(EXAMPLE)

Essential Principles of Safety and Performance of Medical Devices

EP Checklist control number:
Product Owner Name:
Product Name:

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
General Requirements 1. Medical devices shall 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 the use of the medical device for its intended purpose constitute acceptable risks when weighed against the intended 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 shall conform to safety principles, taking account of the generally acknowledged state of the art. In selecting an appropriate solution for the design and manufacture of a medical device so as to minimise any risks associated with the use of the medical device, the product owner shall apply the following principles:			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
☐ identify any hazard and associated risk arising from the use of the medical device for its intended purpose, and any foreseeable misuse of the medical device, ☐ eliminate or reduce risks as far as reasonably practicable through inherently safe design and manufacture, ☐ if appropriate, ensure that adequate protective measures are taken, including alarms if necessary, in relation to any risk that cannot be eliminated, and ☐ inform users of any residual risks. safe design and manufacture, ☐ if appropriate, ensure that adequate protective measures are taken, including alarms if necessary, in relation to any risk that cannot be eliminated, and ☐ inform users of any residual risks.			
3. Medical devices shall 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 shall 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 and calibrated, if appropriate, in accordance with the product owner's instructions.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
5. The medical devices shall be designed, manufactured and packed in such a way that their characteristics and performances, when it is being used for its intended purpose, will not be adversely affected during its transport and storage, if the transport and storage is carried out in accordance with 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. Medical devices shall require 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 shall be conducted.			
Design and Manufacturing Requirements **8. Chemical, physical and biological properties**			
8.1 The medical devices shall be designed and manufactured in such a way as to ensure the characteristics and performance requirements referred to in Clauses 1 to 6 of the 'General Requirements' are met. Particular attention shall be paid to: ☐ the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, ☐ the chemical and physical properties of the material used,			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
☐ 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 shall reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
8.2 The medical devices shall 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 and to patients, taking account of the intended purpose of the product. In minimising risks, particular consideration shall be given to the duration and frequency of any tissue exposure associated with the transport, storage or use of the medical device.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
8.5 The medical devices shall 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 shall 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 nature of the environment in which the medical device is intended to be used.			
9. Infection and microbial contamination			
9.1 The medical devices and manufacturing processes shall 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 persons. The design shall: ☐ 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, ☐ if appropriate, minimises contamination of the medical device, or specimen where applicable, by the patient, user or other person, or contamination of the patient by the medical device, during its use.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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 labelled 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.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
9.8 Medical devices labelled 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			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
10.1 If 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;			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
☐ 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 of the medical device. The limits of accuracy, precision and stability shall be indicated by the product owner.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
12.1 General 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			

(EXAMPLE)

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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 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 Ionising 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			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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 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.			
14. Protection against mechanical risks			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
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 incorporate, display, emit or exhibit a code or unique characteristic that can be used to identify:-			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
☐ 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.			

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
18. Information supplied by the product owner The following information shall be provided with a medical device, having regard to the training and knowledge of potential users of the medical device: • information identifying the medical device; • information identifying the product owner of the medical device; • information explaining how to use the medical device safely			
19. Clinical Investigation 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. 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.			

EP Checklist prepared by (name/signature/date):
EP Checklist approved by (name/signature/date):