Essential Principles in Japan

Essential Principles (EPs) from GHTF document※1 was introduced in Japanese regulation and all devices shall be in conformity with the EPs. EPs in Japan was revised in 2014 because GHTF published the revised GHTF document※2 . Furthermore, the cybersecurity requirement was introduced in 2023 to align with IMDRF documents※4. Conformance to IMDRF GRRP WG/N47 can be supported by conforming to Japanese Essential Principles※3 and relevant notifications etc. ※1：GHTF/SG1/N41R9:2005, ※2：GHTF/SG1/N68:2012, ※3：Add to the requirement of the public notice of e-package inserts（2021）, ※4:IMDRF GRRP WG/N47:2018 and IMDRF CYBER WG/N60:2020

Pharmaceuticals and Medical Device Agency
Office of Standards and Compliance for Medical Devices

A comparative table of the prior and revised Essential Principles in Japan

Essential Principles in Japan：2014 （It's based on GHTF/SG1/N68:2012）	Essential Principles in Japan：2005 （It's based on GHTF/SG1/N41R9:2005）
Chapter 1　General Requirements	Chapter 1　General Requirements
(Design)	(Design)
Article 1　Medical devices (excluding devices to be exclusively used for animals; the same shall apply hereinafter) 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, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users (limited to persons having the required technical knowledge when it is needed for the correct use of the medical device; the same shall apply hereinafter) or, where applicable, other persons (limited to those persons whose safety and health may be affected when using the medical device; the same shall apply in Article 4), 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.	Article 1　Medical devices (excluding devices to be exclusively used for animals; the same shall apply hereinafter) 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, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (limited to cases where the safety and health of other persons are affected by using the medical devices), 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.
(Risk management)	(Risk management)
Article 2　The marketing authorization holder or manufacturer (hereinafter referred to as "MAHs") involved in design and manufacturing of medical devices shall conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the MAHs shall control the risks in such a way that the residual risk associated with each hazard is judged to be within an acceptable range. In this case, the MAHs shall apply the following principles to the management of risk in the priority order listed:	Article 2　The marketing authorization holder or manufacturer (hereinafter referred to as "MAHs") involved in design and manufacturing of medical devices shall conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the MAHs shall control the risks in such a way that the residual risk associated with each hazard is judged to be within an acceptable range. In this case, the MAHs shall apply the following principles to the management of risk in the priority order listed:
(1) to identify known or foreseeable hazards and estimate the associated risks arising from the intended use method and foreseeable misuse;	(1) to identify known or foreseeable hazards and estimate the associated risks arising from the intended use method and foreseeable misuse;
(2) to eliminate risks estimated in the previous item as far as reasonably practicable through inherently safe design and manufacture;	(2) to eliminate risks estimated in the previous item as far as reasonably practicable through inherently safe design and manufacture;
(3) to reduce as far as reasonably practicable the residual risks after eliminating the risks based on the previous item by taking adequate protection measures (including alarm systems); and	(3) to reduce as far as practicable the residual risks after eliminating the risks based on the previous item by taking adequate protection measures (including alarm systems); and
(4) to indicate any residual risks after eliminating the risks based on item 2.	(4) to indicate any residual risks after eliminating the risks based on item 2.
(Performance and function of medical devices)	(Performance and function of medical devices)
Article 3　Medical devices shall achieve the performance intended by the MAHs and be designed and manufactured in such a way that they may perform their functions as medical devices.	Article 3　Medical devices shall achieve the performance intended by the MAHs and be designed, manufactured, and packaged in such a way that they may perform their functions as medical devices.
(Term of validity or lifetime of the products)	(Lifetime of the products)
Article 4　The characteristics and performance shall not be adversely affected by deterioration, etc. to such a degree that the health and safety of the patient, user, and other persons are threatened during the term of validity or lifetime of the medical device established by the MAHs, when the device is subjected to the stresses which may occur under normal conditions of use and has been properly maintained in accordance with the MAHs' instructions.	Article 4　The characteristics and performance shall not be adversely affected by deterioration, etc. to such a degree that the health and safety of the patient or user, or other persons are threatened during the lifetime of the medical device established by the MAHs, when the device is subjected to the stresses which may occurunder normal conditions of use and has been properly maintained in accordance with the MAHs' instructions.

(Transport and storage, etc.)	(Transport and storage, etc.)
Article 5 Medical devices shall be designed, manufactured, and packaged in such a way that their characteristics and performance will not be adversely affected when transported and stored under the conditions subject to the instructions and information provided by the MAHs and used in accordance with their intended usage.	Article 5 Medical devices shall be designed, manufactured, and packaged in such a way that their characteristics and performance will not be adversely affected when transported and stored under the conditions subject to the instructions and information provided by the MAHs and used in accordance with their intended usage.
