MINISTRY OF HEALTH ———	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness
Number: /QD-BYT	*Hanoi, date month year 2023*

DECISION

Regarding the promulgation of criteria and principles for evaluating Common Technical Documents of medical equipment according to ASEAN regulations (Common Submission Dossier Template - CSDT) for in vitro diagnostic medical equipment

HEALTH MINISTER

Pursuant to Decree No. 95/2022/ND-CP dated November 15, 2022 of the Government on Regulations, functions, tasks, powers and organizational structure of the Ministry of Health;

Pursuant to Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical equipment management;

Pursuant to Decree No. 07/2023/ND-CP dated March 3, 2023 of the Government amending and supplementing a number of articles of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical equipment management;

Pursuant to Circular No. 19/2021/TT-BYT dated November 16, 2021 of the Minister of Health stipulating sample documents and reports for implementation of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical equipment management;

Pursuant to Circular No. 10/2023/TT-BYT dated May 11, 2023 of the Minister of Health amending and supplementing a number of articles of Circular No. 19/2021/TT-BYT dated November 16, 2021 of The Minister of Health stipulates sample documents and reports for implementation of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical equipment management;

Pursuant to Decision No. 2426/QD-BYT dated May 15, 2021 of the Minister of Health promulgating Instructions on how to prepare common technical documents on medical equipment according to ASEAN regulations;

At the request of the Director of the Department of Infrastructure and Medical Equipment.

DECISION:

Article 1. Promulgate together with this Decision criteria and principles for evaluating Common Technical Documents on medical equipment according to ASEAN regulations (Common Submission Dossier Template - CSDT) for diagnostic medical equipment in vitro.

Article 2. This Decision takes effect from the date of signing.

Article 3. Mr. and Mrs.: Chief of the Ministry Office, Chief Inspector of the Ministry, Director of the Department of Infrastructure and Medical Equipment, Director of the Department, Director of the Ministry of Health, Directors of the Department of Health of the provinces and cities under The central government and relevant agencies, organizations and individuals are responsible for implementing this decision.

During the implementation process, if there are any difficulties or problems, agencies, organizations and individuals are requested to promptly report them to the Ministry of Health for consideration and resolution./.

Recipients :
- As Article 3;
- Minister (to report);
- Deputy Ministers;
- Electronic information portal of the Ministry of Health;
- Saved: VT, HTTB.

KT. MINISTER
DEPUTY

Do Xuan Tuyen

CRITERIA AND PRINCIPLES FOR EVALUATION OF GENERAL TECHNICAL DOCUMENTS ON MEDICAL EQUIPMENT
ACCORDING TO ASEAN REGULATIONS (Common Submission Dossier Template - CSDT)
FOR I N VITRO DIAGNOSTIC MEDICAL EQUIPMENT

(Issued together with Decision No. /QD-BYT dated / /2023 of the Ministry of Health)

first . Principles for evaluating database records

CSDT records need to be evaluated according to the following criteria:

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
first	**summary of medical equipment**				
	1.1	Brief, general description of medical equipment	Descriptive information about medical equipment.	- Descriptive information about medical equipment includes: + Name + Model (type), type + Device identification code (Global Medical Device Nomenclature – GMDN) (if any) + Software, software version (if any) + Name and exclusive registration code (if any)	- Instructions for use and comparison of related documents in the file.
			Purposes and indications for use.	- The purposes and indications of use for which the device is intended are according to the data provided by the manufacturer on the label, in the instructions for use of that medical device.	
			New features if any.	- New features, if any (for example, using nanotechnology, artificial intelligence, etc.).	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
	1.2	History of circulation on the market	List of countries where the product has been marketed (if any).	- Provide a list of countries where the product has been marketed, along with the first year (if any) of starting to sell the product on that market . + Declare a list of countries where the product has been marketed . + Time of first product commercialization	Declare a list of countries where the product has been marketed . Attached documents such as: CFS, circulation number link,... (if any).
	1.3	Intended use and indications use	State the purpose of use and indications for use of the medical equipment.	State the purpose of use and indications for use of the medical equipment as on the label or user manual that medical equipment.	Labels, user manuals, etc.
	1.4	Licensing information for circulation in different countries	Information about product licensing status in different countries on the list of reference	- Provide information on the status of product licensing in countries on the list of reference management agencies as follows: EU member countries, Japan, Canada, Australia (TGA), USA (FDA), England, Switzerland … + Includes licensing status (approved, awaiting approval, refused licensing, not registered for circulation, ...), + Intended use ,	- Provide copies (or online search links) of

<table>
<tr><th colspan="2">No</th><th>TITLE</th><th>REQUEST CONTENT</th><th>ASSESSMENT GUIDELINES</th><th>PROOF DOCUMENTS</th></tr>
<tr><td></td><td></td><td></td><td>regulatory agencies .</td><td>+ Indications for use,
+ N times a day head. For products licensed for circulation in EU member countries, if there is no information on the date of first issuance, the most recent date of issuance can be recorded.
This information can be presented in table form as follows:
<table>
<tr><th>No</th><th>Country name or Licensing agency name</th><th>Intended use/indications for use</th><th>Licensing status</th><th>Date Range</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>licensing documents for circulation in the above countries (if any).</td></tr>
<tr><td></td><td>1.5</td><td>Important information regarding the safety and effectiveness of medical devices international</td><td>Provide information about adverse events that have occurred.</td><td>- Provide a summary of adverse events that have occurred in the market since the product was first marketed or in the last 5 years This.
- Summary information about adverse events that have occurred should include, at a minimum, a description of the adverse event, the number of adverse events, or the frequency of occurrence (i.e., the total number of adverse events recorded in total). number of products sold).
- This information can be presented in table form as follows:
<table>
<tr><th>No</th><th>Day</th><th>Description of adverse events</th><th>Quantity or frequency happened</th></tr>
<tr><td>first</td><td></td><td></td><td></td></tr>
<tr><td>2</td><td></td><td></td><td></td></tr>
<tr><td>3</td><td></td><td></td><td></td></tr>
</table></td><td>-Documents declaring adverse events, number of adverse events or frequency of occurrence, Corrective action or written confirmatio</td></tr>
<tr><td></td><td></td><td></td><td>Provide information on corrective actions to ensure</td><td>- Provide information on corrective actions to ensure safety in the market since the product was first introduced to the market or within the last 5 years This must include, at a minimum: the date of occurrence, a brief description of</td><td></td></tr>
</table>

