MINISTRY OF HEALTH

THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No. 2426/QD-BYT

Hanoi, May 15, 2021

DECISION

ON PROMULGATION OF GUIDANCE ON THE PREPARATION OF ASEAN COMMON SUBMISSION DOSSIER FOR MEDICAL DEVICES

MINISTER OF HEALTH

Pursuant to the Government's Decree No. 75/2017/ND-CP dated June 20, 2017 defining the functions, tasks, entitlements and organizational structure of the Ministry of Health;

Pursuant to the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on management of medical devices;

Pursuant to the Government's Decree No. 169/2018/ND-CP dated December 31, 2018 on amendments to the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on management of medical devices;

Pursuant to the Government's Decree No. 03/2020/ND-CP dated January 1, 2020 on amendments to the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on management of medical devices, amended by the Government's Decree No. 169/2018/ND-CP dated December 31, 2018;

At the request of Director of Department of Medical Devices and Works.

HEREBY DECIDES:

Article 1. Scope

Issue together with this Decision the ASEAN Common Submission Dossier Template (CSDT) for medical devices, applied to applications for registration of medical devices of class B, C, D.

Article 2. Entry in force

This Decision comes into force as of its date of promulgation.

Article 3. Implementation

The Chief of the Ministry Office, the Ministerial Chief Inspector, Directors, General Directors affiliated to the Ministry of Health, Directors of the Departments of Health of provinces or central-affiliated cities and relevant entities shall implement this Decision.

Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Health for consideration./.

PP. MINISTER
DEPUTY MINISTER

Truong Quoc Cuong

ASEAN COMMON SUBMISSION DOSSIER TEMPLATE FOR MEDICAL DEVICES

(Issued together with Decision No. 2426/QD-BYT dated May 15, 2021 of the Ministry of Health)

ASEAN COMMON SUBMISSION DOSSIER FOR MEDICAL DEVICES

Name of registrant of medical devices (name, address)

The registrant declares that all the information given above is true and correct to the best of our knowledge and belief; if not, we are aware that we may be held liable for it.

1. Executive summary

1.1. Overview about the medical device

Overview about the medical device: introductory descriptive information on the medical device, the intended purposes and indications for use of the medical device, any novel features (e.g. nanotechnology, artificial intelligence (AI) technology, etc.).

1.2. Commercial marketing history

A list of countries where the medical device is currently marketed is to be provided. The date and country of first introduction globally is also to be provided.

1.3. Intended uses and indications for use

Intended purposes and indications for use of the medical device in labeling or manual.

1.4. Registration status in countries

Registration status in countries: EU member states, Japan, Canada, Australia (TGA), USA (FDA), England, Switzerland, including registration status (i.e. approval, pending approval, rejected, non-registered, etc.), intended use and indications for use, first registration date1.

This information is to be provided in a tabular format as given below:

No.	Country or Reference agency	Intended uses/indications for use	Registration status	Date
1				
2				
3				

copies (or links) of certificates or approval letters from each reference agency (if any).

1.5. Important safety/performance related information

summary of reportable adverse events and field safety corrective actions (FSCAs) for the medical device since its first introduction on the global market or in the last 5 years

The summary of reported adverse events at least contains description of the adverse events, number and frequency of occurrence of adverse events (number of reports/total units sold). This is to be provided in a tabular format as given below:

No.	Description of adverse event	Number or frequency of occurrence
1		
2		
3		

For reported field safety corrective actions (FSCAs), at least containing: date of FSCA, summary of event, names of countries or territories where FSCA was conducted. This is to be provided in a tabular format as given below:

No.	Date	Summary of event	Name of country/territory
1			
2			

3			

If there have been no adverse events or FSCAs since first introduction on the global market or within the last 5 years, an attestation from the product owner that this is the case, is required.

If the medical device contains one or more of the following, a description of the following must be provided:

● animal or human cells, tissues and/or derivatives thereof, rendered non-viable (e.g. porcine heart valves, catgut sutures, etc);

● cells, tissues and/or derivatives of microbial or recombinant origin (e.g. dermal fillers based on hyaluronic acid derived from bacterial fermentation processes)

● irradiating components, ionising (e.g. x-ray) or non-ionising (e.g. lasers, ultrasound, etc).