(Benefits of medical devices)	(Benefits of medical devices)
Article 6 All known or foreseeable risks and undesirable effects shall be minimized as far as reasonably practicable and be acceptable when weighed against the intended benefits of medical devices under normal conditions of use	Article 6 The intended benefits of the medical devices shall outweigh any possible undesirable effects.
Chapter 2 Requirements for design and manufacture	Chapter 2 Requirements for design and manufacture
(Chemical properties, etc. of medical devices)	(Chemical properties, etc. of medical devices)
Article 7 Regarding the selection of materials used, medical devices shall be designed and manufactured, where necessary, with attention given to the matters provided in each of the following items.	Article 7 Regarding the selection of materials used, in addition to meeting the requirements provided in the preceding chapter, medical devices shall be designed and manufactured, where necessary, with attention given to the matters provided in each of the following items.
(1) Toxicity and flammability,	(1) Toxicity and flammability,
(2) Compatibility between the materials used and biological tissues, cells and body fluids, and	(2) Compatibility between the materials used and biological tissues, cells body fluids, and specimens, and
(3) Hardness, wear, and degree of fatigue, etc.	(3) Hardness, wear, and degree of fatigue, etc.
2 Analytical instruments, etc. (meaning medical devices which are exclusively used for diagnosing diseases and are not directly used for treatment; the same shall apply hereinafter) shall be designed and manufactured, where necessary, taking into account the reduced performance of the analytical instruments attributable to incompatibility between the materials used and specimens and the analytes (including biological tissues, cells, body fluids, and microorganisms).	
3 Medical devices shall be designed, manufactured, and packaged in such a way as to minimize the risk posed by contaminants and residues (hereinafter referred to as "contaminants, etc.") to the persons involved in the transport, storage, and use of the devices and to patients, according to their purpose of use, and attention shall be paid to the biological tissues that come into contact with the contaminants, etc., contact duration, and contact frequency.	2 Medical devices shall be designed, manufactured, and packaged in such a way as to minimize the risk posed by contaminants and residues (hereinafter referred to as "contaminants, etc.") to the persons involved in the transport, storage, and use of the devices and to patients, according to their purpose of use, and attention shall be paid to the biological tissues that come into contact with the contaminants, etc., contact duration, and contact frequency.
4 Medical devices shall be designed and manufactured in such a way that they can be used safely with the substances or gases which are simultaneously used with the medical devices during their normal use procedure, and if the medical devices are intended to administer medicinal products, the devices shall be designed and manufactured in such a way as to be capable of administrating the medicinal product properly, and to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	3 Medical devices shall be designed and manufactured in such a way that they can be used safely with the various materials, substances or gases which are simultaneously used with the medical devices during their normal use procedure, and if the medical devices are intended to administer medicinal products, the devices shall be designed and manufactured in such a way as to be capable of administrating the medicinal product properly, and to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.
5 If a medical device incorporates, as an integral part, a substance which is considered to be a medicinal product that can be used alone, and acts on the human body to support the performance of the medical device, the safety, quality and performance of the medical device (including the substance concerned) shall be properly verified, taking the purpose of its use into account.	4 If a medical device incorporates, as an integral part, a substance which is considered to be a medicinal product that can be used alone, and acts on the human body to support the performance of the medical device, the safety, quality and efficacy of the substance concerned shall be properly verified, taking the purpose of its use into account.
6 Medical devices shall be designed and manufactured in such a way as to reduce, appropriately and as far as reasonably practicable, the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic, or reproductively toxic.	5 Medical devices shall be designed and manufactured in such a way as to reduce, appropriately and as far as reasonably practicable, the risks posed by substances that may leach or leak from the device.
7 Medical devices shall be designed and manufactured in such a way as to reduce appropriately and as far as reasonably practicable, risks posed by the unintentional ingress or egress of certain substances into or from the device, taking into account the device and its intended use environment.	6 Medical devices shall be designed and manufactured in such a way as to reduce risks posed by the unintentional ingress or egress of certain substances into or from the device, taking into account the device and its intended use environment appropriately and as far as reasonably practicable.

(Prevention of microbial contamination, etc.)	(Prevention of microbial contamination, etc.)
Article 8 Medical devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce, appropriately and as far as reasonably practicable, the risk of infection to patients, users, or other persons (limited to those persons at risk of infection during use of the medical device; the same shall apply in this Article.), taking the following items into account.	Article 8 Medical devices and their manufacturing processes shall be designed in such a way as to eliminate or alleviate, appropriately and as far as reasonably practicable, the risk of infection to patients, users, or other persons (limited to cases where other persons are at risk of infection during the use of medical devices), taking the following items into account.
