Ordinance of the Ministry of Health, Labour and Welfare No. 169 of 2004

Ministerial Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and in Vitro Diagnostics

Based on the provisions of Article 14, paragraph (2), item (iv) and Article 14, paragraph (2), item (iv) as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Pharmaceutical Affairs Act (Act No. 145 of 1960), the following ministerial ordinances concerning production control and quality control standards for medical devices and in vitro diagnostic drugs are established:

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Chapter I General Provisions

(Purpose)

Article 1 this Ministerial Ordinance shall stipulate the provisions of the Act on Securing Quality, Effectiveness, and Safety of Pharmaceuticals, Medical Devices, etc. (Act No. 145 of 1960). Hereinafter referred to as 'law.') Article 23-2-5, paragraph (2), item (iv) (including the cases where it is applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5). The same shall apply hereinafter.) And the standards specified by an Ordinance of the Ministry of Health, Labour and Welfare as prescribed in Article 80, paragraph (2) shall be established.

(Definition)

Article 2 (1) in this Ministerial Ordinance, "manufacturer, etc." means a medical device or an in vitro diagnostic drug (hereinafter referred to as "medical equipment, etc."). (The appointed manufacturer and seller of medical devices, etc. prescribed in Article

23-2-17, paragraph (4) of the Act (hereinafter referred to as the "appointed manufacturer and seller of medical devices, etc.") And a manufacturer and seller of highly controlled medical devices, etc. appointed pursuant to the provisions of Article 23-3, paragraph (1) of the Act (hereinafter referred to as the "appointed foreign designated manufacturer and seller of highly controlled medical devices, etc.") Except for.) A person who has obtained special approval for medical devices manufactured in a foreign country as prescribed in Article 23-2-17, paragraph (4) of the Act (hereinafter referred to as "person who has obtained special approval for medical devices manufactured in a foreign country") Or a foreign designated manufacturer, etc. of highly controlled medical devices prescribed in Article 23-2-20, paragraph (1) of the Act (hereinafter referred to as a "foreign designated manufacturer, etc. of highly controlled medical devices") It refers to.

(2) the term "products" as used in this Ministerial Ordinance shall be used to refer to products consisting of component parts, etc. that have gone through the manufacturing process at a manufacturing plant (those manufactured in the intermediate process of manufacturing and become products through subsequent manufacturing processes (hereinafter referred to as "intermediate products"). Includes. The same shall apply hereinafter.) This shall mean the medical device program prescribed in Article 2, paragraph (13) of the Act.

(3) the term "component parts, etc." as used in this Ministerial Ordinance means parts and assemblies (limited to those used in products) used in manufacturing processes. Raw materials, materials, containers, packaging, Displays (including attachments). The same shall apply hereinafter.) Components, etc. that are part of products and software of products (excluding medical device programs prescribed in Article 2, paragraph (13) of the Act) It refers to.

(4) the term "substances for production" as used in this Ministerial Ordinance means substances used in intermediate products in the manufacturing process (excluding substances that become part of products). It refers to.

(5) the term "lot" as used in this Ministerial Ordinance shall mean products, substances for production, and component parts, etc. (hereinafter referred to as "products, etc.") manufactured in such a way that they are homogeneous through a series of manufacturing processes within the manufacturing period of - (hereinafter referred to as "products, etc.") It refers to a group of groups.

(6) the term "facilities" as used in this Ministerial Ordinance means the series of operations carried out from development to shipment and the provision of services incidental to the product realization included in the quality control supervision system. The same shall apply hereinafter.) Facilities (including manufacturing facilities) It refers to.

(7) the term "validation" as used in this Ministerial Ordinance shall be used to refer to structural and equipment of facilities, procedures, processes and other manufacturing control and quality control methods (hereinafter referred to as "manufacturing procedures, etc."). This means verifying that the results are expected to be obtained and documenting them.

(8) the term "process input information" as used in this Ministerial Ordinance means information, etc. necessary for production control and quality control provided in the implementation of a process.

(9) the term "process output information" as used in this Ministerial Ordinance means information, etc. obtained as a result of the implementation of a certain process.

(10) the term "management supervisor" as used in this Ministerial Ordinance means an officer, etc. who controls and supervises the business pertaining to the quality control and supervision system of a manufacturer, etc. at the highest level. However, in the case of chapters II to V-2 as applied mutatis mutandis by replacing certain terms pursuant to Article 82 and Article 83, this shall mean officers, etc. who control and supervise operations pertaining to the quality control and supervision system of a manufacturer at the highest level.

(11) the term "product recipient" as used in this Ministerial Ordinance means a person who handles the product after shipment (excluding a person who is involved only in transportation). The same shall apply hereinafter.) It refers to. However, in Chapter II through Chapter V-2 as applied mutatis mutandis by replacing certain terms in Article 82 and Article 83, this term refers to a person who handles a product after its shipment from the manufacturer.

(12) the term "quality policy" as used in this Ministerial Ordinance means the basic policy established and disclosed by the management supervisor in order to ensure the quality of products.

13 In this Ministerial Ordinance, the term "Quality Control and Supervision System" means a system for manufacturers, distributors, etc. to carry out quality control and supervision, where resources for such control and supervision are allocated and used appropriately. However, in chapters II to V-2 as applied mutatis mutandis by replacing terms in Article 82, the term refers to the system for the manufacturer to carry out the control and supervision of manufacturing facilities with regard to quality, and in chapters II to V-2 as applied mutatis mutandis by replacing terms in Article 83, the term refers to the system for the manufacturer to carry out the control and supervision with regard to quality.

14 In this Ministerial Ordinance, the term "review" means determining the appropriateness and effectiveness of achieving the set objectives.

(15) the term "resources" as used in this Ministerial Ordinance shall mean knowledge and skills possessed by individuals, as well as technology, equipment, and other resources utilized for business in facilities.

(16) the term "business operation infrastructure" as used in this Ministerial Ordinance shall mean a system of facilities, equipment and services necessary for business at facilities.

(17) the term "written notice" as used in this Ministerial Ordinance means a document issued by a manufacturer, etc. after delivery of a product in order to supplement the information provided at the time of delivery or to advise on measures to be taken in the use or collection of medical devices, etc. pertaining to said product.

(18) in this Ministerial Ordinance, "special adoption" means requirements pertaining

to products (hereinafter referred to as "product requirements"). With regard to products that do not conform to the provisions of laws and regulations concerning pharmaceutical affairs, or orders or dispositions based on such laws and regulations (hereinafter referred to as "provisions of laws and regulations, etc.") without hindrance to the manufacturing control and quality control of the products. Permission to use or operate, permission to proceed to the next stage of the process, or a decision to ship or accept it after properly confirming that it conforms.

(19) the term "remanufactured single-use medical device" as used in this Ministerial Ordinance means a single-use medical device (meaning a medical device that is intended to be used one-time). The same shall apply hereinafter.) Remanufacturing (for the purpose of manufacturing and selling new medical devices after they have been used, inspection, disassembly, and Cleaning, sterilization and other necessary processing. The same shall apply hereinafter.) It means something that has been done.

2 (0) the term "regenerative parts" as used in this Ministerial Ordinance means, among the component parts, etc. prescribed in paragraph (3), all or part of single-use medical devices used by medical institutions and used for reproduction.

(21) the term implantable medical devices as used in this Ministerial Ordinance means medical devices that are buried in a person's body or inserted into natural openings of the person's body, or that replace the surface of a person's skin or eyes, for the purpose of being permanently in whole or in part for thirty days or longer.