2. Essential Principles Conformity Checklist (in Vietnamese or in English)

Provide the Essential Principles Conformity Checklist demonstrating the safety and efficacy of the medical devices issued by the owner as described in the Annex hereto appended to demonstrate conformity to the Essential Principles.

If the medical device is registered in EU member states, a Essential Principles Conformity Checklist under EU legislation may be provided.

3. Medical device description

3.1. Medical device description and features

A detailed description of the medical device attributes is necessary to explain how the medical device function, the basic scientific concepts that form the fundamentals for the medical device. Describe the component materials and accessories used in its principles of operation as well as packaging. A complete description of each functional component, material or ingredient of the medical device should be provided, with labeled pictorial representation of the medical device in the form of diagrams, photographs or drawings, as appropriate.

3.2. Intended purpose

This means the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device.

3.3. Indications

This is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended.

3.4. Instructions for use

These are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device.

3.5. Contraindications

Conditions under which the medical device should not be used for the safety of the patient, e.g. disease history, physiology characteristics of the patient, etc. on the labeling or manual of the medical device.

This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit.

3.6. Warnings

This is the specific hazard alert information that a user needs to know before using the medical device.

3.7. Precautions

This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the User should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects.

3.8. Potential adverse effects

These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions.

3.9. Alternative therapy

This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended.

3.10. Materials (in Vietnamese or in English)

A description of the materials of the medical device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles.

For medical devices other than IVD medical device:

- List of materials of the medical device making either direct (e.g. with the mucous membrane) or indirect contact (e.g. during extracorporeal circulation of body fluids) with a human body, and chemical, biological and physical characterization of the materials of the device.

- For medical devices intended to emit ionising radiation, information on radiation source (e.g. radioisotopes) and the material used for shielding of unintended, stray or scattered radiation from patients, users shall be provided.

- Where there are specific concerns related to the safety of materials used in the medical device e.g. impurities, residue levels and exposure to plasticizers such as Bis(2-ethylhexyl) phthalate (DEHP), additional information to address these safety concerns shall be provided. This could include conformity to relevant material standards, Certificate of Analysis, or a risk assessment on the safety of the materials used. Depending on the risk of the exposure of these materials to the patient and/or user, additional mitigation measures such as informing users of the presence of these materials via the device labelling, may be required.

For IVD reagents, calibrators, controls:

- A list of all materials used to manufacture the product shall be provided, including: name of material, role in the finished product.

- All components, biological characteristics and source of the materials used in the reactions for testing shall be characterised: including antibodies, antigens, enzymes, conjugates, PCR primers, probes, calibrators, controls, etc.

- If the medical device contains controlled substances (drugs or irradiating components, nonionising or ionising), information on their ingredients, content, roles, e.g. Buprenorphine in drug assay kit, odide-131 in the Radioimmunoassay kit, radio-labeled Phosphorus-32 DNA probes in Southern blots, etc. must be provided.

- For IVD medical devices of class C, D: information on standards or testing of materials used in reaction (except stabilizer) shall be provided. Information is presented for each active ingredient (antigen, antibody, conjugate, etc.).

3.11. Other Relevant Specifications

The functional characteristics and technical performance specifications for the medical device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and

packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.

3.12. Other Descriptive Information

Other important descriptive characteristics not detailed above, to the extent necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished medical device, etc.).

Note: *The above information will typically be contained in already existing instructions for use.*

4. Summary of Design Verification and Validation Documents (in Vietnamese or in English)

This section should summarise or reference or contain design verification and design validation data to the extent appropriate to the complexity and risk class of the medical device.

Such documentation should typically include:

● declarations/certificates of conformity to the "recognized" standards listed as applied by the product owner; and/or

● summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.

