of risk & usability	
	c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;	A	Horizontal standards: ISO 23640:2011: Stability IVD reagent CLSI EP25 Evaluation of stability IVD reagent EN 13640:2002: Stability testing of IVD reagent Vertical standards: -	Yes	Real time stability report (shelf life, transport simulation, in-use stability) Accelerated stability report	
	d) risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during intended conditions of use;	A	Horizontal standards: Spec. of mat Vertical standards: -	Yes	COA	
	e) risks associated with the possible negative interaction between software and the information technology (IT) environment within which it operates and interacts; (additional)	NA (non-active device)				
	f) environmental risks from unexpected egress of substances from the medical device during use, taking into account the medical device and the nature of the environment in which it is intended to be used;	NA (IVD reagent solution)				
	g) risks of incorrect identification of specimens;	A	Horizontal standards: ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	Label and instruction for use	
	h) risks of reciprocal interference with other medical devices normally used in diagnosis, monitoring or for the treatment given.	NA (non-active device)				
12.2	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate,	NA (no flammable				

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	sub. use with)				
12.3	Medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. Specifically,	NA (disposable device)				
	a) when maintenance is not possible (e.g. with implants), the risks from ageing of materials used, will be eliminated or reduced, as low as reasonably practicable and appropriate).					
	b) when adjustment and calibration are not possible (e.g. with certain kinds of thermometers), the risks from loss of accuracy of any measuring or control mechanism will be eliminated or reduced, as low as reasonably practicable and appropriate.					
12.4	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.	A	Horizontal standards: ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	Label and instruction for use, IFU is evidence of risk cont. measure of risk & usability	CSDT file no. XYZ
12.5	Any measurement, monitoring or display scale should be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the medical devices are intended to be used.	NA (non-active device)				
12.6	Medical devices must be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of any waste substances by the user, patient or other person. The instructions for use should identify safe disposal procedures and measures.	A	Horizontal standards: ISO 13485:2016: Medical device QMS ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	ISO 13485 Certificate no. ABC Label and instruction for use, IFU is evidence of risk cont. measure of risk & usability	CSDT file no. XYZ
Essential Principles - Active medical devices connected to or equipped with an energy source						
13. Active medical devices connected to or equipped with an energy source		NA (it's for non-IVD, active device),				
13.1	Medical devices where the safety of the patients depends on an internal					

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	power supply should be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical.					
13.2	Medical devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.					
13.3	Medical devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.					
13.4	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.					
13.5	Medical devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.					
Essential Principles - Medical devices that incorporate software or are standalone software or mobile applications						
14. Medical devices that incorporate software or are standalone software or mobile applications		NA (it's for non-IVD, active device),				
14.1	Medical devices that incorporate electronic programmable systems, including software, or are standalone software or mobile applications, should be designed to ensure accuracy, reliability, precision, safety, and performance in line with their intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce, as far as possible and appropriate, consequent risks or impairment of performance.					
14.2	For medical devices that incorporate software or are standalone software or mobile applications, the software must be developed, manufactured and maintained in accordance with the state of the art taking into account the principles of development life cycle (e.g. rapid development cycles, frequent changes, the cumulative effect of changes), risk management (e.g. changes to system, environment, and data), including information security (e.g. safely implement updates), verification and validation (e.g. change management process).					
14.3	Software that is intended to be used in combination with generic computing platforms should be designed and developed taking into account the platform itself (e.g. size and contrast ratio of the screen, connectivity, memory, etc.) and the external factors related to their use (varying environment as regards level of light or noise). (additional)					
14.4	Product owner should set out minimum requirements concerning hardware, IT networks characteristics and IT security measures,					