2 (2) the term "similar Product Group" as used in this Ministerial Ordinance means a group of products manufactured and sold by manufacturers, etc. of medical devices, etc. pertaining to said medical devices, etc. that have the same basic design in terms of function, performance and safety corresponding to the intended use of said medical devices, etc. pertaining to said products.

2 (3) the term "post-marketing surveillance" as used in this Ministerial Ordinance means systematic work (including work concerning post-marketing safety management) pertaining to the collection and analysis of information obtained from the manufacture and sale of medical devices, etc. It refers to.

2 (4) the term "purchased goods, etc." as used in this Ministerial Ordinance means intermediate products, component parts, etc., substances used in the manufacture and services provided by manufacturers, etc.

(5) the term "sterile barrier system" as used in this Ministerial Ordinance means a package used for the purpose of preventing medical devices, etc. pertaining to the product from contamination by microorganisms until the time of use.

26. "Usability" as used in this Ministerial Ordinance means, among the characteristics of medical devices, etc. pertaining to the product, that are necessary for the safe and appropriate use or operation by the user, and that the function, performance and safety corresponding to the intended use are fully demonstrated; In addition, it is necessary to satisfy the requirements of the user.

(Scope of Application)

Article 3 (1) a manufacturer, etc. shall carry out manufacturing control and quality control of products pursuant to the provisions of chapters 2 and 3.

(2) the manufacturer, etc. shall, in accordance with the provisions of the Minister of Health, Labour and Welfare designated by the Minister of Health, Labour and Welfare as set forth in Article 43, paragraph (2) of the Act, prepare medical devices, etc. consisting of cells or tissues of humans or animals. The same shall apply hereinafter.) (Hereinafter collectively referred to as "Biological Medical Devices, etc.") In addition to the provisions of chapters II and III, the manufacturing and quality control of such products shall be carried out in accordance with the provisions of Chapter IV.

3 A manufacturer, etc. may, in the case of a radiopharmaceutical (meaning a radiopharmaceutical prescribed in item (I) of Article 1 of the Ordinance on the Manufacture and Handling of Radiopharmaceuticals (Ordinance of the Ministry of Health, Labour and Welfare No. 4 of 1961)). The same shall apply hereinafter.) In vitro diagnostic products (hereinafter referred to as "radioactive in vitro diagnostic products") In addition to the provisions of chapters II and III, the manufacturing and quality control of such products shall be carried out in accordance with the provisions of Chapter V.

4 The manufacturer, etc. shall, in addition to the provisions of chapters II and III, implement the manufacturing control and quality control of products pertaining to remanufactured single-use medical devices in accordance with the provisions of Chapter V-2.

Chapter II Basic requirements for manufacturing and quality control of medical devices, etc.

Section 1 General Rules

(Application)

Article 4 the provisions of Articles 30 to 36-2 shall not apply to products pertaining to medical devices, etc. other than the medical devices and in vitro diagnostics prescribed in Article 23-2-5, paragraph (1) of the Act and designated highly controlled medical devices, etc. prescribed in Article 23-2-23, paragraph (1) of the Act.

2 Where the manufacturer, etc. is unable to apply any of the provisions of sections 4 to 6 of this Chapter due to the characteristics of the medical device, etc. pertaining to the product, the manufacturer, etc. may not apply said provisions to its quality control supervision system.

3 In cases where the manufacturer, etc. falls under any of the provisions of the preceding two paragraphs, a document specifying the standards for the quality control supervisory system (hereinafter referred to as the "Standards for the quality control supervisory system") shall, A statement to that effect and the reasons therefor shall be stated in .

Section 2 Quality Control and Supervision System

(Requirements for Quality Control and Supervision Systems)

Article 5 (1) the manufacturer, etc. shall, in accordance with the provisions of this Chapter, document the quality control and supervision system and maintain its effectiveness.

2 The manufacturer, etc. shall establish all requirements, procedures, activities and procedures required to be documented by this Ministerial Ordinance, and It shall be implemented and maintained.

3 A manufacturer, etc. may, in accordance with the provisions of Article 23-2, paragraph (1) of the Act, register a manufacturing industry pursuant to the provisions of Article 213-2-3, paragraph (1) of the Act, register a foreign manufacturer of medical devices, etc. pursuant to the provisions of Article 23-2-4, paragraph (1) of the Act, permit the sale of pharmaceuticals pursuant to the provisions of Article 24, paragraph (1) of the Act, In cases where a license for the sales and rental business of highly controlled medical devices, etc. pursuant to the provisions of Article 39, paragraph (1) of the Act or permission for the repair business of medical devices pursuant to the provisions of Article 40-2, paragraph (1) of the Act has been obtained, or where a notification of the sales and rental business of controlled medical devices pursuant to the provisions of Article 39-3, paragraph (1) of the Act has been made, the relevant documents (excluding the quality control system and other documents prescribed in this Ministerial Ordinance). Hereinafter referred to as "Quality Control Supervision Document") It shall be described in the .

(Establishment of Quality Control and Supervision System)

Article 5-2 (1) a manufacturer, etc. shall establish a quality control supervision system by clarifying the following matters:

一 Steps required for a quality control supervisory system (hereinafter simply referred to as "steps") (Including the results achieved by such procedures) The nature of the involvement of each facility and its departments in the process

二 Risks related to the function, performance, and safety of medical devices, etc. related to products and the degree of management corresponding to such risks

(III) the sequence of processes and their mutual relationship

(Work of Quality Control and Supervision System)

Article 5-3 (1) a manufacturer, etc. shall perform the following duties for each of the processes:

To establish the criteria and methods necessary for ensuring the effectiveness of the implementation and management of the process. (D) making available resources and information necessary for the implementation, monitoring and measurement of processes;

三 Take necessary measures to obtain the results achieved by the process and to maintain the effectiveness of the process.

四 In addition to monitoring the process, if it is necessary to grasp quantitatively, measure and analyze it together.

五 Create and maintain records necessary to demonstrate compliance with the

requirements related to the provisions of laws and regulations.

(Management and Supervision of Quality Management and Supervision System)

Article 5-4 (1) the manufacturer, etc. shall control and supervise the process in accordance with the provisions of this Chapter.

2 When the manufacturer, etc. intends to change the process, the manufacturer, etc. shall confirm the following matters in advance:

The impact of this change on the quality control supervisory system

(II) the effect of said change on the function, performance and safety of medical devices, etc. pertaining to the product according to the intended use

三 Application, notification, report, submission and other procedures required for such change

(Outsourcing)

Article 5-5 (1) when a manufacturer, etc. has decided to outsource a process that affects conformity to product requirements, the business operator to which said process is to be outsourced (hereinafter referred to as a "entrusted Business Operator" in this Article). It must be managed by the .

(2) the manufacturer, etc. shall manage the process set forth in the preceding paragraph by a method corresponding to the risks related to the product and the capabilities of the entrusted business operator.

(3) when the manufacturer, etc. has agreed with the entrusted business operator on the method of controlling the process set forth in paragraph (1), the manufacturer, etc. shall set forth the agreed contents in the implementation guidelines for quality. However, among general medical devices, medical devices other than those designated by the Minister of Health, Labour and Welfare as those requiring care in production control or quality control (hereinafter referred to as "limited general medical devices") This shall not apply to the process concerned.

(Use of Software)

Article 5-6 (1) a manufacturer, etc. (meaning a manufacturer and seller who manufactures and sells limited type 3 medical devices only) The same shall apply hereinafter.) Except for. The same shall apply hereinafter in this Article.) If the software is used in a quality management supervisory system, the shall document the procedures for validation of the application of the software.