<table>
<tr><th colspan="2">No</th><th>TITLE</th><th>REQUEST CONTENT</th><th>ASSESSMENT GUIDELINES</th><th>PROOF DOCUMENTS</th></tr>
<tr><td></td><td></td><td></td><td>safety in the market</td><td>the event, and the name of the country or territory that took corrective action. This information can be presented in table form as follows:
<table>
<tr><th>No</th><th>Day</th><th>Brief description of the event</th><th>Name of country or territory</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table></td><td rowspan="3">n by the product owner.</td></tr>
<tr><td></td><td></td><td></td><td>If there have been no adverse events, no corrective action has been taken since the product was marketed or within the last 5 years .</td><td>If there have been no adverse events, no corrective action since product circulation or in the last 5 years, provide written confirmation from the product owner.</td></tr>
<tr><td></td><td></td><td></td><td>Other information (if any)</td><td>- The medical device needs to clearly indicate whether it contains one of the following ingredients:
+ Human or animal cells, tissues or their derivatives are used in non-living form, for example artificial heart valves originating from pigs, cat intestines, …
+ Cells, tissues or derivatives (derivatives) of microbial or recombinant origin, e.g. skin plumping products based on hyaluronic acid obtained by bacterial fermentation, …
+ Has a radiation component, ionizing (e.g. X-ray), or non-ionizing (e.g. laser, ultrasound, …).</td></tr>
</table>

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
2		**Essential Principles Compliance Table: (can be in Vietnamese or English)**	Provide compliance tables with essential principles for the safety and effectiveness of medical devices issued by the medical device owner **(** FOR APPENDIX I)	Provide a compliance table with the essential principles of medical device safety and effectiveness issued by the medical device owner as described in attached Appendix I to demonstrate product compliance with relevant essential principles. In case the medical device has been licensed for circulation in EU member countries, a table of compliance with essential principles according to EU regulations can be provided.	
3	**Description of medical equipment (** ***Note:*** *in case the information to be looked up is stated in the user manual, you can refer to the user manual)*				
	3.1	Describe and present the characteristics of medical equipment	Describe in detail the characteristics of medical equipment.	Describe in more detail the characteristics of medical equipment to explain the operating principles of medical equipment, explain the basic scientific concepts that make up the basic principles of medical equipment .	Documents detailing the medical equipment or Technical documents issued by
			Describes the components and	Describes the components and accessories used to help the device operate as well as the packaging .	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			accessories used to help the device operate as well as the packaging.		the owner or instructions for use of the medical equipment.
			Full description of each functional component, material or raw material of the medical device, accompanied by a representative image of the medical device in the form of a diagram, image or drawing, if appropriate fit.	Full description of each functional component, material or raw material of the medical device, accompanied by a representative image of the medical device in the form of a diagram, image or drawing, if appropriate fit.	
	3.2	Uses	State the intended use of the medical equipment.	State the intended use of the medical device in accordance with the data provided by the product owner in the user manual as well as the operating capabilities of the medical device international.	Labels, user manuals, etc.
	3.3	Indications	General description of the disease or condition for which the	A general description of the disease or condition that the medical device diagnoses, treats, prevents, or alleviates and includes a description of the target patient population for which the medical device is designed. use.	Labels, user manuals, etc.

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			medical device is intended to diagnose, treat, prevent or alleviate.		
	3.4	User manual	Provide instructions for use from the product owner.	All necessary information is provided from the product owner including the procedures, methods, frequency, timing, quantities and preparation that should be followed for the safe use of the medical device. international there.	Document detailing the medical equipment (if any) or original instructions for use issued by the medical equipment owner (with Vietnamese translation). Technical documents issued by the owner.
	3.5		Circumstances where medical equipment should not be used because the	Information about cases where medical equipment cannot be used for patient safety reasons, for example: due to medical history, physiological characteristics of the patient... in accordance with the content written on the label or Instructions for use of medical equipment.	Documents detailing the medical equipment (if any) or

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		Contraindications determined (if any)	risks of use clearly outweigh the potential benefits.	General description of diseases or conditions and patient groups for which medical equipment should not be used for the purpose of diagnosis, treatment or mitigation of disease.	original instructions for use issued by the medical equipment owner. Contraindications (if any). Technical documents issued by the owner.
	3.6	Scene newspaper	Warn about specific dangers that users need to know before using medical equipment.	Warning information about specific dangers that users need to know before using medical equipment, including preventive measures to protect patients from risks caused by using medical equipment international.	Document describing details of medical equipment. Technical documents issued by the owner.

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	3.7	Careful	Warn users to apply necessary precautions for safe and effective use of medical equipment.	The information warns the user to take necessary precautions for the safe and effective use of the medical device. May include actions to be taken to avoid effects to the patient/user, which may not be life-threatening or cause serious injury, but of which the user should be aware. . The caution section may also warn the user of the adverse effects of using the medical device or of misuse of the medical device and of the precautions required to avoid such effects. there.	Document describing details of medical equipment. Technical documents issued by the owner.
	3.8	Potential adverse effects hidden (if any)	Unwanted and serious consequences that may occur to the patient/user, or side effects from using the medical device under normal conditions often	These are unwanted and serious consequences (death, injury, or serious adverse events) that may occur to the patient/user, or side effects from the use of the device. medical equipment under normal conditions often recorded through clinical trials and post-marketing monitoring.	Documents detailing the medical equipment (if any) or original instructions for use issued by the medical equipment owner. Potential adverse effects (if any). Technical documents

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
					issued by the owner.
	3.9	Alternative treatments (if any)	Alternative procedure or action for diagnosing, treating or mitigating the disease or condition for which the medical device is intended	T he information describes alternative procedures or actions for the diagnosis, treatment or mitigation of the disease or condition for which the medical device is intended	Document describing details of medical equipment (if any). Alternative treatments (if any).
	3.10	Materials (can be in Vietnamese or English)	Describe the materials of the medical device and its characteristics to demonstrate compliance with the relevant Essential Principles.	- Describe the materials of the medical device and its characteristics to demonstrate compliance with the relevant Essential Principles. - For reagents, calibrators, and *in vitro control materials* : + Provide a list of all materials used to produce the product, including: Material name, role in composition Products. + Provide information about the composition, biological properties, and origin of the materials involved in the reaction for testing: antigens, antibodies, enzymes, conjugates, PCR primers, probes, reagents standards, control substances (controls), ... For medical equipment containing substances subject to special control (narcotics or radiation-generating materials, non- ionizing or ionizing), full information must be provided on ingredients, content, The role of these substances, for example Buprenorphine in the drug testing kit , iodine 131 in	-List of all raw materials used. - Information about the composition , biological properties, and origin of the

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				the radioimmunoassay kit, Phospho-32 radioactive DNA probes in the Southern blot method, etc. . + For *in vitro* diagnostic medical equipment types C and D: provide information on standards or test reports of materials participating in the reaction (except stabilizers). Information is described for each active material (antigen, antibody, conjugate, …).	materials involved in the reaction. - Standards or test reports for materials involved in the reaction. - For medical equipment containing substances subject to special control : full information about the composition, content, and role of these substances