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	including protection against unauthorized access, necessary to run the software as intended. (additional)					
Essential Principles - Medical devices with a diagnostic or measuring function						
15. Medical devices with a diagnostic or measuring function		NA (it's for non-IVD, active device),				
15.1	Medical devices with a diagnostic or measuring (including monitoring) function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device.					
	a) Where applicable, the limits of accuracy should be indicated by the product owner					
	b) Whenever possible, values expressed numerically should be in commonly accepted, standardized units, and understood by users of the medical device.					
	c) The function of the controls and indicators should be clearly specified on the medical device. Where a medical device bears instruction required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.					
Essential Principles - Labelling and Instructions for Use						
16. Labelling and Instructions for Use						
16.1	Each medical device should be accompanied by the information needed to identify the medical device and its product owner. Each medical device should also be accompanied by, or direct the user to any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the medical device itself, on the packaging or in the instructions for use, and should be easily understood.	A	**Horizontal standards:** ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol **Vertical standards:** ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	Label and instruction for use	CSDT file no. XYZ
16.2	The medium, format, content, legibility, and location of the label and instructions for use should be appropriate to the particular medical device, its intended purpose and the technical knowledge, experience, education or training of the intended users. Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. If instructions for use are insufficient, appropriate training should be provided. Some medical devices should include separate information for the professional user and the lay person. (additional)	A	**Horizontal standards:** ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol **Vertical standards:** ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	Label and instruction for use	CSDT file no. XYZ
Essential Principles - Protection against electrical risks, mechanical and thermal risks						

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
17. Protection against electrical risks, mechanical and thermal risks		NA (it's for non-IVD, active device),				
17.1	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks of accidental electric shocks to the user or any other person, during normal use and in single fault condition, provided the medical device is installed and maintained as indicated by the product owner.					
17.2	Medical devices should be designed, manufactured and maintained in such a way as to provide an adequate level of cybersecurity against attempts to gain unauthorized access. (additional)					
17.3	Medical devices should be designed and manufactured in such a way as to protect, as far as possible and appropriate, against unauthorized access that could hamper the device from functioning as intended or impose a safety concern. (additional)					
17.4	Medical devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.					
17.5	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks arising from vibration generated by the medical device, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.					
17.6	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks, arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.					
17.7	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks of error when certain parts within the device are intended to be connected or reconnected before or during use. (additional)					
17.8	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.					
17.9	Medical devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under intended conditions of use.					
Essential Principles - Protection against radiation						
18. Protection against radiation		NA (it's for non-				

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
		IVD, active device),				
18.1	Medical devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be eliminated or reduced, as low as reasonably practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.					
18.2	The operating instructions for medical devices emitting hazardous or potentially hazardous radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient, user and others, and on ways of avoiding misuse and of eliminating the risks inherent to transport, storage and installation, as far as possible.					
18.3	Where medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.					
18.4	Medical devices should be designed and manufactured in such a way that the exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as low as practicable and appropriate.					
18.5	Medical devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.					
18.6	For medical devices emitting hazardous or potentially hazardous radiation and that require installation, information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure should be specified in the operating instructions.					
18.7	Medical devices intended to emit hazardous or potentially hazardous ionizing and/or non-ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality), and other key characteristics of the radiation emitted can be varied and controlled, and where appropriate, monitored during use, taking into account the intended use. Such medical devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.					
Essential Principles - Protection against the risks posed by medical devices intended for use by lay persons						
19. Protection against the risks posed by medical devices intended for use by lay persons		NA (it's prof. use)				
19.1	Medical devices for use by lay persons (such as self-testing or near-patient testing) should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in lay person's					

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	technique and environment. The information and instructions provided by the product owner should be easy for the lay person to understand and apply when using the medical device and interpreting the results.					
19.2	Medical devices for use by lay persons (such as self-testing or near-patient testing) should be designed and manufactured in such a way as to:					
	a) ensure that the medical device can be used safely and accurately by the intended user per instructions for use. If instructions for use are insufficient, appropriate training should be provided.					
	b) reduce, as low as reasonably practicable and appropriate, the risks of error by the intended user in the handling of the medical device and, if applicable, in the interpretation of the results.					
19.3	Medical devices for use by lay persons (such as self-testing or near-patient testing) should, where appropriate, include means by which the lay person:					
	a) can verify that, at the time of use, the medical device will perform as intended by the product owner, and					
	b) is warned if the medical device has failed to operate as intended or to provide a valid result.					
Essential Principles - Medical devices incorporating materials of biological origin						
20. Medical devices incorporating materials of biological origin						
20.1	For medical devices that incorporate tissues, cells, or substances of animal origin, or their derivatives, which are non-viable or rendered non-viable the following should apply:	NA (no animal origin)				
	a) where feasible, taking into account the animal species, tissues and cells of animal origin, or their derivatives, should originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. The product owner is required to retain information on the geographical origin of the animals.					
	b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, should be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regards to viruses and other transmissible agents should be addressed by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the medical device.					
20.2	For products that incorporate tissues, cells, or substances of human origin or their derivatives as medical devices, the following should apply:	NA (no human origin)		-		
	a) donation, procurement and testing of the tissues and cells should be done in accordance with jurisdictional requirements; and					
	b) processing, preservation and any other handling of those tissues					