2 When the manufacturer, etc. uses the software set forth in the preceding paragraph for the first time or changes the software or its application, the manufacturer, etc. shall perform validation in advance. However, if it is possible to indicate a justifiable reason for not requiring validation prior to a change in the software or its application, it shall be sufficient to validate the software after a change in the software or its application.

3 When conducting the validation prescribed in the preceding paragraph, the manufacturer, etc. shall be responsible for the risks associated with the use of software for the quality control supervision system (including the effects of the use of said software on the functions, performance and safety of medical devices, etc.

pertaining to the product). Validation must be performed accordingly.

4 The manufacturer, etc. shall prepare and retain the records obtained from the validation set forth in paragraph (2).

(Documentation of Quality Control and Supervision System)

Article 6 (1) a manufacturer, etc. may, in a quality control supervision document, include the following matters (excluding item (I) in the case of a limited Type III medical device manufacturer and seller): Must be noted.

(I) Quality Policy and Quality Objectives

二 Standards for quality control supervisory systems

(III) the procedures and records prescribed in this Chapter

四 Matters necessary for ensuring effective and planned implementation and management of processes at each facility (including records of such implementation and management)

五 Other matters that are required to be documented in accordance with the provisions of laws and regulations

(Standard Statement for Quality Management and Supervision System)

Article 7 (1) the manufacturer, etc. shall document the Standard Statement for Quality Control and Supervision System containing the following matters:

一 Scope of the Quality Management Supervision System (where there are matters to be excluded or not applicable, details of such matters and the justification thereof)

二 A procedure document prepared for the quality control supervisory system (a document describing established procedures). The same shall apply hereinafter.) The contents of the document or the document number or other reference information of the said procedure

(III) the mutual relationship of each process

(2) manufacturers, etc. (excluding limited Type III medical device manufacturers and sellers) The Quality Control and Supervision System Standards shall provide an overview of the system of Quality Control and Supervision Documents.

(Product Standards)

Article 7-2 (1) a manufacturer, etc. may, for each product or similar product group, make the following matters pertaining to the quality control supervision system (excluding item (v) or item (vi) when there are justifiable grounds): (The "Product Standards"). And store it.

General names and marketing names of medical devices, etc. related to said products or similar product groups or generic names, intended uses, and indications

(II) the specifications of the product or the product pertaining to said similar Product Group

三 Methods for the manufacture, storage, handling and service of such products or products related to such similar product groups

(IV) Procedures pertaining to the measurement and monitoring of said products or products pertaining to said similar product groups

(V) Requirements pertaining to the installation of products

六 Business pertaining to services incidental to the supply of products (hereinafter referred to as "incidental service business") Requirements related to

(Management of Quality Control and Supervision Documents)

Article 8 (1) a manufacturer, etc. shall manage quality control and supervision documents.

2 The manufacturer, etc. shall state the management methods necessary for the following operations in the procedure manual:

一 When issuing a quality control supervision document, review the validity of the quality control supervision document and approve its issuance.

二 Review the necessary quality control supervision documents and approve the updates when updating them.

三 It should be possible to identify the contents of changes and the latest revision status of quality control supervision documents.

四 If the quality control supervision document is revised, the revised version of the quality control supervision document shall be made available.

五 Quality Control Supervision ensure that documents are easy to read and easy to understand.

(VI) Quality control and supervision documents prepared externally (limited to those deemed necessary for planning and implementing the quality control and supervision system); To identify and manage their delivery.

七 To prevent deterioration or loss of quality control supervision documents.

八 To prevent unintended use of obsolete quality control supervision documents. If the document is retained, regardless of its purpose, it shall be appropriately identified as being obsolete.

3 Manufacturers, etc. (excluding limited Type III medical device manufacturers and sellers) In making changes to the QC Supervisory Document, the Company shall review the changes to the QC Supervisory Document by the department that first approved the QC Supervisory Document or any other previously designated department that is in a position to obtain the information on which the decision on such change is based; The approval of the relevant department must be obtained.

4 The manufacturer, etc. shall retain at least a part of the Quality Control and Supervision Document or a copy thereof for the period specified in Article 67.

(Management of Records)

Article 9 (1) the manufacturer, etc. shall prepare and retain records necessary for demonstrating compliance with the requirements prescribed in this Chapter and the effective implementation of the quality control and supervision system.

(2) the manufacturer, etc. shall identify, retain, and secure the records set forth in the preceding paragraph (with regard to said records, leaks, Prevention of loss or damage and other safety management) , Ensuring integrity

(This means keeping the record accurate and without inappropriate alteration from the time the record was created.) Procedures for retrieval, retention periods and required management of disposal shall be documented.

3 The manufacturer, etc. shall not possess personal information (limited to that obtained through the use of medical devices, etc.). Hereinafter the same shall apply in this paragraph.) The Company shall establish methods for the proper management of personal information and manage personal information in accordance with such methods.

4 The manufacturer, etc. shall make it easy to understand the contents of the record set forth in paragraph (1) in an easy-to-read and searchable manner.

5 The manufacturer, etc. shall retain the record set forth in paragraph (1) for the period specified in Article 68.

Section 3 Responsibilities of Management Supervisors

(Involvement of Management Supervisors)

Article 10 (1) a management supervisor shall be responsible for the establishment and implementation of a quality control supervision system and the maintenance of its effectiveness in the following business (limited to the business listed in items (I) and (v) in the case of a management supervisor of a limited Type III medical device manufacturer): It must be demonstrated by doing so.

— Provisions of laws and regulations, etc., and matters required by the product recipient (hereinafter referred to as "Product Recipient Requirements") (Limited to the provisions of laws and regulations, etc. in the case of a Management Supervisor of a Limited Type 3 Medical Device manufacturer) Make all facilities aware of the importance of compliance.

(II) establishing a quality policy.

三 Ensure that quality targets are set.

四 To carry out the verification prescribed in Article 18, paragraph (1).

五 Ensure a system in which resources can be used.

(Emphasis on Product Recipients)

Article 11 (1) a management supervisor (excluding a management supervisor of a limited Type 3 medical device manufacturer). The same shall apply in the following Article to Article 14, Article 16, Article 18 and Article 19) The provisions of applicable laws and regulations and product recipient requirements shall be clarified and ensure that the product conforms to them.

(Quality Policy)

Article 12 (1) a management supervisor shall ensure that the quality policy conforms to the following conditions:

It is appropriate in light of the intentions of the manufacturer, etc.

二 It is stipulated that management supervisors shall be responsible for complying with the requirements of the quality management supervision system and maintaining the effectiveness of the quality management supervision system.

三 It should serve as a framework for the formulation and verification of quality targets.

四 All facilities must be informed and understood.

五　Reviewed to maintain the appropriateness of the quality control supervisory system.

(Quality goal)

Article 13 (1) Management supervisors shall, at each facility, set quality targets for each department and each level (including targets necessary for conforming to product requirements). It shall be as prescribed.

2 The quality targets set forth in the preceding paragraph shall be consistent with the quality policy and shall be able to evaluate the status of achievement thereof.

(Formulation of Plan for Quality Control and Supervision System)

Article 14 (1) a control supervisor shall ensure that a plan for the implementation of the quality control and supervision system conforms to the provisions of Articles 5 to 5-6, as well as quality targets.

2 When planning and implementing changes to the quality control supervisory system, supervisors shall maintain that the quality control supervisory system is flawless.