(1) to allow easy handling;	(1) to allow easy handling;
(2) to reduce, where necessary, appropriately as far as reasonably practicable, any microbial leakage or exposure from using medical devices; and	(2) to alleviate, where necessary, appropriately as far as reasonably practicable, any microbial leakage or exposure from using medical devices; and
(3) to prevent, where necessary, microbial contamination of medical devices or specimens by the patient, user, or other persons.	(3) to prevent, where necessary, microbial contamination of medical devices or specimens by the patient, user, or other persons.
	2 If a bio-derived substance is incorporated into a medical device, appropriate source, donors and substances shall be selected and the risk of infection shall be reasonably and appropriately reduced by performing validated inactivation, preservation, and tests, and implementing control procedures.
2 The tissues, cells, and substances of animal origin which are incorporated into medical devices (hereinafter referred to as "animal origin tissues, etc.") shall be collected from animals that have been subjected to veterinary controls and surveillance adapted to the purpose of use of the animal origin tissues, etc. The MAHs shall retain information on the geographic origin of the animals where the animal origin tissues, etc. have been collected, ensure the optimal level of safety for the patient, user, or other persons in the processing, preservation, testing and handling of animal origin tissues, etc., and ensure safety by elimination or inactivation of viruses and other infectious pathogens in the manufacturing process of the medical device using validated methods, to take preventive measures against the viruses and other infectious pathogens. Provided, however, that this does not apply to analytical instruments, etc. which require viruses and other infectious pathogens for use or the performance of which is reduced by their elimination or inactivation.	3 The tissues, cells, and substances of non-human origin which are incorporated into medical devices (hereinafter referred to as "non-human origin tissues, etc.") shall be collected from animals that have been subjected to veterinary controls and surveillance adapted to the purpose of use of non-human origin tissues, etc. The MAHs shall retain information on the geographic origin of the animals where the non-human origin tissues, etc. have been collected, ensure the highest level of safety in the processing, preservation, testing and handling of non-human origin tissues, etc., and ensure safety by elimination or inactivation of viruses and other infectious pathogens in the manufacturing process of the medical device using validated methods, to take preventive measures against the viruses and other infectious pathogens.
3 The tissues, cells, and substances of human origin which are incorporated into medical devices (hereinafter referred to as "human origin tissues, etc.")shall be obtained from appropriate sources. The MAHs shall ensure the optimal level of safety for the patient, user, or other persons in the selection of donors or human origin substances, and in the processing, preservation, testing and handling of human origin tissues, etc., and ensure safety by elimination or inactivation of viruses and other infectious pathogens in the manufacturing process of the medical device using validated methods, to take preventive measures against theviruses and other infectious pathogens. Provided, however, that this does not apply to analytical instruments, etc. which require viruses and other infectious pathogens for use or the performance of which is reduced by their elimination or inactivation.	4 The tissues, cells, and substances of human origin which are incorporated into medical devices (hereinafter referred to as "human origin tissues, etc.")shall be obtained from appropriate sources. The MAHs shall ensure the highest level of safety in the selection of donors or human origin substances, and in the processing, preservation, testing and handling of human origin tissues, etc., and ensure safety by elimination or inactivation of viruses and other infectious pathogens in the manufacturing process of the medical device using validated methods, to take preventive measures against the viruses and other infectious pathogens.
4 The MAHs shall ensure the optimal level of safety for the patient, user, or other persons in the processing, preservation, testing and handling of microbial origin tissues, etc. (meaning cells and substances originating from microorganisms) incorporated into medical devices, and ensure safety by elimination or inactivation of viruses and other infectious pathogens in the manufacturing process of the medical device using validated methods, to take preventive measures against the viruses and other infectious pathogens. Provided, however, that this does not apply to analytical instruments, etc. which require viruses and other infectious pathogens for use or the performance of which is reduced by their elimination or inactivation.	
5 Medical devices labelled as having a special microbiological state shall be designed, manufactured, and packaged to ensure that they maintain their special microbiological state when placed on the market or when transported and stored under the conditions indicated by the MAHs.	5 Medical devices labelled as having a special microbiological state shall be designed, manufactured, and packaged to ensure that they maintain their special microbiological state when placed on the market or when transported and stored under the conditions indicated by the MAHs.