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					must be provided .
	3.11	Relevant technical specifications other	Functional characteristics and operational specifications of medical equipment .	Functional characteristics and operational specifications of medical devices include: accuracy, sensitivity, and specificity of the devices. medical equipment measurement and diagnosis, reliability and other factors (if relevant) and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage , transportation and packaging to demonstrate compliance with the relevant Essential Principles mandarin.	Document that reports or declares conformity to recognized standards applied by the product owner. Other relevant technical specifications (if any)
	3.12	The information other	Other important features not detailed above, to demonstrate compliance with the relevant	Other important characteristics not detailed above, to demonstrate compliance with the relevant Essential Principles (e.g. biocompatibility of the medical device, etc.).	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			Essential Principles.		
4		**Summary document on design verification and validation** (can be in Vietnamese or English)	Summarizes or references or contains design verification data and design validation data, appropriate to the complexity and risk classification of the medical device.	This section should summarize or reference or contain design verification data and design validation data, appropriate to the complexity and risk classification of the medical device. This document includes: - Certificates or declarations of conformity to recognized standards to which the product owner applies. - Summaries or reports of tests and evaluations based on other standards, manufacturer's methods and tests, or other means of demonstrating product conformity to standards. For example: If the Essential Principles Conformity Table mentions that a manufacturer uses a recognized standard to demonstrate compliance with an essential principle, a Declaration of Conformity must be provided. compliance with that standard, or a certificate of compliance, and summary information on test data if that standard does not include performance requirements. Summaries of test and evaluation data or reports, depending on the complexity and risk classification of the medical device, typically include: - List and conclusions drawn from published reports related to the safety and effectiveness of medical devices in accordance with the Essential Principles;	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				- Technical tests; - Laboratory tests; - Biocompatibility tests; - Animal tests; - Use under simulated conditions; - Software appraisal.	
	4.1	Preclinical studies ready	- Information on biocompatibility tests performed on materials used in medical devices.	- Provides detailed information on all biocompatibility tests performed on materials used in medical devices. All significantly different materials must be described. Information describing the tests, results, and data analysis must be presented.	- Biocompatibility test report. - Preclinical trial data. - Report preclinical studies on animals. - Electrical safety certification. - Sterilization appraisal report. - Cyber security
			- Physical preclinical testing data, if appropriate.	- Provide complete physical pre-clinical testing data, if appropriate. The report must include the product owner's objectives, methods, results, and conclusions for all physical studies of the medical device and components. Physical testing shall be performed to predict the adequate response of the medical device to physical stress, adverse conditions and effects, long-term use and all other adverse effects. Inoperability errors are known and may occur.	
			- Reports on preclinical animal studies	- Provides a report on preclinical animal studies used to demonstrate possible efficacy in humans. These studies must be performed in compliance with good laboratory practice. The report must include the product owner's goals,	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			used to demonstrate possible efficacy in humans.	methods, results, analysis, and conclusions. The conclusion of the study must address the interactions of the medical device with animal fluids and tissues and the functional effectiveness of the medical device in experimental animal model(s). The rationale (and limitations) of choosing specific animal models should be discussed.	certification. - Other preclinical studies (if not mentioned in the Clinical Report).
			- Evidence of electrical safety and electromagnetic compatibility.	- Provide evidence of electrical safety and electromagnetic compatibility. For example, if the owner declares that the product meets the requirements of IEC 60601-1 and IEC 60601-1-2, a summary test report and/or certificate of conformity must be provided. to demonstrate that the device meets these standards.	
			- Sterilization appraisal report.	- For sterilized medical equipment, provide sterilization appraisal reports. If the sterilant is toxic or produces toxic residues (e.g., Ethylene Oxide), data and test methods must be provided to demonstrate that the sterilant or residue is within acceptable limits. receive.	
			- Evidence of network security for medical equipment with a network connection, internet connection or	- Provide evidence of network security for medical equipment with a network connection, internet connection or wireless connection. Such as: analyzing risks and possibilities of cyber attacks, cyber security control methods, plans, processes or mechanisms to monitor, promptly detect and manage security-related threats. Cyber security during the life cycle of medical equipment. Can provide a declaration from the manufacturer or owner stating that the medical device has a network connection, internet connection or wireless connection to ensure network security safety.	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			wireless connection.		
	4.1.1	Software verification and validation studies (if appropriate)	Provide evidence that validates the software design and development process.	- Correctness of a software product is another important product characteristic that cannot be fully validated in a finished product. The product owner must provide evidence confirming the software design and development process. - This information should include the results of all verification, validation and testing performed internally and in the user's environment prior to release to the market, for all software configurations. different hardnesses as mentioned on the label or in the product manual, as well as representative data obtained from both test environments. experience. - Software version - Overview of the verification, validation, and testing performed for the software - Unresolved anomalies in the release version, reasons for acceptance (issues affecting safety, effectiveness & remediation plan)	- Lists software information and versions.

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
	4.1.2	Medical equipment containing biological materials learn	Provide research results that demonstrate that remedial measures related to the risks from infectious agents have been adequately implemented.	Research results must be provided demonstrating that remedial measures related to the risks from infectious agents have been adequately implemented. This section will include virus removal results with known threats. Donor screening concerns must be fully addressed and methods of obtaining human material should be fully described. Process validation results are required to demonstrate that manufacturing processes have been applied to minimize biological risks.	Research results demonstrate that treatment measures related to risks from infectious agents have been fully implemented.
	4.2	Preclinical studies of reagents, calibrators, and *in vitro control materials*			
	4.2.1	Stool performance accumulation	- Provide research reports on analytical performance of	- Provide research reports on analytical performance of medical devices, including: analytical sensitivity, analytical specificity, limit of detection (LOD), limit of quantification (LOQ), Linearity, detection range, accuracy, repeatability, influencing factors, durability, etc. Performance criteria will depend on each medical device. international.	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			medical equipment. - Information about the samples used for evaluation .	- Information about samples used for evaluation (negative and positive control samples, base standard samples, standard panels, influencing substances, ...). - Research reports should include the objectives, methods, results, and conclusions of the research. The results and conclusions must clearly demonstrate that the product has characteristics suitable for its intended use. Analytical results: analytical sensitivity, analytical specificity, limit of detection (LOD), limit of quantification (LOQ), linearity, detection range, accuracy, repeatability, factors Effects and durability are as follows: - **Precision of measurement:** This section should provide information on the precision of the measurement procedure and summarize the data in sufficient detail to permit assessment of the adequacy of the means chosen to establish precision. Precision measures only apply to both quantitative and qualitative testing when a certified reference sample or certified reference method is available. - **Measurement accuracy:** This section should describe repeatability and reproducibility studies. - **Analytical sensitivity:** This section will include information about the study design and results. It must provide a description of the sample type and preparation including the sample matrix, analyte levels, and how the levels were established. The number of replicate tests at each concentration must also be provided as well as a description of the calculation used to determine assay sensitivity.	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				- **Analytical Specificity:** This section will describe interference and cross-reactivity studies performed to determine analytical specificity in the presence of other substances/agents in the specimen. - Information must be provided on the assessment of potentially interfering and cross-reactive substances or agents in the assay, on the substance or agent tested and its concentration, sample type, substance test concentration analysis and its results. - Interfering and cross-reacting substances or agents, which vary widely depending on assay type and design, can originate from exogenous or endogenous sources such as: + Substances used to treat patients such as drugs; + Substances that the patient ingests such as alcohol and food; + Substances added during sample preparation such as preservatives and stabilizers; + Substances found in specific patient samples such as hemoglobin, lipids, bilirubin, proteins; + Analytes that are structurally similar to precursors, metabolites, or medical conditions unrelated to the test condition, including samples that are negative to the test but positive for a possible condition identical to the test conditions.	
	4.2.2	Stability determined	Provide stability study reports, including real-time stability and	- Stability study reports, including real-time stability and stability under accelerated aging conditions (if appropriate). In cases where real-time stability studies are not performed but only under accelerated aging conditions, a full and appropriate explanation is required. physical.	Stability reports.