(Responsibility and Authority)

Article 15 (1) Management supervisors shall ensure that the responsibilities and powers of each department and its members are specified, documented and made known at all facilities.

(2) Management supervisors shall establish mutual relationships with all persons who manage, supervise, implement or verify operations that affect quality, and The independence necessary to perform such duties shall be ensured and the necessary responsibilities and authority shall be granted.

(Person responsible for Management)

Article 16 (1) a management supervisor shall be a person responsible for the implementation and maintenance of the quality control supervision system of a manufacturer, etc. (hereinafter referred to as the "manager responsible person") from among officers, persons in managerial positions of a manufacturer, etc. and other persons equivalent thereto. Shall be appointed.

(2) a management supervisor shall grant the management responsible person responsibility and authority for the following operations:

Ensure that processes are established, documented, implemented and maintained, and that their effectiveness is maintained.

(II) the effectiveness of the quality management and supervision system and the need for improvement shall be reported to the management and supervisors.

(III) to improve awareness of the provisions of laws and regulations and requirements related to the quality management and supervision system at all facilities.

(Internal Information Transmission)

Article 17 (1) Management and supervisors shall establish a mechanism for the appropriate transmission of information within and between each facility, and shall ensure that information concerning the effectiveness of the quality management and supervision system is exchanged reliably.

(Management Supervisor Verification)

Article 18 (1) a manufacturer, etc. shall, with regard to the quality management supervision system, review (quality management supervision system (including quality policy and quality targets) for the purpose of confirming the maintenance of its appropriateness, adequacy and effectiveness. This includes assessing the need for improvements or changes. Hereinafter referred to as "Management Supervisor Verification") Procedures shall be documented.

2 In accordance with the procedures documented in the preceding paragraph, the supervisors shall carry out inspections at predetermined intervals.

3 The manufacturer, etc. shall prepare and keep a record of the results of the inspection by the supervisors.

(Process Input Information pertaining to Management Supervisor Verification)

Article 19 (1) a management supervisor shall use the following information as process input information for the management supervisor verification:

Comments from product recipients and suppliers

(II) Complaints handling

(III) the Minister of Health, Labour and Welfare, prefectural governors, or the Order for Enforcement of the Act on Securing Quality, Effectiveness and Safety of Pharmaceuticals, Medical Devices, etc. (Cabinet Order No. 11 of 1961; Hereinafter referred to as 'Ryo.') Notice to the holder of permission to manufacture and sell medical devices, etc. prescribed in Article 3-23

(IV) an audit

(V) Monitoring and measurement of processes

六 Products (excluding products pertaining to limited general medical devices) Monitoring and Measurement

七 Corrective measures (non-conformity (meaning non-conformity to the requirements, etc. prescribed in this Ministerial Ordinance). The same shall apply hereinafter.) Means measures to eliminate the cause of non-conformity in order to prevent recurrence. The same shall apply hereinafter.)

八 Preventive measures (means measures to eliminate the cause of a possible non-conformity in order to prevent the occurrence of such non-conformity. The same shall apply hereinafter.)

(IX) Measures taken in response to the results of previous management and supervisor inspections

＋ changes that may affect the quality control supervisory system

(XI) Proposals for improvement from departments, members, etc.

Provisions, etc. of newly established or amended laws and regulations after the previous management and supervisory review

(Process Output Information pertaining to Management Supervisor Verification)

Article 20 (1) a manufacturer, etc. may, with regard to the process input information used for the management supervisor verification and the following matters obtained from the management supervisor verification (excluding the matters listed in item (II) in the case of products pertaining to limited general medical devices): And take the

necessary measures.

(I) Improvement necessary to maintain the appropriateness, adequacy and effectiveness of the quality management and supervision system and processes

(II) the improvement of the product in relation to the product recipient requirements

(III) Response to the provisions of laws and regulations that have been newly established or revised after the previous management and supervisory inspection

(IV) necessary resources provided for in the following Article

Section 4 Management and Supervision of Resources

(Securing Resources)

Article 21 (1) a manufacturer, etc. shall clarify and secure the resources necessary for the following operations:

— Implement a quality control supervisory system and maintain its effectiveness.

(II) the provisions of laws and regulations, etc. and product recipient requirements (limited to the provisions, etc. of laws and regulations in the case of a limited Type III medical device manufacturer and seller); Conform to the.

(Competence of Quality workers)

Article 22 (1) a manufacturer, etc. shall ensure that all persons engaged in operations that affect the quality of products have the capacity necessary for such operations, based on appropriate education and training, skills and experience.

(2) the manufacturer, etc. shall document the processes pertaining to the implementation of appropriate education and training for its members and the firm recognition of its members of operations that affect the quality of its products.

(Ability, Recognition and Educational Training)

Article 23 (1) a manufacturer, etc. shall carry out the following duties (in the case of a limited Type III Medical Device manufacturer, excluding the duties listed in item (III)): Must be done.

To clarify what abilities are necessary for those engaged in operations that affect the quality of products.

二 Implementation of education and training or other measures in order to acquire or maintain the capabilities set forth in the preceding item.

三 To evaluate the effectiveness of the measures referred to in the preceding item.

四 Ensure that all members are aware of the meaning and importance of their work and how they can contribute to the achievement of quality targets.

(V) to prepare and keep appropriate records on the education and training, skills and experience of its members.

(Business Operations Foundation)

Article 24 (1) a manufacturer, etc. may, in order to achieve conformity to product requirements, prevent product confusion, and ensure the appropriate handling of products (including the following facilities or services in cases where such facilities or services are possessed or implemented: The same shall apply hereinafter in this paragraph.) The requirements shall be documented. However, it shall be sufficient for

a limited Type 3 medical device manufacturer to clarify, secure, and maintain the following operational foundations necessary to achieve compliance with the product requirements:

Buildings and working rooms of each facility and water and other equipment attached thereto

(D) Equipment (including software) pertaining to the Process

(III) in addition to what is listed in the preceding two items, services that support compliance with product requirements related to transportation, information transmission, etc., prevention of product confusion, and securing appropriate handling of products

2 In the event that maintenance work or lack thereof is likely to affect the quality of the product, the manufacturer, etc. shall, in accordance with the requirements pertaining to said maintenance work (including the requirements pertaining to the interval between the implementation of said maintenance work, the management of the manufacturing, working environment, In cases where equipment pertaining to monitoring and measurement is used, it shall be the requirements pertaining to said equipment.) (2) and document the appropriate operation in relation to the requirements. However, for a limited Type 3 medical device manufacturer and distributor, it shall be sufficient to establish appropriate operation of the maintenance work and to document it.

3 Manufacturers, etc. (excluding limited Type III medical device manufacturers and sellers) The shall prepare and retain records pertaining to the maintenance of the business foundation.

(Working Environment)

Article 25 (1) a manufacturer, etc. (excluding a limited Type 3 Medical Device manufacturer and Seller) Hereinafter the same shall apply in this Article to Article 36-2.) Products (excluding products pertaining to limited general medical devices).

Hereinafter the same shall apply in this Article to Article 36-2.) The requirements of the working environment necessary to comply with the product requirements shall be documented and supervised.

(2) with regard to processes in which the working environment is likely to adversely affect the quality of products, the manufacturer, etc. shall clarify the requirements pertaining to said working environment, establish appropriate operation pertaining to said requirements, and monitor said working environment; Procedures for management must be documented. However, this shall not apply to the process prior to the purification process where the product is purified pursuant to the provision of Article 4, paragraph (1), item (I) or item (II).