6 Medical devices delivered in a sterile state shall be designed and manufactured to be packaged in a non-reusable pack. It shall be ensured that the packages maintain the sterility of medical devices when they placed on the market and that the medical devices remain sterile under the transport and storage conditions indicated by the MAHs unless the package is damaged or until opened using the proper procedure, and that the packages are non-reusable.	6 Medical devices delivered in a sterile state shall be designed and manufactured to be packaged in a non-reusable pack. It shall be ensured that the packages maintain the sterility of medical devices when they placed on the market and that the medical devices remain sterile under the transport and storage conditions indicated by the MAHs unless the package is damaged or until opened using the proper procedure, and that the packages are non-reusable.
7 Medical devices labelled as sterile or having a special microbiological state shall be manufactured upon being sterilized by appropriate, validated methods or processed to create the special microbiological state, and where necessary, shall be sterilized.	7 Medical devices labelled as sterile or having a special microbiological state shall be manufactured upon being sterilized by appropriate, validated methods or processed to create the special microbiological state, and where necessary, shall be sterilized.
8 Medical devices to be sterilized shall be manufactured under appropriately controlled conditions.	8 Medical devices to be sterilized shall be manufactured under appropriately controlled conditions.
9 Packaging for non-sterile medical devices shall maintain the specified cleanliness of the medical devices in order that their qualities are not adversely affected. Packaging for medical devices to be sterilized prior to use shall minimize the risk of microbial contamination. In this case, the package shall be suitable taking into account of the method of sterilization.	9 Packaging for non-sterile medical devices shall maintain the specified cleanliness of the medical devices in order that their qualities are not adversely affected. Packaging for medical devices to be sterilized prior to use shall minimize the risk of microbial contamination. In this case, the package shall be suitable taking into account of the method of sterilization.
10 When identical or similar products are placed on the market in both sterile and non-sterile condition, their packages and labels shall make it possible to distinguish the products from one another.	10 When identical or similar products are placed on the market in both sterile and non-sterile condition, their packages and labels shall make it possible to distinguish the products from one another.
(Consideration of use environment)	(Consideration of manufacturing or use environment)
Article 9 If the medical device is used in combination with other medical devices, in vitro diagnostics, other equipment, etc., the medical device concerned shall be safely connected to the equipment, etc. concerned and the performance of the medical device concerned and the equipment, etc. concerned shall not be impaired by combined use.	If the medical device is used in combination with other medical devices or in vitro diagnostics, or equipment, safety shall be ensured for all combinations, including connection systems, and the performance of each medical device or in vitro diagnostic shall not be impaired. If combined, the limitation on use shall be directly indicated, or clearly described in the package inserts.
2 Any restrictions on use in the case of the previous item shall be made the public notice of e-package inserts, or described on the document attached to the medical device or containers or encapsulation (referred to as “package inserts, etc.” in Article 17).	
3 The connecting part of the medical devices to transfer liquid or gas operated by users or to be mechanically coupled shall be designed and manufactured in such a way as to minimize risks arising from incorrect connection.	
4 Medical devices shall be designed and manufactured in such a way as to eliminate or reduce, appropriately and as far as reasonably practicable, the risks to the patient, user, or other persons (limited to persons who may be subject to any of the risks listed in the following items during their use) during their use as listed in the following items.	Article 9 Medical devices shall be designed and manufactured in such a way as to eliminate or reduce, reasonably and appropriately, the risks listed in the following items.
(1) the risk of injury in connection with their physical and ergonomic features;	(1) the risk of injury in connection with their physical features;
(2) the risk of misuse due to the ergonomic features, human factors and the use environment in which the medical device is intended to be used;	(2) the risk associated with rationally foreseeable, external effects or environmental conditions
(3) the risk associated with the simultaneous use of raw materials, substances, and gases which may come into contact with medical devices under normal conditions of use;	(3) the risk associated with the simultaneous use of raw materials, substances, and gases which may come into contact with medical devices under normal conditions of use;
(4)the risk associated with the use of the medical device when it comes into contact with substances, liquids, or gases to which it is exposed under normal conditions of use;	
(5)the risk associated with software interference between software and their operating environment;	
(6) the risk of accidental penetration of substances into medical devices;	(4) the risk of accidental penetration of substances into medical devices;
(7) the risk of incorrect identification of specimens;	(5) the risk of incorrect identification of specimens;
(8) the risks of reciprocal interference with other medical devices or in vitro diagnostics normally used in studies or for treatment; and	(6) the risks of reciprocal interference with other medical devices or in vitro diagnostics normally used in studies or for treatment; and
(9) the risks arising where maintenance or calibration is not possible, from deterioration of the materials used, or reduced accuracy of any measuring or control mechanism.	(7) the risks arising where maintenance or calibration is not possible, from deterioration of the materials used, or reduced accuracy of any measuring or control mechanism.