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	and cells or their derivatives should be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by appropriate methods of sourcing and by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process.					
20.3	For medical devices manufactured utilizing non-viable biological substances other than those referred to in Clauses 20.1 and 20.2, the processing, preservation, testing and handling of those substances should be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regards to viruses and other transmissible agents should be addressed by appropriate methods of sourcing and by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process.	A	Horizontal standards: ISO 14971:2019: Risk management CLSI EP18: Risk mgt. tech. to iden. and control lab. error source GHTF sg3n99-10:2004: Process validation guidance Vertical standards: EN 13641:2002: Risk of infection related to IVD reagent	Yes	Risk management file, part of FMEA table present risk control measures by 3 alts. 1. design 2. manu proc. 3. info. Process validation reports of the related processes	CSDT file no. XYZ
Essential Principles - Applicable to medical devices other than IVD medical devices						
21. Applicable to medical devices other than IVD medical devices						
21.1 Chemical, physical and biological properties		NA (external use, IVD)				
21.1.1	With regards to chemical, physical, and biological properties of a medical device, particular attention should be paid to the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion. (additional)					
21.1.2	Medical devices should be designed and manufactured in such a way that they can be used safely with the materials, substances, and gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.					
21.1.3	Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks, linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. (additional)					
21.2 Particular requirements for implantable medical devices		NA (external use,				

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
		IVD)				
21.2.1	Implantable medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks connected with medical treatment (e.g. the use of defibrillators, high-frequency surgical equipment). (additional)					
21.2.2	Active programmable implantable medical devices should be designed and manufactured in a manner that allows the unequivocal identification of the device without the need for a surgical operation.					
21.3 Protection against the risks posed to the patient or user by medical devices supplying energy or substances		NA (non-active device)				
21.3.1	Medical devices for supplying the patient with energy or substances should be designed and manufactured in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient, user, and others.					
21.3.2	Medical devices should be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.					
21.4 Medical devices incorporating a substance considered to be a medicinal product/drug		NA (no med. prod. incorporated)				
21.4.1	Where a medical device incorporates, a substance which, if used separately may be considered to be a medicinal product/drug and which is liable to act upon the body with action ancillary to that of the medical device, the safety and performance of the medical device as a whole should be verified, as well as the identify, safety, quality and efficacy of the substance in the specific combination product if dose, mechanism of action and intended use of the substance is similar to that of medicinal product when used separately. Note: Medicinal product includes any stable derivative of human blood or human plasma					
Essential Principles - Applicable to IVD medical devices						
22. Applicable to IVD medical devices (additional)						
22.1 Performance characteristics						
22.1.1	IVD medical devices should achieve the analytical and clinical performances, as stated by the product owner that are applicable to the intended use/purpose, taking into account the intended patient population, the intended user, and the setting of intended use. These performance characteristics should be established using suitable,	A	Horizontal standards:	Yes		CSDT file no. XYZ