(3) with regard to processes in which contact between a member and the product, etc. or the working environment is likely to adversely affect the function, performance, and safety of the intended use of the medical device, etc. pertaining to the said product, the manufacturer, etc. shall clarify the requirements for the health condition, degree of cleanliness, and work clothing, etc. of the member, and The appropriate operation

for such requirements shall be documented. However, in the case where the product is purified pursuant to the provisions of Article 41, paragraph (1), item (I) or item (II), this shall not apply to the process prior to the purifying process.

4 The manufacturer, etc. shall ensure that all members who are required to work temporarily under the conditions of a special working environment receive the education and training prescribed in item (II) of Article 23, and that they have the capabilities necessary for their work. Provided, however, that this shall not apply in cases where a member who has received the education and training prescribed in the same item and who has secured the ability necessary for the work is to supervise other members.

(Pollution Control)

Article 25-2 (1) in order to prevent contamination of other products, etc., the working environment or members, a manufacturer, etc. may manage contaminated or potentially contaminated products, etc. (including identification pursuant to the provisions of Article 47, paragraph (1)). Hereinafter referred to as "Pollution Control" in this paragraph) Implementation procedures for pollution control shall be formulated and documented, except where there is no need to do so.

2 The manufacturer, etc. shall be deemed to be sterilized medical devices, etc. (meaning medical devices, etc. sterilized in the manufacturing process) by foreign substances or microorganisms. The same shall apply hereinafter.) The requirements for controlling the prevention of pollution shall be documented, and the degree of cleanliness in the assembly or packaging process of the product shall be maintained and controlled.

Section 5 Product Realization

(Product Realization Plan)

Article 26 (1) a manufacturer, etc. shall plan the processes necessary for realizing a product (hereinafter referred to as a "product realization plan"). In addition, it must be established.

(2) the manufacturer, etc. shall ensure consistency between the product realization plan and the requirements for processes other than those necessary for product realization.

3 Manufacturers, etc. shall clarify the requirements for product risk management in all processes related to product realization, establish appropriate operation, and document them.

4 The manufacturer, etc. shall prepare and retain records pertaining to the risk management set forth in the preceding paragraph.

5 When formulating a product realization plan, the manufacturer, etc. shall clarify the following matters. However, this shall not apply to such matters that are not applicable due to the characteristics of the product or process.

Quality targets and product requirements for the product concerned

二 Processes specific to the product (including business operation infrastructure and work environment) The need to develop documents related to the process and to

secure the resources required for the process

(III) required verification, validation, monitoring, measurement, test and inspection; Handling, storage, distribution, and traceability (meaning a state in which history, application, or location can be traced). The same shall apply hereinafter.) Operations specific to the said product, standards for permitting progress to the next stage of the process, and standards for deciding whether or not to ship the product (hereinafter referred to as "standards for deciding whether or not to ship the product")

(IV) Records necessary to verify that the process pertaining to the realization of the product and the resulting product conform to the product requirements

6 The manufacturer, etc. shall document the product realization plan in a format appropriate to the implementation of the product realization plan.

(Clarification of Product Requirements)

Article 27 (1) a manufacturer, etc. shall clarify the following matters as product requirements:

- Product recipient requirements pertaining to said product (including requirements pertaining to the delivery of the product to the product recipient and the business after the product recipient has received the product)

二 Requirements that are not specified by the product recipient, but are required by the product recipient in advance, or for the intended use of the product, and are known to the manufacturer, etc.

三 Among the provisions of laws and regulations, those related to the said product

(IV) Requirements pertaining to education and training for users necessary for the safe and appropriate use or operation of medical devices, etc. pertaining to said products

五 Other requirements related to the product that the manufacturer, etc. deems necessary

(Review of Product Requirements)

Article 28 (1) a manufacturer, etc. shall conduct a review of product requirements in advance when supplying products.

2 In carrying out the verification set forth in the preceding paragraph, the manufacturer, etc. shall confirm the following matters:

Product requirements for the relevant product have been established and documented.

(II) in cases where the requirements in an agreement with the product recipient or instructions from the product recipient differ from those previously presented, it has been agreed with the product recipient on such differences.

三 Conforms to the provisions of laws and regulations.

四 The education and training set forth in item (iv) of the preceding Article shall be available or planned to be available to employers.

(V) each facility shall have the capability to conform to the specified requirements.

3 The manufacturer, etc. shall prepare and retain a record pertaining to the results of

the inspection set forth in paragraph (1) and a record pertaining to measures taken based on the results of said inspection.

4 If the product recipient does not indicate the requirements in writing, the manufacturer, etc. shall confirm the contents of the product recipient requirements in advance before accepting the requirements.

5 In the event that product requirements are changed, the manufacturer, etc. shall ensure that the relevant documents are revised, and that the relevant members are made aware of and understand the revised product requirements.

(Exchange of Information, etc.)

Article 29 (1) a manufacturer, etc. shall formulate and document implementation guidelines for the mutual exchange of information and opinions with product recipients concerning the following matters:

- Product information

二 Handling of inquiries, contracts and orders, including changes thereto.

三 Feedback from the recipient of the product, including complaints.

(IV) written notice prescribed in Article 60-3, paragraph (2)

2 The manufacturer, etc. shall, in accordance with the provisions of laws and regulations, communicate with the Minister of Health, Labour and Welfare, prefectural governors, or the investigator of the conformity assessment of medical devices, etc. prescribed in Article 307-23 of the Order for the exchange of information and opinions.

(Design and Development)

Article 30 (1) a manufacturer, etc. shall document procedures for the design and development of products.

2 The manufacturer, etc. shall make a design and development plan (hereinafter referred to as the "design and development plan"). In addition, design and development must be managed.

3 The manufacturer, etc. shall document and keep the design and development plan, and update it as the design and development progresses if it is necessary to change the design and development plan.

4 In formulating a design and development plan, the manufacturer, etc. shall document the following matters:

- Design and development phase

(II) appropriate review at each stage of design and development

(III) appropriate verification, validation, and design transfer work at each stage of design and development (meaning work to make specifications pertaining to the manufacturing process after verifying in advance whether process output information from design and development is suitable for actual manufacturing); The same shall apply hereinafter.)

(IV) Responsibility and authority of the department or members pertaining to design and development

(V) method to ensure traceability from process input information to process output information in design and development 6. Resources necessary for design and

development

(Process Input Information for Design and Development)

Article 31 (1) in the case of design and development, the manufacturer, etc. shall clarify the process input information for the following design and development related to the product requirements, and shall prepare and retain records related to said process input information:

Product requirements related to function, performance, usability, and safety according to the intended application

二　Requirements based on the provisions of laws and regulations

三　Requirements for process output information pertaining to risk management prescribed in Article 26, paragraph (3)

四 Requirements that are obtained from design and development similar to the previous design and development and that can be applied as process input information to the design and development

(V) other requirements essential for design and development

2 The manufacturer, etc. shall review and approve the appropriateness of the process input information for design and development prescribed in the preceding paragraph.

3 The manufacturer, etc. shall, with regard to the requirements listed in the items of paragraph (1), be free of omissions and not ambiguous, and We must try not to contradict each other.

(Process Output Information from Design and Development)

Article 32 (1) a manufacturer, etc. shall satisfy the following conditions with regard to process output information from design and development:

It conforms to the requirements related to process input information for design and development.

二　Provide appropriate information for purchasing, manufacturing, and provision of services.