5 Medical devices shall be designed and manufactured in such a way as to minimize the risk of fire or explosion during normal use and under single fault conditions. Particular attention shall be paid to the design and manufacturing of medical devices the intended use of which includes use in association with flammable substances or substances which could cause combustion (including cases where medical devices are exposed or used with these substances).	2 Medical devices shall be designed and manufactured in such a way as to minimize the risk of fire or explosion during normal use and under single fault conditions. Particular attention shall be paid to the design and manufacturing of medical devices the intended use of which includes use in contact with flammable substances or substances which could cause combustion.
6 Medical devices shall designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be performed safely.	
7 Medical devices shall be designed and manufactured in such a way as to facilitate the safe disposal of all waste substances.	3 Medical devices shall be designed and manufactured in such a way as to facilitate the safe disposal of all waste substances.
(Consideration of measuring or diagnostic function)	(Consideration of measuring or diagnostic function)
Article 10 Medical devices and diagnostic medical devices with a measuring function (meaning medical devices exclusively used for diagnosing diseases) shall be designed and manufactured in such a way as to provide sufficient accuracy, precision, and stability, based on appropriate scientific and technical methods, taking the purpose of use of the medical devices into account. The limits of accuracy shall be indicated by the MAHs.	Article 10 Medical devices with a measuring function shall be designed and manufactured in such a way as to provide sufficient accuracy, precision, and stability, taking into account the purpose of use of the medical devices, if inaccuracy may result in the patient suffering serious adverse effects. The limits of accuracy shall be indicated by the MAHs.
2 Analytic instruments, etc. shall be designed and manufactured in such a way that the performance is coincident with the purpose of use, based on appropriate scientific and technical methods. In designing medical devices, appropriate attention shall be paid to trueness and precision (including repeatability and reproducibility) associated with sensitivity, specificity, and accuracy, and control of known interference factors and limits of detection. These performances shall be maintained during the term of validity or lifetime of the medical devices indicated by the MAHs.	2 Diagnostic medical devices shall be designed and manufactured in such a way as to provide sufficient accuracy, precision, and stability, based on appropriate scientific and technical methods, taking the purpose of use of the medical devices into account. In designing the diagnostic medical devices, appropriate attention shall be paid to sensitivity, specificity, accuracy, repeatability, reproducibility, and control of known interference factors, and limits of detection.
3 If the performance of analytical instruments, etc. depends on the use of calibrators or reference materials, the traceability of values assigned to such calibrators or reference materials shall be assured through available reference measurement methods or available reference materials of a higher order.	3 If the performance of diagnostic medical devices depends on the use of calibrators or reference materials, the traceability of values assigned to such calibrators or reference materials shall be assured through a quality control system.
4 Scales of any measuring, monitoring, or display devices shall be designed from an ergonomic viewpoint, taking the purpose of use of the medical devices into account.	4 Scales of any measuring, monitoring, or display devices shall be designed from an ergonomic viewpoint, taking the purpose of use of the medical devices into account.
5 In principle, the values expressed numerically shall be standardized units as far as possible, and understood by the users of medical devices.	5 In principle, the values expressed numerically shall be standardized units as far as possible, and understood by the users of medical devices.
(Protection against radiation)	(Protection against radiation)
Article 11 Medical devices (excluding analytical instruments, etc.) shall be designed, manufactured and packaged in such a way that exposure of patients, users, or other persons to radiation (limited to persons at risk of exposure to radiation during use of the medical devices; the same shall apply in Paragraph 6) shall be appropriately reduced as far as reasonably practicable, while not restricting the level of irradiation required for treatment and diagnosis consistent with the purpose of their use.	Article 11 Medical devices shall be designed, manufactured and packaged in such a way that exposure of patients, users, or other persons to radiation shall be reasonably and appropriately reduced, while not restricting the level of irradiation required for treatment and diagnosis consistent with the purpose of their use.
2 Analytical instruments, etc. shall be designed, manufactured, and packaged in such a way that exposure of patients, users, or other persons to radiation (limited to persons at risk of exposure to radiation during use of the analytical instruments, etc.) shall be appropriately reduced as far as reasonably practicable, while not restricting the level of irradiation required for measurement consistent with the purpose of their use.	