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			stability under accelerated aging conditions (as appropriate). Provides in-use stability study reports for products that are used multiple times after opening. Provides reports of stability studies during transportation, performed under real or simulated conditions.	- Report on in-use stability studies for products that are used multiple times after opening. - Report on stability studies during transportation, performed under real or simulated conditions. Stability study reports should include objectives, methods, results, and conclusions. - **Claimed Shelf Life:** This section will provide information on stability testing studies to support the claimed shelf life for the device. Testing shall be carried out on at least three different batches produced under conditions substantially equivalent to normal production conditions. The backpacks do not need to be consecutive. Accelerated studies or data extrapolated from real-time data may be acceptable for initial shelf-life claims but must be followed up with real-time stability studies. Such detailed information will include: + Research report including procedure, batch number, acceptance criteria and testing period + When accelerated studies have been performed in anticipation of real-time studies, the method used for accelerated studies must be described; + Conclusion and declaration of shelf life - **In-use stability:** This section will provide information on in-use stability studies for a batch that reflects actual routine use of the device, whether actual or simulated. This may include open vial stability and/or, for automated devices, on-machine stability. In the case of automatic measuring equipment, if calibration stability is required, supporting data must be included. Such detailed information will include:	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				+ Research report (including protocol, acceptance criteria and trial period); + Conclusions and confirmation of stability in use - **Transport Stability:** This section should provide information on a transport stability study for a batch of equipment to evaluate the equipment's ability to withstand expected transport conditions. Transport studies can be performed under real and/or simulated conditions and must include various transport conditions such as extreme heat and/or extreme cold. That information will describe: + Research report (including outline and acceptance criteria); + Method used for simulation conditions; +Conclusion and recommended shipping conditions.	
	4.3	Forestry evidence ready	Provide a clinical evaluation report of medical equipment.	- Provide a clinical evaluation report of medical equipment. This assessment may take the form of a systematic review of available reference literature, be based on clinical experience with that or similar medical devices, or may be by research. clinical research. Clinical studies are often necessary for medical devices with a high level of risk, or medical devices with little or no clinical experience. - The clinical evaluation report should include the purpose and context of the clinical evaluation, clinical input, data evaluation and analysis, and conclusions regarding the safety and effectiveness of the medical device. international. - evaluation report should have all the necessary information as an independent document for review by regulatory agencies . - Clinical evaluation report should be summarized turn off:	- Clinical evaluation report.

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				+ The technology used by the medical device, indications for use, statements about the safety and clinical effectiveness of that medical device if applicable. Have; + Nature, scope and scale of clinical data assessed price; + Clinical data and recognized standards prove the safety and effectiveness of medical equipment international.	
	4.3.1	Data from references available available	Provide evidence of clinical effectiveness, which may include medical device-related studies conducted in Vietnam or other countries.	- Where the product owner uses available research or reference documents to demonstrate the safety and effectiveness of the medical device, copies of these documents must be provided. - Clinical evidence of effectiveness may include medical device-related studies conducted in Vietnam or other countries. This evidence can be cited from related studies published in international medical journals. Documentation of clinical evidence must include objectives, methods and results, presented in context, clearly and meaningfully. Before drawing conclusions about the results of clinical studies, there must be a discussion in context with the published literature.	List of available research or reference documents that demonstrate the safety and effectiveness of the medical device
	4.3.2	Data from forestry experience ready	Provides data on the clinical experience of the same or similar product on one's own.	- Clinical experience refers to clinical data obtained from clinical use of the product, not from clinical studies. Clinical experience may be with the product itself or a similar product on one's own. - Clinical experience can be obtained from the following data: + Post-marketing surveillance reports from product owners, regulatory agencies, and system-wide studies (may contain unpublished long-term study	- Post-sale data reporting.

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				data on safety and efficacy) . fruit). + Data on adverse events that have occurred, from product owners or regulatory agencies physical. + Data from patients using the medical equipment in the pre-market aid program Products. + Information on clinically relevant corrective actions such as recalls, notifications, hazard warnings dangerous.	
	4.3.3	Data from forestry research ready	Provides clinical research data for the purpose of evaluating the safety and effectiveness of a medical device international.	A clinical study is a systematic study, performed on or in the human body, for the purpose of evaluating the safety and effectiveness of a medical device. international. Clinical studies may be performed by the medical device owner or by a third party on behalf of the owner. Clinical studies should be designed, performed and reported in accordance with ISO 14155, *Parts 1 and 2, Clinical Investigations* of Medical Devices for Human Subjects, or conform to an equivalent standard, and comply with host country regulations. Clinical research must conform to the ethical standards of the Declaration of Helsinki. *in vitro* diagnostic medical devices : Clinical research is research performed to establish or confirm the clinical performance of *in vitro* diagnostic medical devices . The manufacturer must have clinical evidence supporting its clinical claims , including: diagnostic sensitivity (clinical sensitivity) and diagnostic specificity (clinical specificity). sieve).	ISO 14155 (*Parts 1 and 2, Clinical studies of medical devices for human use)* , or equivalent standards, or standards in host countries

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
5	**Label of medical equipment**				
	5.1	Sample labels on medical equipment and packaging packaging	Label samples must meet the requirements according to the provisions of Decree 43/2017/ND-CP and Decree No. 111/2021/ND-CP.	A printed, written or pictorial representation, provided or attached to one or more layers of packaging, including the outer packaging and the immediate packaging. If it is not physically possible to include label samples (e.g. a large warning label attached to an X-ray machine), then information can be provided in an alternative form, such as an image or copy. technical drawing . The label sample must meet the requirements as prescribed by Decree 43/2017/ND-CP and Decree No. 111/2021/ND-CP as follows: - Name of medical equipment: appropriate to the medical equipment requested for circulation number. - Name and address of the owner of the medical equipment circulation number: consistent with the declared content. - Circulation number of medical equipment. - Origin of medical equipment, in case the origin cannot be determined, write down the place where the final step of completing the goods was performed. - Name and address of medical equipment owner: consistent with the declared content. - Manufacture date expiry date. Sterilized, single-use medical equipment, reagents, calibrators, control materials, and chemicals must have an expiration date. In other cases, write the date of manufacture or expiration date; For medical equipment, it is machinery and equipment with the year of manufacture or month and year of manufacture - Batch number or serial number of medical equipment. - Warning information, instructions for use, storage instructions, warranty basis : Can be shown directly on the medical equipment label or clearly state	Original product label (for imported equipment). Vietnamese product label design