For example: The completed Table of Conformity to the Essential Principles that a recognized test Standard was used as part of the method to demonstrate conformity to one Essential Principle. The CSDT would then include a declaration of conformity to the Standard, or other Certification permitted by the relevant Regulatory Authority, and a summary of the test data, if the Standard does not include performance requirements.

The data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the medical device:

- a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles;

- engineering tests;

- laboratory tests;

- biocompatibility tests;

- animal tests;

- simulated use;

- software validation.

4.1. Pre-clinical Studies

Details must be provided on all biocompatibility tests conducted on materials used in a medical device. All materials that are significantly different must be characterised. Information describing the tests, the results and the analyses of data must be presented.

Complete pre-clinical physical test data must be provided, as appropriate. The report must include the objectives, methodology, results and product owner's conclusions of all physical studies of the medical device and its components. Physical testing must be conducted to predict the adequacy of medical device response to physiological stresses, undesirable conditions and forces, long-term use and all known and possible failure modes.

Pre-clinical animal studies used to support the probability of effectiveness in humans must be reported. These studies must be undertaken using good laboratory practices. The objectives, methodology, results, analysis and product owner's conclusions must be presented. The study conclusion should address the medical device's interactions with animal fluids and tissues and the functional effectiveness of the medical device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

Proof of electrical safety and electromagnetic compatibility must be provided. For example, if the owner claims 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 equipment meets these standards.

For medical devices provided sterile, sterilization validation reports shall be provided. if the sterilant is toxic or produces toxic residuals (e.g. ethylene oxide residues), test data and methods that demonstrate that post-process sterilant and/or residuals are within acceptable limits must be presented.

For connected medical devices (e.g. wireless enabled, internet-connected and network-connected devices), information to support the cybersecurity of these devices shall be provided. This will include, but is not limited to: Cybersecurity vulnerabilities and risk management approach for the device, cybersecurity controls measures, on-going plans for surveillance, timely detection and management of the cybersecurity related threats during the useful life of the device. A declaration of manufacturer or product owner for wireless enabled, internet-connected and network-connected devices to ensure cyber security.

4.1.1. Software Verification and Validation Studies (if applicable)

The correctness of a software product is another critical product characteristic that cannot be fully verifies in a finished product. The product owner must provide evidence that validates the software design and development process. This information should include the results of all verification, validation and testing performed in-house and in a user's environment prior to final

release, for all of the different hardware configurations identified in the labelling, as well as representative data generated from both testing environments.

4.1.2. Medical Devices Containing Biological Material

Results of studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents must be provided. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimise biological risks.

4.2. Pre-clinical Studies for IVD reagents, calibrators, controls

4.2.1. Analytical performance

Studies to determine analytical performance of the medical device shall be provided, including: analytical sensitivity, analytical specificity, limit of detection (LOD), limit of quantitation (LOQ), linearity, range, accuracy, repeatability, interfering substances, robustness, etc. Performance criteria will depend on each medical device.

Information on samples used for evaluation (negative controls, positive controls, baseline standards, calibrator panels, reagents, ...).

Study reports should include objectives, methods, results, and conclusions of the study. The results and conclusions should clearly demonstrate that the product has the characteristics suitable for its intended use.

4.2.2. Stability

Provides stability study reports, including real-time stability and accelerated aging stability (where applicable). In the case of not doing a real-time stability study but only under accelerated aging conditions, a full and reasonable explanation should be given.

In-use stability study reports for products that are used repeatedly after opening shall be provided.

Transport stability studies, performed under real or simulated conditions shall be provided.

Stability study reports should include objectives, methods, results, and conclusions of the study.

4.3. Clinical evidence

A clinical evaluation report of medical device should be provided. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar medical devices, or by clinical investigation. Clinical investigation is

most likely to be needed for higher risk class medical devices, or for medical devices where there is little or no clinical experience.

The clinical evaluation report should include the purpose and context of the clinical evaluation, clinical data input, evaluation and data analysis, and conclusions about the safety and efficacy of the medical device.

The clinical evaluation report should contain all the necessary information as an independent document for review by regulatory authorities. The clinical evaluation report should summarize:

- The technology that the medical device uses, the indications for use, the safety and clinical efficacy claims, if any.