3 Regarding the radiation output of medical devices, where medical devices are designed to emit hazardous or potentially hazardous levels of visible or invisible radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks associated with the emission, it shall be possible for the user to control the dose. Such medical devices shall be designed and manufactured to ensure the reproducibility of the relevant variable parameters within an acceptable tolerance.	2 Regarding the radiation output of medical devices, where medical devices are designed to emit hazardous or potentially hazardous levels of visible or invisible radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks associated with the emission, it shall be possible for the user to control the dose. Such medical devices shall be designed and manufactured to ensure the reproducibility of the relevant variable parameters within an acceptable tolerance.

4 If medical devices emit hazardous or potentially hazardous levels of visible or invisible radiation, they shall be fitted, as far as reasonably practicable, with visual displays or audible warnings to check such emissions.	3 If medical devices emit potentially hazardous, visible or invisible radiation, they shall be fitted, with visual displays or audible warnings to check such emissions, where necessary.
5 Analytical instruments, etc. shall be designed and manufactured in such a way that the characteristics and the dose of radiation emitted can be appropriately controlled or adjusted, as far as reasonably practicable.	
6 Medical devices shall be designed and manufactured in such a way that exposure of patients, users, or other persons to the emission of unintended, secondary or scattered radiation is reduced as far as reasonably practicable.	4 Medical devices shall be designed and manufactured in such a way that exposure of patients, users, or other persons to the emission of unintended, secondary or scattered radiation is alleviated as far as possible.
7 Instruction manuals for medical devices emitting radiation shall provide detailed information on the characteristics of the radiation emitted, protective measures for patients and users, protective method in the event of misuse, and the method for eliminating the specific risk during installation.	5 Instruction manuals for medical devices emitting radiation shall provide detailed information on the characteristics of the radiation emitted, protective measures for patients and users, protective method in the event of misuse, and the method for eliminating the specific risk during installation.
8 Medical devices emitting ionizing radiation shall be designed and manufactured in such a way as to allow variation and control of the dose, geometry and energy distribution, or quality of the radiation emitted, as far as reasonably practical, taking the purpose of their use into account.	6 Medical devices emitting ionizing radiation shall be designed and manufactured in such a way as to allow the variation and control of the dose, geometry and energy distribution (or quality) of the radiation emitted, where necessary, taking the purpose of their use into account.
9 Diagnostic medical devices emitting ionizing radiation shall be designed and manufactured in such a way as to enhance quality of the appropriate image or output signal in order to achieve the intended diagnostic purpose whilst minimizing radiation exposure of the patient and user.	7 Diagnostic medical devices emitting ionizing radiation shall be designed and manufactured in such a way as to enhance the quality of the appropriate image or output signal in order to achieve the intended diagnostic purpose whilst minimizing radiation exposure of the patient and user.
10 Therapeutic medical devices emitting ionizing radiation shall be designed and manufactured in such a way as to enable reliable monitoring and control of the dose to be emitted, the beam type and energy, and where necessary, the energy distribution of the radiation beam.	8 Therapeutic medical devices emitting ionizing radiation shall be designed and manufactured in such a way as to enable reliable monitoring and control of the dose to be emitted, the beam type and energy, and where necessary, the energy distribution of the radiation beam.
(Consideration of medical devices using software)	
Article 12 Medical devices using software (including Software as a Medical Device (SaMD) or recording media containing SaMD; the same shall apply hereinafter) shall be designed in such a way as to ensure the reproducibility, reliability and performance taking the purpose of their use into account. In the event of a single fault condition in the system, appropriate measures shall be adopted to eliminate or reduce, as far as reasonably practicable, the risks that may arise from the fault.	
2 For medical devices using software, their quality and performance shall be validated, taking into account the development lifecycle based on the latest technologies, risk management, and verification and validation in order to operate the medical devices properly.	
3 For medical devices using software that are used in connection with other devices and networks, etc., or that may be subject to external unauthorized access and attack, etc., appropriate requirements shall be identified, taking into account the operating environment and network use environment of the medical device, the risk related to cybersecurity that may affect the function of the medical device or cause safety concerns shall be identified and evaluated, and risk management shall be conducted to reduce such cyber risks. In addition, such medical devices shall be designed and manufactured based on a plan to ensure cybersecurity throughout the total product life cycle of the medical device.	
(Consideration of active medical devices and medical devices connected to them)	(Consideration of active medical devices)
Article 13 For active medical devices, in the event of a single fault condition, appropriate measures shall be adopted to eliminate or reduce, appropriately and as far as reasonably practicable, the risks that may arise from the fault.	Article 12 Medical devices with built-in electrical program systems, including software, shall be designed to ensure the reproducibility, reliability, and performance of the systems, taking their purpose of use into account. In the event of a single fault condition, appropriate measures shall be adopted to eliminate or alleviate, appropriately and as far as practicable, the risks that may arise from the fault.