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				instructions for looking up this information on the equipment label medical condition. - Instructions for looking up information about: warranty facilities, instructions for using medical equipment. For imported medical equipment, the label sample must include both the original label and the Vietnamese secondary label. The label sample must include all products in the circulation registration dossier. In case the application is submitted according to the medical device family, a representative label sample can be submitted but must note the differences between the label samples of the products. there.	
	5.2	Instructions for using the language Vietnamese	Instructions for the physician or end user to use the medical device safely and for the intended use of the medical device .	- Includes instructions for the physician or end user to use the medical device safely and for its intended use . Instructions for use should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative treatments, and conditions of storage and use to maintain safety. safety and effectiveness of medical equipment international. - *in vitro* diagnostic medical devices , instructions for use include the following information: - *printed* diagnostic medical equipment *vitro* . - Historical purpose Use: + Detect or measure something What; + Functions of medical equipment (e.g. screening, monitoring, diagnosing or supporting diagnosis, prognosis, prediction) guess); + Using the same medical equipment (testing machine) automatically or not; + Quantitative or semi-quantitative or qualitative or definite name...;	Instructions for use of medical equipment

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				+ Type of sample used in the test (eg serum, plasma, whole blood, tissue biopsy, water urination); + Population considered experience. - Indicative information: product used in *printing diagnostics vitro* . - Users (e.g. laypersons, healthcare professionals, ...). - Principle of review experience. - Description of reagents, calibrators, standards, control materials , and limitations on their use (e.g., suitable for use only with a specific analyzer) can). - List of materials to be supplied and list of materials specifically requested but not supplied grant. - *in vitro* diagnostic medical equipment used in combination with other medical equipment and/or in combination with non-medical equipment and devices international: + Information to identify these devices or equipment, including important performance characteristics important. + Information on known limitations when combined with the device or device there. - Special storage conditions (e.g. temperature, light, humidity), conditions when using medical equipment, if relevant mandarin. - Stability during use, which may include storage conditions and shelf life after initial opening; storage conditions and stability of working solutions, as appropriate. The instructions for use must clearly state the product's lifespan. - If the medical device is supplied as sterile, it is necessary to clearly state the medical device's sterility, the sterilization method, and instructions for	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				handling in case the sterile packaging is damaged before use. use. - Information to enable the user to be informed of any warnings, precautions, measures to be taken and restrictions on use of the *in vitro diagnostic medical device* . This information should be included, if desired fit: + Warnings, precautions and/or measures to be taken in case the *in vitro diagnostic medical device* is damaged or the deterioration is reflected through a change in the appearance of the device Medical conditions may affect effectiveness power; + Warnings, precautions and/or measures to be taken regarding exposure to foreseeable external influences or environmental conditions, such as external magnetic, electrical and electromagnetic fields, electrical discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity or heat degree; + Warnings, precautions and/or measures to be taken regarding possible risks during the use of the medical device for specific diagnosis, evaluation, treatment (e.g. interference The electromagnetic radiation emitted by the device affects the device other); + Precautions regarding materials incorporated into medical devices that contain carcinogenic, mutagenic or reproductively harmful substances, endocrine disruptors, or other substance that may cause sensitivity or allergy in the patient or user use. - Conditions for collection, manipulation and preparation sample - Instructions for preparing or handling medical equipment before use, such as sterilization, assembly , calibration, etc., so that the equipment is used as intended by the owner property. - *in vitro* diagnostic medical device is properly installed and ready for performance safely and as intended by the owner, together with the following	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				information, when available contact mandarin: + Details of the nature and frequency of preventive and periodic maintenance, including cleaning or disinfection bacteria; + Consumables and replacement methods they; + Information about the calibration that needs to be performed to ensure the medical device operates properly and safely throughout its life use; + Measures to reduce the risk to persons involved in installation , calibration or repair, e.g. contaminated surfaces infected. - Recommend quality control procedures as needed set. - Instructions on how to retrieve the values assigned to calibrators and control materials, including information to identify reference materials and reference measurement procedures used use. - Test procedure, including calculation and interpretation of results, and recommendation for additional confirmatory testing if appropriate fit. - Analytical performance characteristics, such as sensitivity, specificity, and precision (which is a combination of precision and accuracy). body). - Clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity when relevant mandarin. - Reference interval when relevant mandarin. - Information on interferences or limitations (e.g. visual evidence of hyperlipidemia or hemolysis, specimen storage time) that may affect the performance of the analysis. - Warnings or precautions should be taken regarding the disposal of the device, accessories and consumables if any. This information should include the following, if desired fit:	

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
				+ Bacterial or microbial contamination hazards (for example, consumable materials contaminated with potentially infectious substances of human origin); + Environmental hazards (e.g. batteries or materials that emit potentially dangerous levels of radiation dangerous); - Physical hazards (eg _ explode). - *in vitro* diagnostic medical devices intended for use by non-professionals, users should be instructed to consult with health care professionals before making any medical decisions . any. - References, if relevant mandarin. - The name and address of the owner in a format that is identifiable and allows information about the owner to be identified. In case the instructions for use contain information about the manufacturing facility and origin, this information must include complete information about the name and address of the manufacturing facility. - Document identification information, such as version number or release date.	
6	**Risk Analysis (** (can be in Vietnamese or English)				
		Results of risk analysis ro	List of possible risks to medical devices. Present an assessment of these risks against the declared benefits	Provide a list of possible risks to medical devices. Indirect risks from medical devices may originate from hazards associated with the medical device, such as moving parts, leading to long-term injury, or from user-related hazards, such as ionizing radiation from an X-ray machine. An assessment of these risks against the declared benefits of the medical device and the method used to reduce the risks to an acceptable level must be presented. The individuals or organizations performing the risk analysis must be clearly identified. The	Risk analysis list

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
			of the medical device and the methods used to reduce the risks to acceptable levels.	technique used for risk analysis must be defined, to ensure appropriateness to the medical device and the risks involved. mandarin.	
7	**Production information** (can be in Vietnamese or English) This section should summarize or reference or contain documentation relevant to the manufacturing processes, including quality assurance measures, appropriate to the complexity and risk classification of the medical device.				
	7.1	Information about the property export	Names and addresses of all manufacturers involved in the production and sterilization process.	List the names and addresses of all manufacturers involved in the production and sterilization process (including third-party manufacturers and sterilizers).	List of names and addresses of manufacturers
	7.2	Production process export	Overview of the production process.	- Includes information to give a general understanding of the manufacturing process. No proprietary details are required. This information can be presented in the form of a production flow diagram that briefly describes the manufacturing process, in-process quality control, assembly, quality control, and packaging of the final product. Information related to final product quality inspection. - If multiple manufacturers are involved in the production process to complete a product, it is necessary to clearly state which activities each manufacturer is involved in.	- General description of the production process - Standards and test reports for

No		TITLE	REQUEST CONTENT	ASSESSMENT GUIDELINES	PROOF DOCUMENTS
					final products. - Finished product quality inspection process.