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
	validated, state of the art methods. For example: a) The analytical performance can include, but is not limited to,		CLSI EP12: User protocol for eval. of quali. test performance CLSI EP 24: Assess. of diag. acc. of lab. test use operating charac. curve		Analytical performance report (sensitivity, specificity)	
	b) Traceability of calibrators and controls;		ISO 17511:2020: IVD med. dev.- Require. for estab. metro. traceability of values assigned to calibrators, trueness cont. mat. and human sam. CLSI EP32: Metrological traceability and its implementation		Support report of metrological traceability	
	c) Accuracy of measurement (trueness and precision);		CLSI EP05: Eval. of precision of quanti. measure. Procedure CLSI EP09: Measure. procedure compare and bias est. using patient sample (accuracy) CLSI EP15: User verification of Precision and estimation of bias		Support report of precision and accuracy	
	d) Analytical Sensitivity/Limit of detection;		CLSI EP06: Eval. of linear of quanti. measure. procedures CLSI EP17: Eval. of detect cap. for cli. lab. measure. procedure (LLoD)		Support report of LLoD	
	e) Analytical specificity;		CLSI EP07: Interfere test in cli. Chem. CLSI EP14: Eval. of commutability of process sample		Support report of analytical specificity	
	f) Measuring interval/range;		CLSI EP06: Eval. of linear of quanti. measure. procedures CLSI EP34: Estab. and verify an ext. measure interval through specimen dilution and spiking		Support report of interval	
	g) Specimen stability.		CLSI EP35 cl.4.3: Assess. of equi. or suit. of specimen for med. lab. measure procedure, specimen stability Vertical standards: -		Support report of specimen stability	

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
22.1.2	The clinical performance, such as diagnostic/clinical sensitivity, diagnostic/clinical specificity, positive predictive value, negative predictive value, likelihood ratios, and expected values in normal and affected populations.	A	Horizontal standards: CLSI EP12: User protocol for eval. of quali. test performance CLSI EP 24: Assess. of diag. acc. of lab. test use operating charac. curve Vertical standards: -	Yes	Clinical performance report (sensitivity, specificity)	CSDT file no. XYZ
22.1.3	Where the performance of an IVD medical device depends on the use of calibrators or control materials, the traceability of values assigned to such calibrators or control materials should be ensured through available reference measurement procedures or available reference materials of a higher order.	A	Horizontal standards: ISO 17511:2020: IVD med. dev.- Require. for estab. metro. traceability of values assigned to calibrators, trueness cont. mat. and human sam. CLSI EP32: Metrological traceability and its implementation CLSI EP30: Charact. and quali. of commutable refer. mat. for lab med. Vertical standards: -	Yes	Support report of metrological traceability	CSDT file no. XYZ
22.1.4	Wherever possible, values expressed numerically should be in commonly accepted, standardized units and understood by the users of the IVD medical device. (* Report in value when analytical performance → A)	A	Horizontal standards: ISO 2955:1983: Info. processing - Represent^{n}.of SI and other units in systems with limited character sets IEC 62366-1 IEC 62366-2 IEC 80000 (all parts) Vertical standards: -	Yes	Analytical performance report, part of presenting value of the test result	CSDT file no. XYZ
22.1.5	The performance characteristics of the IVD medical device should be evaluated according to the intended use statement which may include the following: a) intended user, for example, lay person, laboratory professional; b) intended use environment, for example, patient home, emergency units, ambulances, healthcare centers, laboratory; c) relevant populations (e.g. pediatric, adult, pregnant women, individuals with signs and symptoms of a specific disease, patients undergoing differential diagnosis, blood supply screening, etc.). Populations evaluated should represent, where appropriate, ethnically and genetically diverse populations so as to be representative of the population(s) where the device is intended to be marketed. For infectious diseases, the populations selected should also have similar prevalence rates.	A	Horizontal standards: CLSI EP12: User protocol for eval. of quali. test performance ประกาศ สธ. เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขการแสดงฉลากและเอกสารกำกับเครื่องมือแพทย์ 2563 ISO 15223-1:2016: Symbol Vertical standards: ISO 18113-2:2009: Info. supply IVD reagent for professional use	Yes	Clinical performance report, part of user interface char. described in the report) Label and instruction for use (IFU is evidence of risk cont. measure of risk & usability)	CSDT file no. XYZ
22.2 Chemical, physical and biological properties						

No.	Requirement	A = app. NA = not app.	Applied standard	Comply	Testing report	Maintenance
22.2.1	With regards to chemical, physical, and biological properties for IVD medical devices, attention should be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.	A	Horizontal standards: Spec. of mat. Vertical standards: -	Yes	COA	CSDT file no. XYZ

EP Checklist

Prepared by (name/signature/date):

Reviewed by (name/signature/date):