2 If the safety of patients may be directly affected by the fluctuation of voltage or other electric parameters of medical devices with an internal power supply, measures shall be taken to determine the state of the power supply.	2 If the safety of patients may be directly affected by the fluctuation of voltage or other electric parameters of medical devices with an internal power supply, measures shall be taken to determine the state of the power supply.
3 If the safety of patients may be directly affected by a power failure of medical devices with an external power supply, the device shall be equipped with a built-in alarm system to alert any power supply failure.	3 If the safety of patients may be directly affected by a power failure of medical devices with an external power supply, the device shall be equipped with a built-in alarm system to alert any power supply failure.

4 Medical devices displaying one or more clinical parameters of a patient on a monitor shall be equipped with appropriate alarm systems to alert the user of any life-threatening situation or one that could lead to the patient suffering serious health damage.	4 Medical devices displaying one or more clinical parameters of a patient on a monitor shall be equipped with appropriate alarm systems to alert the user of any life-threatening situation or one that could lead to the patient suffering serious health damage.
5 Medical devices shall be designed and manufactured in such a way as to reduce, as far as reasonably practicable, the risks of creating electromagnetic interference which may impair the operation of such medical devices or other equipment used in a normal use environment.	5 Medical devices shall be designed and manufactured in such a way as to reduce, reasonably and appropriately, the risks of creating electromagnetic interference which may impair the operation of such medical devices or other equipment used in a normal use environment.
6 Medical devices shall be designed and manufactured in such a way as to maintain an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to be operated as intended.	6 Medical devices shall be designed and manufactured in such a way as to maintain an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to be operated as intended.
7 Medical devices shall be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to patients, users, or other persons (limited to persons at risk of accidental electric shocks during use of the medical devices) during normal installation and maintenance as indicated by the MAHs, either under normal use conditions or in the event of a single fault condition.	7 Medical devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal installation and maintenance as indicated by the MAHs, both under normal use conditions and in the event of a single fault condition.
(Consideration of mechanical risks)	(Consideration of mechanical risks)
Article 14 Medical devices shall be designed and manufactured in such a way as to protect the patient, user, or other persons (limited to persons exposed to a mechanical risk during use of the medical devices) against mechanical risks associated with resistance to movement, instability, and moving parts.	Article 13 Medical devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks associated with resistance to movement, instability, and moving parts.
2 If there are risks due to moving parts, risks due to break-up or detachment, or leakage of substances, appropriate measures to prevent risks arising shall be incorporated into the analytical instruments, etc.	
3 Medical devices shall be designed and manufactured in such a way as to reduce to the lowest level the risks arising from vibration generated by the medical devices, as far as reasonably practicable, referring to technical progress and to existing technology for limiting vibration, particularly at source, unless the vibration is part of the specified performance.	2 Medical devices shall be designed and manufactured in such a way as to reduce to the lowest level the risks arising from vibration generated by the medical devices, as far as practicable, referring to technical progress and to the existing technology for limiting vibration, particularly at source, unless the vibration is part of the specified performance.
4 Medical devices shall be designed and manufactured in such a way as to reduce to the lowest level the risks arising from noise emitted by medical devices, as far as reasonably practicable, referring to technical progress and to existing technology for limiting noise, particularly at source, unless the noise emitted is part of the specified performance.	3 Medical devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from noise emitted by medical devices, referring to technical progress and to existing technology for limiting noise, particularly at source, unless the noise emitted is part of the specified performance.
5 Terminals and connectors connected to electricity or gas, or to hydraulic or pneumatic sources of energy which the user or other persons have to manage shall be designed and manufactured in such a way as to minimize all possible risks.	4 Terminals and connectors connected to electricity or gas, or to hydraulic or pneumatic sources of energy which the user has to manage shall be designed and manufactured in such a way as to minimize all possible risks.
6 Medical devices shall be designed and manufactured in such a way as to reduce to the lowest level, as far as reasonably practicable, the risk of misconnection of certain parts where connection is required before or during use.	
7 Easily accessible parts of medical devices (excluding parts intended to heat up or maintain certain temperatures) and their surroundings shall not reach potentially dangerous temperatures under normal conditions of use.	5 Easily accessible parts of medical devices (excluding parts intended to heat up or maintain certain temperatures) and their surroundings shall not reach potentially dangerous temperatures under normal conditions of use.
(Consideration of medical devices supplying energy or substances)	(Consideration of medical devices supplying energy)
Article 15 Medical devices supplying the patient with energy or substances shall be designed and manufactured in such a way that the supplied amount can be set and maintained to guarantee the safety of the patient and user.	Article 14 Medical devices supplying the patient with energy or substances shall be designed and manufactured in such a way that the supplied amount can be set and maintained to guarantee the safety of the patient and user.