APPENDIX I

COMPLIANCE SHEET OF ESSENTIAL PRINCIPLES

(Issued together with Decision No. /QD-BYT dated / /2023 of the Ministry of Health)

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
2	**General requirements**				
	2.1		Medical devices must be designed and manufactured so that, when used under the conditions and for the intended purposes, and with the knowledge and experience of the user, they will not cause harm to health. and the safety of the patient, user, or others, provided that any risks associated with the use of the medical device for its intended purpose are acceptable risks when taking into account the benefits to the patient and in accordance with the requirements of a high level of health and safety protection.	Enter "Yes" if the essential principle applies to medical equipment; Write "No" if the essential principle does not apply to medical devices. If an essential principle does not apply to medical devices, the reason should be explained. For example, if medical equipment does not contain materials of biological origin, for the essential principle on materials of	Technical documents proving the product meets essential principles, e.g. certificates , research reports, test results: - ISO 13485 - ISO 14971 - EN ISO 18113-1 - IEC 61326-1 - IEC 61326-2-6 - IEC 60601-1 *Note: Reports other than the form in the Appendix Table of Compliance with the essential principles of*
	2.2		The solutions of medical equipment owners for the design and production of medical equipment must be in accordance with safety principles, taking into account the level of scientific and technical development. In the process of choosing the appropriate solution for the design and production of medical equipment, to minimize the risks associated with the use of medical equipment, the product owner must follow the following principles:		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			• identify the hazards and associated risks arising from the use of the medical device, the potential for misuse, • eliminate or minimize risks as far as possible and reasonably through safe design and manufacturing, • for risks that cannot be eliminated, adequate protective measures must be taken, including warnings where necessary, and • inform users of remaining risks.	biological origin, write "No" in the "Apply" column and clearly state the medical equipment. Contains no materials of biological origin.	*Decision 2426 are accepted.*
	2.3		Medical devices must achieve the performance intended by the medical device owner and be designed, manufactured, and packaged to perform one or more functions within the definition of a device. medical equipment.		
	2.4		The technical characteristics and features in Clauses 1, 2 and 3 shall not have such an adverse effect that the health or safety of the patient or user and of others is impaired throughout the period. The useful life of the medical equipment is as expected by the owner of the medical equipment, when the medical equipment is subjected to impacts that may occur under normal use conditions and has been maintained and effective. according to the instructions of the medical device owner.		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
	2.5		Medical devices must be designed, manufactured and packaged so that their characteristics and technical performance when used for their intended purpose will not be adversely affected during transport and storage if transportation and storage are followed Follow the instructions and information provided by the medical equipment owner		
	2.6		The benefits must outweigh any unwanted side effects to the intended effect.		
	2.7		Medical devices require clinical evidence, appropriate to their use and risk classification, to demonstrate that the medical device complies with the relevant essential principles. response. Clinical assessment must be performed.		
	Design and manufacturing requirements				
	2.8 Chemical, physical and biological properties				
	2.8.1		Medical devices must be designed and manufactured to ensure that they meet the requirements for technical characteristics and features set out in Clauses 1 to 6 of "General Requirements". with: • the choice of materials used, in particular regarding toxicity, flammability, • physical and chemical properties of the materials used,		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			• compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking into account the intended purpose of the medical device, • the choice of materials used should reflect issues such as abrasion, hardness and resistance of the metal.		
	2.8.2		Medical devices must be designed, manufactured and packaged to minimize the risk posed by contaminants and residues to patients and those involved in transportation and storage. Management and use of medical equipment. In minimizing risk, Special attention should be paid to the time and frequency of tissue contact during transportation, storage and use of medical equipment.		
	2.8.3		Medical devices must be designed and manufactured so that they can be used safely with the materials, substances and gases to which they are exposed under normal use or in routine process; If medical devices are used to administer drugs, they must be designed and manufactured so that they are compatible with the medicinal product concerned and that the action of the drug is maintained for its intended use.		
	2.8.4		Where a medical device contains a substance that, if used separately, could be considered a medicinal product under relevant laws and has the effect of		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			supporting the effects of the device. medical equipment on the body, the safety, quality and performance of that medical device as well as the safety, quality and effectiveness of the combined medicinal product must be verified. “Medicinal product” referred to herein includes stable derivatives from human blood or plasma.		
	2.8.5		Medical devices must be designed and manufactured to minimize risks caused by substances that may leach or leak from the medical device.		
	2.8.6		Medical devices must be designed and manufactured to minimize risks caused by inadvertent penetration or release of substances from the medical device, taking into account the nature of the environment. environment in which the medical device is intended to be used.		
	2.9 Infection and microbiological contamination object				
	2.9.1		Medical devices and manufacturing processes must be designed to eliminate or reduce as far as is reasonably and appropriately possible the risk of infection to any person. Design must: • allows for easy handling, and, when needed: • minimize, as far as is reasonable and appropriate, microbial leakage and/or microbial exposure during use;		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			• minimize the transfer of contamination from the patient, user or other person to the medical device or specimen and vice versa during use.		
	2.9.2		In case a medical device is composed of substances of biological origin, the risk of contamination must be minimized to the maximum reasonable and appropriate level by selecting the source, sample donor and appropriate substances, and use validated inactivation, conservation, testing and control procedures, as appropriate. This requirement may not apply to certain in vitro diagnostic medical devices if viral activity and infectious agents are an essential part of the intended use of the product or if removal or inactivation is required. will affect the effectiveness of that in vitro diagnostic medical device.		
	2.9.3		Products made from non-living tissues, cells, and substances of animal origin that are determined to be medical devices will be considered ingredients of animal origin and applicable regulations will apply. relevant and subject to veterinary control and supervision for the intended use of this tissue. Medical device owners need to maintain information about the geographical origin of animals. The processing, storage, inspection and handling of tissues, cells and substances of animal origin must be carried out to		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			ensure optimal safety. In particular, safety related to viruses and other infectious agents must be achieved by validated methods of removal or inactivation during the manufacturing process. This requirement may not apply to certain in vitro diagnostic medical devices if viral activity and other infectious agents are an essential part of the intended use of the product or if removal or destruction is necessary. activity will affect the effectiveness of that in vitro diagnostic medical device.		
	2.9.4		For products made from cells, tissues and derivatives of bacterial or recombinant origin that are determined to be medical equipment, the selection of sample sources/donors, processing and preservation , testing and handling of cells, tissues and derivatives of such origin must be carried out to achieve optimal safety levels. In particular, safety related to viruses and other infectious agents must be addressed by implementing validated removal or inactivation methods during the manufacturing process. This requirement may not apply to certain in vitro diagnostic medical devices if viral and other infectious agent activity is an essential part of the product's intended use or if removal or inactivation is necessary. will affect the effectiveness of that in vitro diagnostic medical device.		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
	2.9.5		For products composed of non-living tissues, cells, and substances of human origin determined to be in vitro diagnostic medical devices, the selection of source, sample donor, and/or substances of human origin, the processing, storage, testing and handling of tissues, cells and substances of such origin must be carried out to ensure optimal safety. In particular, safety related to viruses and other infectious agents must be achieved by validated methods of removal or inactivation during the manufacturing process. This requirement may not apply to certain in vitro diagnostic medical devices if viral and other infectious agent activity is essential to the intended use of the product or if removal or inactivation would affect the effectiveness of that in vitro diagnostic medical device.		
	2.9.6		Medical devices in a special microbiological state must be designed, manufactured and packaged to ensure that the product retains its properties when placed on the market and during transportation and storage. according to the regulations of the medical equipment owner.		
	2.9.7		Sterile medical equipment must be designed, manufactured and packaged to ensure that the product remains sterile when placed on the market and during		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			transportation and storage according to the owner's regulations. own medical equipment.		
	2.9.8		Medical devices that are sterile or in a special microbiological state must be handled, manufactured, and, if necessary, sterilized using appropriate, validated methods.		
	2.9.9		Medical devices intended to be sterilized must be manufactured under suitably controlled (e.g. environmental) conditions.		
	2.9.10		Packaging for non-sterile medical equipment must be capable of keeping the products at the prescribed level of cleanliness. If the medical equipment needs to be sterilized before use, it must be minimized to maximum risk of microbial infection; Packaging must be appropriate, taking into account the sterilization method prescribed by the owner of the medical equipment. The medical device must be manufactured under appropriately controlled conditions.		
	2.9.11		The packaging and/or labeling of the medical device must be distinguishable from identical or similar products on the market under both sterile and non-sterile conditions.		
	2.10. Production and environmental characteristics				