三　Must include criteria for deciding whether to ship or not, or be able to refer to the criteria for deciding whether to ship or not.

(IV) the characteristics of the product that are indispensable for the safe and appropriate use or operation of the product are specified.

2 The manufacturer, etc. shall make the process output information from design and development into a format suitable for verification against the process input information to design and development.

3 In order to allow the process to proceed from design and development to the next stage of the process, the manufacturer, etc. shall, in advance, approve the process output information from the design and development.

4 Manufacturers, etc. shall create and keep records of process output information from design and development.

(Design and Development Verification)

Article 33 (1) a manufacturer, etc. shall conduct a systematic reference pertaining to design and development for the purposes of the following matters (hereinafter

referred to as "design and development review"): The design and development review shall be carried out in accordance with the design and development plan and the relevant implementation guidelines at the appropriate stage.

To evaluate whether the results of design and development can meet all requirements.

二　If there is a problem in design and development, make it possible to identify the content of the problem and propose necessary measures.

(2) the manufacturer, etc. shall have the representatives of the departments related to the design and development stage subject to the design and development review and experts pertaining to the design and development review participate in the design and development review.

(3) a manufacturer, etc. shall record the results of the design and development review and all necessary measures based on the results (including information on the design and development, participants, and the implementation date subject to said design and development review). Must be created and stored.

(Verification of Design and Development)

Article 34 (1) in order to ensure that process output information from design and development conforms to the requirements pertaining to process input information for design and development, a manufacturer, etc. shall establish in documents the implementation guidelines necessary for verifying design and development, and verify said design and development in accordance with the design and development plan and said implementation guidelines (hereinafter referred to as "design and development verification" in this Article). Must be carried out.

2 The manufacturer, etc. shall make a plan pertaining to design and development verification (method of design and development verification (in the case where statistical methods are used for design and development verification, including the basis for setting the number of samples). And evaluation criteria.) Must be documented.

(3) where the medical device, etc. pertaining to the product subject to design and development verification is a medical device, etc. that is used or operated in an integrated manner with other machinery and equipment, etc., the manufacturer, etc. shall carry out the design and development verification while maintaining the state in which the product is used or operated in an integrated manner.

4 The manufacturer, etc. shall record the results and conclusions of the design and development verification (in the case where necessary measures have been taken based on said results and conclusions, such records shall be included). Must be created and stored.

(Design and Development Validation) Article 35 (1) a manufacturer or seller, etc. shall validate the design and development (hereinafter referred to as "Design and Development Validation" in this Article) in order to conform the design and development product to the requirements for the pre-defined function or performance or intended use. The design and development validation must be carried out in

accordance with the design and development plan and the relevant implementation guidelines.

2 The manufacturer, etc. shall make a plan pertaining to design and development validation (design and development validation method (in the case where statistical methods are used for design and development validation, the basis for setting the number of samples shall be included). And evaluation criteria.) Must be documented.

3 A manufacturer, etc. shall, when designing and developing products (limited to those representing the products) selected from the products for which the manufacturer, etc. has designed and developed Design and development validation must be carried out.

4 A manufacturer, etc. shall make a group of medical devices, etc. and lots (including those equivalent thereto) pertaining to the initial manufacture. In addition to the selection of the products set forth in the preceding paragraph, a record of the basis for the selection shall be made and retained.

5 When the medical device, etc. pertaining to design and development is a medical device, etc. specified by an Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 23-2-5, paragraph (3) of the Act or a medical device, etc. specified by an Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 23-2-9, paragraph (4) of the Act, the manufacturer, etc. shall collect and prepare materials based on these provisions as part of the design and development.

6 In the case where the medical devices, etc. pertaining to design and development are medical devices, etc. specified by an Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 23-2-5, paragraph (3) of the Act, the service of the products pertaining to the medical devices, etc. pertaining to said design and development conducted by the manufacturer, etc. for the purpose of collecting and preparing said materials shall not be deemed to be shipment of the product.

7 If the medical device, etc. pertaining to the product subject to design and development validation is a medical device, etc. that is used or operated in an integrated manner with other machinery and equipment, the manufacturer, etc. shall carry out the design and development validation while maintaining the state in which the product is used or operated in an integrated manner.

8 The manufacturer, etc. shall complete the design and development validation in advance before shipping the product. However, if the design and development validation cannot be performed only after the assembly or installation of the medical device related to the product during use, the design and development validation must be performed prior to delivery to the product recipient using the said medical device.

9 The manufacturer, etc. shall record the results and conclusions of the Design and Development Validation (in cases where necessary measures have been taken based on said results and conclusions, such records shall be included). Must be created and stored.

(Design Transfer Services)

Article 35-2 (1) a manufacturer, etc. shall carry out design transfer operations (including

the following operations): Procedures shall be documented.

Before deciding the specifications for the manufacturing process, confirm that the process output information from design and development is appropriately verified to match the actual manufacturing.

二 By going through the manufacturing process described in the preceding item, a conforming product (a product that conforms to the product requirements) is required. The same shall apply hereinafter.) Make sure that the can be manufactured correctly.

2 When a manufacturer, etc. has carried out a design transfer operation, the manufacturer, etc. shall record the results and conclusions thereof and retain them.

(Management of changes in Design and Development)

Article 36 (1) a manufacturer, etc. shall document procedures for alterations in design and development.

(2) when implementing a design and development change, the manufacturer, etc. shall verify the existence and extent of the impact of said change on the function, performance, safety and usability according to the intended use of the medical device, etc., as well as the conformity of the provisions of laws and regulations.

3 Manufacturers, etc. shall identify design and development changes.

4 When implementing design and development changes, the manufacturer, etc. shall, in advance, review, verify, and Validation and approval must be carried out. However, this shall not apply if there is a justifiable reason for not performing validation.

5 The manufacturer, etc. shall, when the scope of the inspection set forth in the preceding paragraph is changed, the change in design and development, the component parts, etc., the products in the process, It shall include an assessment of the product already delivered, process input or output information related to risk management, and the impact on the process related to product realization.

(6) a manufacturer, etc. shall create and retain records pertaining to changes in design and development, verification of said changes, and necessary measures.

(Record Book pertaining to Design and Development)

Article 36-2 (1) a manufacturer, etc. shall, for each product or similar product group, prepare and retain a record book pertaining to a record certifying conformity to the requirements pertaining to design and development, a record of changes in design and development, and a record book pertaining to the materials referenced in design and development.

(Purchasing Process)

Article 37 (1) a manufacturer, etc. may, when purchasing goods, etc. have requirements pertaining to purchase goods, etc. prescribed by the manufacturer, etc. (hereinafter referred to as "requirements for purchase goods, etc.") Procedures to ensure compliance with the must be documented.

2 Manufacturers, etc. shall establish criteria for the evaluation and selection of suppliers of purchased Goods, etc., taking into consideration the following matters, and shall evaluate and select suppliers in accordance with such criteria. However, in

the case of a limited Type III medical device manufacturer and seller, the Purchase Goods, etc. shall be transferred to the process or final product (meaning products other than intermediate products) pertaining to the subsequent realization of the product. It shall be sufficient to establish standards for the evaluation of suppliers of such purchased goods, etc., and to evaluate such suppliers in accordance with such standards.

The ability to supply purchased goods, etc. that conform to the requirements of purchased goods, etc.

(II) actual results related to the supply of purchased Goods, etc.