2 Medical devices shall be fitted with the means of preventing or warning of any undesirable energy or substances which could pose a danger, and appropriate measures shall be adopted for preventing, as far as possible, accidental release of dangerous levels of energy or substances from an energy or substance source.	2 Medical devices shall be fitted with the means of preventing or warning of any undesirable energy or substances which could pose a danger, and appropriate measures shall be adopted for preventing, as far as possible, accidental release of dangerous levels of energy or substances from an energy or substance source.
3 The function of the controls and indicators shall be clearly specified on medical devices. If a medical device bears instructions required for its operation or visually indicates operating or adjustment parameters, such information shall be easily understandable to users and, as appropriate, the patient (if the medical device may affect the safety and health, etc. of patients during its use).	3 The function of the controls and indicators shall be clearly specified on medical devices. If a medical device bears instructions required for its operation or visually indicates operating or adjustment parameters, such information shall be easily understandable to users and, as appropriate, the patient (if the medical device may affect the safety and health, etc. of patients during its use).

(Consideration of medical devices intended to be used by lay persons)	(Consideration of self-check medical devices)
Article 16 Medical devices intended to be used by lay persons (meaning devices which are intended to be used by persons who may not always have specialized knowledge regarding the use of self-check medical devices or self-administration medical devices and other devices; the same shall apply hereinafter)shall be designed and manufactured in such a way that they can be appropriately operated, in consideration of the technique and methodology available totheir users and technical and environmental changes affecting the user that may be expected to normally occur.	Article 15 Self-check medical devices or self-administration medical devices (hereinafter referred to as "self-check medical devices, etc.") shall be designed and manufactured in such a way that they can be appropriately operated, in consideration of the technique and methodology available totheir users and technical and environmental changes affecting the user that may be expected to normally occur.
2 Medical devices intended to be used by lay persons shall be designed and manufactured in such a way as to reduce, as far as reasonably practicable, the risk of misuse by the users during the use of the medical devices, use of the specimens (limited to medical devices using specimens), and interpretation of test results.	2 Self-check medical devices, etc. shall be designed and manufactured in such a way as to reduce, as far as possible, the risk of misuse during the handling of the medical devices, handling of the specimens (limited to cases where specimens are handled), and interpretation of test results.
3 For medical devices intended to be used by lay persons, as far asreasonably practicable, procedures by which users can verify whether the devices are performing their functions as intended by the MAHs shall beprovided.	3 For self-check medical devices, in as far as reasonably practicable, procedures by which users can verify, when using, whether the devices are performing their functions as intended by the MAHs shall be included.
(Information provision to users by the public notice of e-package inserts or indication of package inserts, etc.)	(Information provided by manufactures and marketing authorization holders)
Article 17 The MAHs shall provide, when medical devices are placed on the market, the information needed to identify the name of MAHs, methods to ensure safe use, and their performance in the public notice of e-package inserts or indication of the package inserts, etc. of the medical devices, in a manner that users can easily understand such information, in consideration of the degree of training and knowledge users have on the medical devices.	Information necessary to check the name of MAHs, methods to ensure safe use, and the intended performance of medical devices or in vitro diagnostics shall be provided to users, in consideration of the degree of training and knowledge of the users. This information shall be easily understandable.
(Performance evaluation and clinical studies)	(Performance evaluation)
Article 18 All data collected to evaluate the performance of medical devices shall be collected in accordance with the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 1960) and other relevant laws and regulations.	Article 16 All data collected to evaluate the performance of medical devicesshall be collected in accordance with the Pharmaceutical Affairs Act (Act No. 145 of 1960) and other relevant laws and regulations.
2 Clinical studies shall be conducted in accordance with the Ministerial Ordinance on Good Clinical Practices for Medical Devices (MHLW Ministerial Ordinance No. 36 of 2005).	2 Clinical studies shall be conducted in accordance with the Ministerial Ordinance on Good Clinical Practices for Medical Devices (MHLW Ministerial Ordinance No. 36 of 2005).
3 Medical devices shall be continuously evaluated by the test results and data and other records required according to the medical devices based on the laws and regulations provided in Paragraph 1 and 2, in addition to the Ministerial Ordinance on Good Post-marketing Study Practice for Medical Devices (MHLW ministerial ordinance No. 38 of 2005) and Ministerial Ordinance on Good Vigilance Practice for Drugs, Quasi-Drugs, Cosmetics, Medical Devices, and Regenerative Products (MHLW ministerial ordinance No. 135 of 2004).	