- The nature and scope and scale of the clinical data to be evaluated.

- Clinical data, recognized standards that demonstrate the safety and effectiveness of medical device.

4.3.1. Use of Existing Bibliography

Copies are required of all literature studies, or existing bibliography, that the product owner is using to support safety and effectiveness.

Clinical evidence of effectiveness may comprise medical device-related investigations conducted in Vietnam or other countries. It may be derived from relevant publications in a peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

4.3.2. Data from clinical experience

Clinical experience is clinical data obtained from clinical use of the product, not clinical investigation. Clinical experience can be with the product itself or with a similar product.

Clinical experience can be obtained from the following data:

- Post-marketing surveillance reports from product owners, regulatory authorities, cohort studies (may contain unpublished long-term data on safety and efficacy).

- Data on adverse events that have occurred, either from product owners or from regulatory authorities.

- Data from patients using the medical device in the pre-marketing aid program.

- Information on clinically relevant corrective actions such as recalls, notifications, hazard warnings.

4.3.3. Data from clinical investigation

A clinical investigation is a systematic study performed on or in the human body for the purpose of evaluating the safety and effectiveness of a medical device.

Clinical investigation may be performed by the medical device owner or by a third party acting on behalf of the owner. Clinical investigation should be designed, conducted 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 local regulations.

Clinical investigation must conform to the ethical standards set forth in the Declaration of Helsinki.

For IVD medical devices: A clinical investigation is a study conducted to establish or confirm the clinical performance of an IVD medical device. The manufacturer must have clinical evidence to support its clinical claims, including: diagnostic sensitivity (clinical sensitivity) and diagnostic specificity (clinical specificity).

5. Medical Device Labelling

This is the descriptive and informational product literature that accompanies the medical device, such as: any physician's manuals, pack labeling. This section should summarise or reference or contain the following labelling data to the extent appropriate to the complexity and risk class of the medical device, which is generally considered as "labelling":

● Labels on the medical device and its packaging;

● Instructions for use;

● Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable).

5.1. Samples of labels on the medical device and its packaging

This is the printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of applicable legislation.

As for imported medical devices, the labeling must include primary and secondary labels in Vietnamese.

The label sample must include all products in the application for registration. In case the application is submitted under the medical device family, a representative sample of the label may be submitted, but the differences between the label samples of those products must be noted.

5.2. Instructions for use in Vietnamese

Includes instructions for the physician or end user to safely and correctly use the medical device for its intended use. This should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the medical device.

For IVD medical devices, the instructions for use should contain the following particulars:

- Type and code (if any) of IVD medical device.

- The intended purpose:

● what is detected or measured;

● its function (e.g. screening, monitoring, diagnostic, aid to diagnostic, prognosis, prediction);

● Whether the same automatical medical device (testing machine) is used;

● Whether the test is quantitative or semi-quantitative or qualitative or nominal, etc;

● Type of specimen to be used e.g. serum, plasma, whole blood, tissue biopsy, urine);

● Testing population.

- An indication that it is for in vitro diagnostic use.

- The intended user, (e.g. lay person, health worker, ...).

- Test principle.

- A description of the reagent, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only).

- A list of materials provided and a list of special materials required but not provided.

- For IVD medical devices intended for use together with other medical devices and/or intended for use together with devices other than medical devices.

● Information to identify these devices, including important performance characteristics.

● information on any known restrictions to combinations of medical devices and equipment.

- An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions that apply.

- In use stability which may include, the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant. The instructions for use must specify the shelf life of the product.

- If the IVD medical device is supplied as sterile, it should be clearly stated that the medical device is sterile, the method of sterilization, and instructions for handling in the event of the sterile packaging being damaged before use.

- Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD medical device. This information should cover, where appropriate:

● warnings, precautions and/or measures to be taken in the event of malfunction of the IVD medical device or its degradation as suggested by changes in its appearance that may affect performance;

● warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

● warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);

● precautions related to materials incorporated into the IVD medical device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction.