	2.10.1		If the medical device is intended to be used in combination with other medical devices or devices, the		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			entire combination, including the connection system, must be safe and must not affect the effectiveness of the device. determined performance of the medical device or instrument used with it. Any restrictions on use in such combinations must be stated on the label and/or in the instructions for use.		
	2.10.2		Medical devices must be designed and manufactured to eliminate or minimize to a reasonable and appropriate level: • risk of injury, related to their physical features, including, as appropriate, mass/pressure ratio, dimensional and design characteristics; • risks related to environmental conditions or reasonably foreseeable external influences, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or pressure changes and acceleration; • risks associated with the use of medical devices in combination with materials, substances or gases to which they may come into contact under normal conditions of use; • risks due to accidental penetration of substances into medical devices; • risks due to incorrect identification of test samples;		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			• risks resulting from interactions with other medical devices commonly used in research or for certain treatments; • risks arising from failure to maintain or calibrate (as with implantable devices), from aging of the materials used or from the loss of accuracy of some measurement or control mechanism.		
	2.10.3		Medical equipment must be designed and manufactured to minimize the risk of fire or explosion during normal use or when an error occurs. Particular attention should be paid to medical devices whose intended use includes contact with or use in combination with flammable substances or substances that may cause fire.		
	2.10.4		Medical devices must be designed and manufactured to facilitate safe disposal of waste.		
	2.11 Medical equipment with diagnostic or measurement functions				
	2.11.1		Medical devices with measuring functions must be designed and manufactured to provide sufficient accuracy, precision and stability for their intended use. The limits of accuracy, precision, and stability must be determined by the medical device owner.		
	2.11.2		Medical devices must be designed and manufactured to provide sufficient accuracy, precision and stability for their intended use according to appropriate scientific		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			and technical methods. Specifically, the design must address sensitivity, specificity, precision, repeatability, reproducibility, control of known confounders, and limits of detection, if any.		
	2.11.3		Where the performance of medical devices depends on the use of calibration materials and/or control materials, traceability of the values assigned to those calibration materials and/or Controlled materials must be ensured through a quality management system.		
	2.11.4		Any measurement, monitoring or display scale must be designed in accordance with design science principles, taking into account the purpose of the medical device.		
	2.11.5		When values are expressed in numbers, if possible, standard units, generally accepted, and clearly understood by the user of the medical device should be used.		
	2.12 Radiation protection				
	2.12.1	generality			
	2.12.1.1		Medical devices must be designed, manufactured and packaged to minimize, as far as possible and appropriately, the exposure of the patient, user and other persons to any radiation emitted without adverse effects. intended use, and at the same time does not limit the product's scope of treatment and diagnosis.		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
	2.12.2	Intended radiation			
	2.12.2.1		In the case of a medical device designed to emit visible and/or invisible hazardous or potentially hazardous radiation for a specific medical purpose, the benefit is considered is greater than the inherent risks of such radiation, and the radiation can be controlled by the user, such medical devices should be designed and manufactured to ensure reproducibility of the parameters. associated variation within acceptable tolerances.		
	2.12.2.2		Where medical devices are designed to emit potentially dangerous radiation, visible and/or invisible, they must be equipped with visual displays and/or audible warnings. for that emission.		
	2.12.3		Unintentional radiation		
	2.12.3.1		Medical devices should be designed and manufactured so that exposure of patients, users and others to unintentionally stray or scattered emitted radiation is minimized to the extent possible and Fit.		
	2.12.4		User manual.		
	2.12.4.1		Instructions for use for medical devices that emit radiation must provide detailed information on the nature of the radiation emitted, means of protecting		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			patients and users, and how to prevent misuse. and how to eliminate risks during installation.		
	2.12.5		Ionizing radiation.		
	2.12.5.1		T he medical equipment emitting ionizing radiation must be designed and manufactured to ensure that the quantity, shape and energy distribution (or quality) of the emitted radiation can be varied and control where possible, taking into account the intended use.		
	2.12.5.2		Medical devices emitting ionizing radiation used in diagnostic radiology must be designed and manufactured to achieve appropriate image and/or output quality for the intended medical purpose while minimizing to maximize radiation exposure to patients and users.		
	2.12.5.3		Medical equipment emitting ionizing radiation used in therapeutic X-rays must be designed and manufactured to provide good monitoring and control of dose, beam type, energy and, where applicable, monitoring. , controlling the energy distribution of the radiation beam.		
	2.13 Requirements for medical devices connected to or equipped with a power source.				
	2.13.1		Medical devices incorporating programmable electronic systems, including software, must be designed to ensure repeatability, reliability and		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			operability of these systems as intended. use. In the event of a system single fault condition (SFC), appropriate means shall be used to eliminate or minimize the resulting risks to the extent possible and appropriate.		
	2.13.2		For medical devices combined with medical software or are medical software themselves, the software must be evaluated based on advanced scientific and technical foundations, taking into account the principles on development lifecycle, risk management, evaluation and verification.		
	2.13.3		Medical devices where patient safety depends on an internal power source shall be equipped with a means of determining the status of the power source.		
	2.13.4		Medical equipment where patient safety depends on an external power supply must be equipped with an alarm system to signal a power outage.		
	2.13.5		Medical devices intended to monitor one or more patient clinical parameters must be equipped with appropriate alarm systems to warn the user of situations that could lead to death or deterioration. serious health condition of the patient.		
	2.13.6		Medical devices should be designed and manufactured to minimize, as far as is practicable and appropriate, the risks of generating electromagnetic interference that		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			could impair the performance of the medical device itself or other devices. Other medical equipment placed near that equipment.		
	2.13.7		Medical devices must be designed and manufactured to ensure immunity to electromagnetic interference so that they can operate as intended.		
	2.13.8	Protect against electrical risks			
	2.13.8.1		Medical equipment must be designed and manufactured so that the patient or anyone else is best protected against the risk of electric shock when the equipment is installed and maintained according to the owner's instructions. possession of the product, in normal operating condition and in single fault condition (SFC).		
	2.14 Protect against mechanical risks				
	2.14.1		Medical devices must be designed and manufactured to protect patients and users against mechanical risks associated with the use of the device.		
	2.14.2		Medical devices must be designed and manufactured to minimize the risks arising from vibrations generated by the medical device, taking into account technical advances and available facilities. to limit vibrations,		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			especially at the source, unless vibrations are part of the operation of the equipment.		
	2.14.3		Medical equipment must be designed and manufactured to minimize the risks arising from noise emissions, taking into account technical advances and available means to limit noise, especially at the source, unless the noise emitted is part of the operation of the device.		
	2.14.4		Terminals and connections to electrical, gas or hydraulic and pneumatic power supplies controlled by the user shall be designed and constructed to minimize any possible risks.		
	2.14.5		Open parts on the equipment (not including parts or areas intended to provide heat or reach a certain temperature) and their surroundings must not be allowed to rise to a temperature that is hazardous under operating conditions. conditions of normal use.		
	2.15 Protect against risks posed to the patient by the administration of energy or substances				
	2.15.1		Medical devices used to deliver energy or substances to patients shall be designed and installed so that the delivery rate and/or delivery quantity can be established and maintained accurately and sufficiently to ensure safety for patients and users.		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
	2.15.2		Medical equipment must be equipped with means to prevent and/or detect potentially dangerous rates and/or shortages of supply. Medical devices shall be equipped with suitable means to prevent, as far as possible, the sudden release of energy or substances at dangerous levels.		
	2.15.3		Control functions and indicator displays must be clearly identified on medical equipment. Where a medical device has instructions necessary for its operation or displays operating or adjustment parameters by visual means, such information must be understandable to the user, and to the patient if needed.		
	2.16 Actively implanted medical devices				
	2.16.1		Actively implanted medical devices must have clear information to identify: • Types of medical equipment; • Owners of medical equipment; and • Year of manufacture of medical equipment.		
	2.16.2		That information must be readable without the need for surgery by the implant recipient.		
	2.17 Protect against risks to patients with medical equipment that patients test or use themselves				
	2.17.1		These medical devices should be designed and manufactured so that they perform in a manner suitable for their intended purpose, taking into account the		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			existing skills and facilities of the user and the effects of variations that may occur. can be reasonably predicted in terms of the user's technology and environment. The information and instructions provided by the medical device owner must be easy for the user to understand and apply.		
	2.17.2		These medical devices must be designed and manufactured to minimize the risk of errors occurring in the use of the medical device and, where appropriate, in the handling of test specimens, and also in the interpretation of the medical device. solve the results.		
	2.17.3		Where applicable, these medical devices must have a process by which the user can verify, at the time of use, that the product will perform as intended by the device owner. medical.		
	2.18 Information provided by medical equipment owners				
	2.18.1		Users must be provided with the necessary information to identify the medical equipment, determine the owner of the medical equipment, and explain information to use the medical equipment safely. ..		
	2.19 Clinical research				
	2.19.1		Clinical studies on human subjects must be conducted in the spirit of the Declaration of Helsinki. This requirement covers all steps in clinical research from		