(III) influence of purchased Goods, etc. on the quality of products

四　Risks related to the function, performance, and safety of medical devices, etc. according to the intended use

3 The manufacturer, etc. shall formulate a plan pertaining to the monitoring and reevaluation of suppliers of purchased goods, etc. (and, in the case of suppliers of purchased goods, etc. of products pertaining to limited general medical devices, reevaluation).

4 The manufacturer, etc. shall, based on the plan set forth in the preceding paragraph, monitor the supplier's performance in supplying the purchased Goods, etc. and reevaluate the supplier, taking into account the results of such monitoring. However, for suppliers of purchased goods, etc. of products related to limited general medical devices, it shall be sufficient to reevaluate such suppliers.

5 If it is found that the purchased goods, etc. supplied do not conform to the requirements for the purchased goods, etc., it is necessary to cooperate with the supplier according to the risk of such non-conformity

Measures shall be taken.

(6) a manufacturer, etc. shall be limited to records pertaining to the evaluation and selection set forth in paragraph (2) and the results of the monitoring and reevaluation set forth in paragraph (3) (in cases where necessary measures are taken based on the results of the evaluation and selection set forth in paragraph (2) and the monitoring and reevaluation set forth in paragraph (3), such records shall be included, and in the case of a limited to records pertaining to the limited to the results of the evaluation set forth in paragraph (3)). Must be created and stored.

(Purchasing Information)

Article 38 (1) a manufacturer, etc. may provide information on purchased Goods, etc. (hereinafter referred to as "Purchasing Information"). In addition, the following requirements for purchased goods, etc. must be included in the purchase information. However, this shall not apply to the requirements for purchased goods, etc. that are not applicable due to the characteristics of the purchased goods, etc.

— Specifications of purchased goods, etc.

(II) Requirements pertaining to the acceptance of purchased Goods, etc., procedures, processes, and equipment and apparatus at the place of business of the supplier of purchased Goods, etc.

(III) Requirements pertaining to confirmation of the eligibility of members of suppliers

of purchased Goods, etc.

(IV) Requirements pertaining to the quality control and supervision system of suppliers of purchased goods, etc.

(2) in presenting the requirements for purchased goods, etc. to the supplier of purchased goods, etc., a manufacturer, etc. shall confirm the appropriateness of the requirements for purchased goods, etc. in advance.

3 In addition to the requirements for purchased goods, etc., manufacturers, etc. shall include in the purchase information the contents agreed in writing that the supplier notifies the said manufacturer, etc. in advance of changes that affect the conformity with the requirements for purchased goods, etc.

4 Manufacturers, etc. (excluding limited Type III medical device manufacturers and sellers) The shall prepare and retain documents and records containing the relevant purchase information in accordance with the matters prescribed in the procedure manual pursuant to the provisions of Article 48, paragraph (2). However, this shall not apply to products pertaining to limited general medical devices.

(Verification of purchased Goods, etc.)

Article 39 (1) a manufacturer, etc. shall establish and implement procedures pertaining to test inspections and other verification in order to ensure that purchased goods, etc. conform to the requirements for purchased goods, etc. In this case, the manufacturer, etc. shall determine the scope of verification according to the risks related to the purchased Goods, etc., based on the results of the supplier's evaluation.

(2) the manufacturer, etc. shall, when altering the purchased Goods, etc., verify the effect of the alteration on the processes pertaining to product realization or on medical devices, etc.

(3) when a manufacturer, etc. or a related product recipient decides to conduct a verification of purchased Goods, etc. at the place of business of a supplier of purchased Goods, etc., the manufacturer, etc. shall clarify the method of such verification and the method of determining whether or not to ship the purchased Goods, etc. from the supplier in the Purchasing Information.

4 The manufacturer, etc. shall prepare a record of verification of purchased goods, etc. and keep it.

(Management of Manufacturing and Service Provision)

Article 40 (1) a manufacturer, etc. (excluding a limited Type 3 Medical Device manufacturer and Seller) The same shall apply in paragraph (3).) Products (excluding products pertaining to limited general medical devices). The same shall apply in paragraph (3)) With regard to the manufacture and provision of services, a plan shall be developed to conform the products to the requirements related to the specifications of the products, and shall be implemented, monitored and managed under the following conditions and other appropriate conditions. However, this shall not apply to cases where it is possible to demonstrate that it is appropriate to implement, monitor and manage under conditions other than the aforementioned conditions.

A manufacturing procedure manual and a document that specifies the manufacturing management method must be available.

二 A business operation foundation commensurate with the manufacture of the said products and the provision of services shall be established.

三 Monitoring and measurement of process index values and product characteristics.

四 Equipment and instruments for monitoring and measuring shall be available and such equipment and instruments shall be used.

五 Work related to packaging and labeling specified in procedures and documents describing requirements must be carried out.

六 In accordance with the provisions of this Ministerial Ordinance, the approval to proceed to the next stage of the process, the decision to ship to the market, the delivery of the product to the product recipient, and the operation after the product recipient has received the product.

2 The manufacturer, etc. shall be responsible for each lot of the product (for products that do not constitute a lot, the said product). The same shall apply hereinafter.) In accordance with the provisions of Article 48, paragraph (2), a record that enables traceability within the scope specified in the procedure manual shall be prepared and retained so that the quantity of manufactured and the quantity determined to be shipped can be identified. However, for products pertaining to limited general medical devices, it shall be sufficient to create a record for each lot of the product so that the quantity manufactured and the quantity decided to be shipped can be identified, and keep this record.

3 The manufacturer, etc. shall verify and approve the record for each lot of products prepared pursuant to the provisions of the preceding paragraph.

(Cleanliness Management of Products)

Article 41 (1) a manufacturer, etc. (excluding a limited Type 3 Medical Device manufacturer and Seller) Hereinafter the same shall apply in this Article through Article 51 and Article 53) Shall be its products (excluding products related to limited general medical devices). Hereinafter the same shall apply in this Article through Article 51 and Article 53) In any of the following cases, the requirements for cleanliness and pollution control of the product shall be documented.

Before the product is sterilized, used, or operated, the product is purified by the manufacturer, etc. or the person who manufactures the product

二 Supplied unsterilized by the said manufacturer, etc. (including shipment) Before sterilization, use or operation, the user cleans the product

三 It is not possible to clean before sterilization by the manufacturer, etc., or before use or operation by the recipient of the product, but it is important to clean during use or operation

(IV) where the user uses or operates non-sterile, but cleaning during use or operation is important

五 In the case where the manufacturer, etc. intends to remove the manufacturing substance during its manufacture

2 In cases where the manufacturer, etc. carries out the purification set forth in items (I) and (II) of the preceding paragraph, the manufacturer, etc. may not apply the requirements set forth in Article 25, paragraphs (2) and (3) to the process prior to the purification process.

(Establishment Services)

Article 42 (1) a manufacturer, etc. may, pursuant to the Ordinance for Enforcement of the Act on Securing Quality, Effectiveness, and Safety of Pharmaceuticals, Medical Devices, etc. (Ordinance of the Ministry of Health, Labour and Welfare No. 1 of 1961) Hereinafter referred to as "Enforcement regulations") When handling a product or similar medical device as prescribed in Article 114-55, paragraph (1), the requirements including the decision criteria for the installation of the medical device and the verification of the installation shall be clarified, and the appropriate operation pertaining to the said requirements shall be documented, except where it can be shown that it is appropriate to use other methods.

2 In the case referred to in the preceding paragraph, if a person other than the manufacturer, etc. or the person designated by the manufacturer, etc. in advance is permitted to install the medical device and verify the installation, the requirements for the installation and verification of the installation shall be documented and provided to the person conducting the installation and verification of the installation.