- Conditions for collection, handling, and preparation of the specimen.

- Details of any preparatory treatment or handling of the IVD medical device before it is ready for use (e.g. reconstitution, calibration, etc.).

- The information needed to verify whether the IVD medical device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

● details of the nature, and frequency, of preventative and regular maintenance (including cleaning and disinfection);

● identification of any consumable components and how to replace them;

● information on any necessary calibration to ensure that the IVD medical device operates properly and safely during its intended life span;

● methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing IVD medical devices, e.g. contaminated surfaces.

- Where relevant, recommendations for quality control procedures.

- The metrological traceability of values assigned to calibrators and trueness control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.

- Assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing should be considered.

- Analytical performance characteristics, such as sensitivity, specificity, and accuracy (which is a combination of trueness and precision).

- Where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity.

- Where relevant, reference intervals.

- Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen/sample) that may affect the performance of the assay.

- Warnings or precautions to be taken related to the disposal of the device, its accessories, and the consumables used with it, if any. This information should cover, where appropriate:

● infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin);

● environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);

● x physical hazards (e.g. explosion).

- For IVD medical devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.

- Where relevant, a bibliography.

- The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance.

- Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

6. Risk Analysis (in Vietnamese or in English)

This section should summarise or reference or contain the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the medical device.

6.1. Results of Risk Analysis

A list of possible hazards for these medical devices must be prepared. Indirect risks from medical devices may result from medical device-associated hazards, such as moving parts, which lead to sustained injury, or from user-related hazards, such as ionizing radiation from an X-ray machine. The evaluation of these risks against the claimed benefits of the medical device and the method(s) used to reduce risk to acceptable levels must be described. The individual or organization that carries out the risk analysis must be clearly identified. The technique used to analyse risk must be specified, to ensure that it is appropriate for the medical device and the risk involved.

7. Manufacturing Information (in Vietnamese or in English)

This section should summarise or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the medical device.

7.1. Manufacturer Information

Names, addresses of all manufacturers involved in the manufacturing and steritise process (including those being a third party).

7.2. Manufacturing Process

Information on the manufacturing process should be provided in sufficient detail to allow a general understanding of the manufacturing processes. Detailed proprietary information on the manufacturing process is not required. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, packaging of the finished medical device.

If the manufacturing process is carried out at multiple sites, the manufacturing activities carried out at each site should be clearly identified.

Legal representative
Signature (Full name, position)
Certified by seal or digital signature

ANNEX

ESSENTIAL PRINCIPLES CONFORMITY CHECKLIST
(in Vietnamese or in English)

Product Owner Name:

Product Name:

Product code (if any):

Essential Principles	**Applicable to the medical device? (Yes/No)**	**Method of conformity**	**Identity of Specific Documents**
General requirements	Insert "Yes" if the essential principle is applicable to the medical device; Insert "No" if the essential principle is not applicable to the medical device. If the answer is 'No' this should be briefly explained. For example: For a medical device that does not	(state the title and reference of the standard(s), industry or in-house test method(s) used to demonstrate compliance. For example: - ISO 13485 - ISO 14971 - EN ISO 18113-1 - IEC 61326-1 - IEC 61326-	(state the technical documentation that demonstrates compliance to the EP, for example: the certificates, test reports, study reports, etc.)

		incorporate biological substances, the answer to this column would be “No - The medical device does not incorporate biological substances.”	2-6 - IEC 60601-1)		
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.				
2.	The solutions adopted by the product owner for the design and manufacture of the medical 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. The product owner should apply the following principles in the priority order listed: ● identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, ● eliminate or reduce risks as far as reasonably practicable through inherently safe design and manufacture,				

● reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,

● inform users of any residual risks.

3. Devices should achieve the performance intended by the product owner and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device.

4. The characteristics and performances referred to in Clauses 1, 2 and 3 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 lifetime of the medical device, as indicated by the product owner, when the medical device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the product owner's instructions.

5. The medical devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions taking account of the instructions and information provided by the product owner.