No		TITLE	REQUEST CONTENT	INSTRUCT EVALUATE	DOCUMENT PROVE
			initial consideration of the need and justification of the study to publication of the results.		

APPENDIX II

REPORT ON EVALUATION OF GENERAL TECHNICAL DOCUMENTS ON MEDICAL EQUIPMENT ACCORDING TO ASEAN REGULATIONS (Common Submission Dosier Template -CSDT) FOR IN VITRO DIAGNOSTICS MEDICAL EQUIPMENT

(Issued together with Decision No. /QD-BYT dated / /2023 of the Ministry of Health)

No	CONTENT RATED		RESULT		
			Fit	Not suitable	Do not apply
first	**General summary document on medical equipment**				
	1.1	Brief, general description of medical equipment			
	1.2	History of circulation on the market			
	1.3	Intended use and indications use			
	1.4	Licensing information for circulation in different countries			
	1.5	Important information regarding the safety and effectiveness of medical devices international			
2	**Table complies with the Essential Principles**				
3	**Document describing medical equipment**				
	3.1	Describe and present the characteristics of medical equipment			
	3.2	Uses			
	3.3	Indications			
	3.4	User manual			

No	CONTENT RATED		RESULT		
			Fit	Not suitable	Do not apply
	3.5	Contraindications determined			
	3.6	Scene newspaper			
	3.7	Careful			
	3.8	Potential adverse effects hidden			
	3.9	Alternative treatments			
	3.10	Materials			
	3.11	Relevant technical specifications other			
	3.12	The information other			
4	**Summary document on design verification and validation**				
	4.1	Preclinical studies ready			
	4.1.1	Software verification and validation studies			
	4.1.2	Medical equipment containing biological materials learn			
	4.2	Preclinical studies of reagents, calibrators, and *in vitro control materials*			
	4.2.1	Stool performance accumulation			
	4.2.2	Stability determined			
	4.3	Forestry evidence ready			
	4.3.1	Data from references available available			
	4.3.2	Data from forestry experience ready			
	4.3.3	Data from forestry research ready			
5	**Label of medical equipment**				
	5.1	Sample labels on medical equipment and packaging packaging			
	5.2	Instructions for using the language Vietnamese			
6	**Risk analysis**				
		Results of risk analysis ro			

No	CONTENT RATED		RESULT		
			Fit	Not suitable	Do not apply
7	**Production information**				
	7.1	Information about the property export			
	7.2	Production process export			