6. The benefits must be determined to outweigh any undesirable side effects for the performances intended.

7. Every medical device requires clinical evidence, appropriate for the use and classification of the medical device, demonstrating that the medical device complies with the applicable provisions of the essential principles. A clinical evaluation should be conducted.

Design and Manufacturing Requirements

8. Chemical, physical and biological

	characterisation				
8.1	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 6 of the 'General Requirements'. Particular attention should be paid to: ● the choice of materials used, particularly as regards toxicity, flammability, ● physical and chemical properties of materials used, ● the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the medical device, ● the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.				
8.2	The medical devices should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the medical devices. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure during the transport, storage and use of the medical devices.				
8.3	The medical devices shall 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 normal use or during routine procedures; if the medical devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these medicinal products and that the performance of the medicinal product is maintained in accordance with the intended				

	purpose of the medicinal product.				
8.4	Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in the relevant legislation that applies and which is liable to act upon the body with action ancillary to that of the medical device, the safety, quality and performance of the medical device as a whole shall be verified, as well as the safety, quality and efficacy of the incorporated substance in relation to the intended purpose of the medical device. For the purposes of this paragraph, “medicinal product” includes any stable derivative of human blood or human plasma.				
8.5	The medical 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 medical device.				
8.6	Medical devices 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 or egress of substances into or from the medical device taking into account the medical device and the nature of the environment in which it is intended to be used.				
9.	Infection and microbial contamination				
9.1	The medical devices and 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 any person. The design should: ● allow easy handling, and, where necessary: ● reduce as far as reasonably practicable and appropriate any microbial leakage from the medical device and/or microbial				

	exposure during use; ● prevent microbial contamination of the medical device, or specimen where applicable, by the patient, user or other person.				
9.2	Where a medical device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.				
9.3	Products incorporating non-viable tissues, cells and substances of animal origin falling within the definition of a medical device, shall originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended purpose of the tissues. The product owner is required to retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the Performance of the IVD medical device.				
9.4	For products incorporating cells, tissues and				

	derivatives of microbial or recombinant origin falling within the definition of a medical device, the selection of sources/donors, the processing, preservation, testing and handling of cells, tissues and derivatives of such origin shall be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the Performance of the IVD medical device.				
9.5	For products incorporating non-viable human tissues, cells and substances falling within the definition of an IVD medical device, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical device if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.				
9.6	Medical devices labeled as having a special microbiological state shall 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.				

9.7	Medical devices delivered in a sterile state shall be designed, manufactured and packed to ensure that they remain sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the product owner.				
9.8	Medical devices labeled either as sterile or as having a special microbiological State shall have been processed, manufactured and, if applicable, sterilised by appropriate, validated methods.				
9.9	Medical devices intended to be sterilised shall be manufactured in appropriately controlled (e.g. environmental) conditions.				
9.10	Packaging systems for non-sterile medical devices shall keep the product at the level of cleanliness stipulated and, if the medical devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the product owner. The medical device shall be produced in appropriately controlled conditions.				
9.11	The packaging and/or label of the medical device shall distinguish between identical or similar Products placed on the market in both sterile and non-sterile condition.				
10.	Manufacturing and environmental properties				
10.1	lf the medical device is intended for use in combination with other medical devices or equipment, the whole combination, including the connection System shall be safe and shall not impair the specified performance of the medical devices, or equipment with which it is used. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.				
10.2	Medical devices shall be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and				

	appropriate: ● the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; ● 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; ● the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; ● the risks of accidental penetration of substances into the medical device; ● the risk of incorrect identification of specimens; ● the risks of reciprocal interference with other medical devices normally used in the investigations or for the treatment given; ● risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.				
10.3	Medical devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to medical devices whose intended purpose includes exposure to or use in association with flammable substances or substances which could cause combustion.				
10.4	Medical devices must be designed and manufactured in such a way as to facilitate				

	the safe disposal of any waste substances.				
11.	Medical devices with a diagnostic or measuring function				
11.1	Medical devices with a measuring function shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose. The limits of accuracy, precision and stability shall be indicated by the product owner.				
11.2	Medical devices shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. In particular the design shall address the sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.				
11.3	Where the performance of medical devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials shall be assured through a quality management system.				
11.4	Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking into account of the intended purpose of the medical device.				
11.5	Wherever possible values expressed numerically shall be in commonly accepted, standardised units, and understood by the users of the medical device.				
12.	Protection against radiation				
12.1	General				
12.1.1	Medical devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be				

	reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.				
12.2	Intended radiation				
12.2.1	Where medical devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it shall be possible for the User to control the emissions. Such medical devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.				
12.2.2	Where medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall be fitted, where practicable, with visual displays and/or audible warnings of such emissions.				
12.3	Unintended radiation				
12.3.1	Medical devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.				
12.4	Instructions for use.				
12.4.1	The operating instructions for medical devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.				
12.5	lonising radiation.				
12.5.1	Medical devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or				

	quality) of radiation emitted can be varied and controlled taking into account the intended purpose.				
12.5.2	Medical devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.				
12.5.3	Medical devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.				
13.	Requirements for medical devices connected to or equipped with an energy source.				
13.1	Medical devices incorporating electronic programmable Systems, including software, shall be designed to ensure the repeatability, reliability and performance of these Systems according to the intended purpose. In the event of a single fault condition in the System, appropriate means shall be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.				
13.2	For medical devices which incorporate software or which are medical software in themselves, the software shall be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.				
13.3	Medical devices where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply.				
13.4	Medical devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.				

13.5	Medical devices intended to monitor one or more clinical parameters of a patient shall 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.				
13.6	Medical devices shall be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other medical devices or equipment in the vicinity Where the medical device is located.				
13.7	Medical devices shall 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.				
13.8	Protection against electrical risks				
13.8.1	A medical device shall be designed and manufactured in a way that ensures that, as far as possible, a patient, or any other person is protected against the risk of accidental electric shock when it is installed and maintained as indicated by the product owner, is being used under normal conditions of use and in the event of a single fault condition (SFC).				
14.	Protection against mechanical risks				
14.1	Medical devices shall be designed and manufactured in such a way as to protect the patient and User against mechanical risks associated with the use of the medical device.				
14.2	Medical devices shall be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the medical devices, 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.				
14.3	Medical devices shall be designed and manufactured in such a way as to reduce to the lowest practicable level 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.				
14.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle shall be designed and constructed in such a way as to minimise all possible risks.				
14.5	Accessible parts of the medical devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal use.				
15.	Protection against the risks posed to the patient by supplied energy or substances				
15.1	Medical devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the delivered rate and/or amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.				
15.2	Medical devices shall be fitted with the means of preventing and/or indicating any inadequacies in the delivered rate and/or amount which could pose a danger. Medical devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.				
15.3	The function of the controls and indicators shall be clearly specified on the medical devices. Where a medical device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the				

	user and, as appropriate, the patient.				
16.	Active implantable medical devices				
16.1	An active implantable medical device shall express clear information that can be used to identify: ● the type of medical device; ● the product owner of the medical device; and ● the year of manufacture of the medical device.				
16.2	The identifier shall be readable without the need for surgery to the person in whom the medical device is implanted.				
17.	Protection against the risks posed to the patient for medical devices for self-testing or self-administration				
17.1	Such medical devices shall 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 users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the product owner shall be easy for the user to understand and apply.				
17.2	Such medical devices shall be designed and manufactured in such a way as to reduce as far as practicable the risk of error in the handling of the medical device and, if applicable, the specimen, and also in the interpretation of results.				
17.3	Such medical devices shall, where reasonably possible, include a procedure by which the user can verify that, at the time of use, the medical device will perform as intended by the product owner.				
18.	Information supplied by the product owner				
18.1	The following information shall be provided				

	with a medical device, having regard to the training and knowledge of potential users of the medical device, etc.			
19.	Clinical Investigation			
19.1	Clinical investigations on human subjects shall be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.			

1 For products registered in EU member states, if there have been no information about the first registration date, state the latest registration date.