3 The manufacturer, etc. shall install the medical device set forth in paragraph (1) that has been implemented and verify said installation (limited to those implemented by the manufacturer, etc. or a person designated in advance by the manufacturer, etc.) A record of the must be created and retained.

(Incidental Service Business)

Article 43 (1) in cases where the implementation of the ancillary service business is a pre-determined requirement, the manufacturer, etc. shall document a system pertaining to the procedure for the implementation of said business and verification of conformity with said requirements. If necessary, reference samples and measurement procedures should also be documented.

2 A manufacturer, etc. shall, in order to achieve the following objectives, carry out incidental service operations (including incidental service operations carried out by other parties): Records must be analyzed.

To determine whether the feedback from the recipient of the product is a complaint.

(II) Improvement of the quality control and supervision system (including changes prescribed in Article 62); The same shall apply in Article 61, paragraph (3)) (Limited to cases where said improvement is necessary) Of the system.

3 The manufacturer, etc. shall, in the case where the Supplementary Service Business has been performed (including the case where the Supplementary Service Business has been performed by another party) In such cases, a record pertaining to said incidental service business shall be prepared and retained.

(Special Requirements for Manufacturing Management of Sterile Medical Devices, etc.)

Article 44 (1) a manufacturer, etc. that handles sterile medical devices, etc. shall prepare a record of the process indicator value of the sterilization process for each sterilization lot and keep it.

2 The manufacturer, etc. handling sterile medical devices, etc. shall be able to track the records set forth in the preceding paragraph to each production lot of the product.

(Validation of Manufacturing Process, etc.)

Article 45 (1) in cases where, with regard to a process pertaining to the manufacture of products and the provision of services implemented, the manufacturer, etc. is unable to verify the process output information resulting from such process through subsequent monitoring or measurement (including cases where the defect becomes apparent only after the product is used or operated, or the service is provided). Or, if the process output information is not verified, validation must be performed for the process.

(2) the manufacturer, etc. shall demonstrate through validation that the processes subject to validation pursuant to the provisions of the preceding paragraph can obtain the results specified in the Product Realization Plan

It must be.

3 The manufacturer, etc. shall document the validation procedures pertaining to the following matters with respect to the processes subject to validation pursuant to the provisions of paragraph (1) and establish appropriate operation based on the procedures.

- Criteria for review and approval of the process concerned

(II) Approval of equipment and instruments and confirmation of eligibility pertaining to members

(III) methods, procedures and criteria for judgment

四 Statistical methods (limited to cases where statistical methods are used for validation, including the basis for setting the number of samples)

五 Article 9 (excluding paragraph (3)) Requirements related to the records set forth in

六 Re-validation (meaning re-validation in the event of a change in the manufacturing procedure, etc.) The same shall apply hereinafter.)

(VII) Criteria for revalidation

(VIII) Approval of changes to said process

4 When a manufacturer, etc. uses software for manufacturing and providing services, the manufacturer, etc. shall document the validation and revalidation procedures pertaining to the application of the software.

5 When using the software set forth in the preceding paragraph for the first time for the purpose of manufacturing or providing services, or when changing the software or its application, the manufacturer, etc. shall validate the software in advance. However, if it is possible to indicate a justifiable reason for not requiring validation prior to a change in the software or its application, it shall be sufficient to validate the software after the change in the software or its application.

6 The manufacturer, etc. is responsible for the risks associated with the use of software for the manufacture and provision of services (the effects of the use of such software on the functions, performance, and safety of medical devices, etc. pertaining to the product)

Including Hibiki.) The software must be validated and re-validated accordingly.

7 The manufacturer, etc. shall record the results and conclusions of the validation or revalidation prescribed in paragraph (1), paragraph (2), paragraph (5) and the preceding paragraph (in cases where necessary measures have been taken based on said results and conclusions, such records shall be included). Must be created and stored.

(Validation of Sterilization Process and Process pertaining to Sterile Barrier System)

Article 46 (1) a manufacturer, etc. that handles sterile medical devices, etc. shall document the procedures pertaining to the validation of the sterilization process and the process pertaining to the sterile barrier system.

2 A manufacturer, etc. that handles sterile medical devices, etc. shall perform validation in advance when implementing the sterilization process or the process pertaining to the sterile barrier system for the first time, or when changing the sterile medical devices, etc. or the process concerned. However, this shall not apply in cases where it is possible to indicate justifiable reasons for not requiring validation prior to implementation or change of the process.

3 A manufacturer, etc. that handles sterile medical devices, etc. shall record the results and conclusions of the validation or revalidation of the sterilization process and the process related to the sterile barrier system (including records of the necessary measures based on said results and conclusions). Must be created and stored.

(Identification)

Article 47 (1) a manufacturer, etc. shall document the procedures pertaining to product identification and identify products by appropriate means at all stages pertaining to product realization.

2 At all stages of product realization, the manufacturer, etc. shall identify the condition of the product in light of the requirements for monitoring and measurement.

3 The manufacturer, etc. shall be responsible for the products that have passed the test and inspection (including those for which the decision to ship has been made under the approved special adoption). In order to ensure that only the product is shipped or that the product is used, operated, or installed, Identification shall be made and maintained at all stages of manufacturing, storage, installation and ancillary service operations.

4 The manufacturer, etc. shall document the procedures for ensuring that the products returned to the manufacturer, etc. are clearly identified from the conforming products.

(Securing Traceability)

Article 48 (1) a manufacturer, etc. shall document procedures for ensuring traceability of products and component parts, etc.

2 In the procedures documented pursuant to the provisions of the preceding paragraph,

the manufacturer, etc. shall, based on the provisions of laws and regulations, specify the scope of ensuring traceability and the records to be kept for each product and component part, etc.

(Securing Traceability of Products pertaining to Implantable Medical Devices)

Article 49 (1) where there is a risk that a product pertaining to implanted medical devices will not conform to the product requirements due to component parts, etc. or working environment conditions, the manufacturer, etc. shall record said component parts, etc. and working environment conditions pursuant to paragraph (2) of the preceding Article, and shall ensure traceability of records pertaining to all of these conditions.

(2) in order to ensure traceability of products pertaining to implanted medical devices after shipment, a manufacturer, etc. (meaning a seller or a lender) who handles such products shall, in order to secure the traceability of said products. The same shall apply hereinafter.) The Company shall have the record of the distribution of such products be made and retained.

3 Article 23-2-5, paragraph (7) or (9) of the Act or Article 23-2-6-2, paragraph (2) of the Act (including the cases where it is applied mutatis mutandis pursuant to Article 23-2-8, paragraph (2) of the Act, limited to the part pertaining to the investigation of manufacturing control or quality control methods of medical devices or in vitro diagnostics. The same shall apply in Article 81-2-6, paragraph (3)) Any investigation pursuant to the provisions of Article 23-2-10-2, paragraph (4) of the Act, investigation pursuant to the provisions of Article 23-2-23, paragraph (4) or paragraph (6) of the Act, or an on-site inspection, etc. pursuant to the provisions of paragraph (1), paragraph (4), paragraph (5) or paragraph (6) of Article 69 of the Act, other Minister of Health, Labour and Welfare, When requested by a prefectural governor or an implementer of a conformity survey of medical devices, etc. prescribed in Article 37-23 of the Order, the seller, etc. shall keep the record set forth in the preceding paragraph so that the seller, etc. can present the record set forth in the preceding paragraph.

4 The manufacturer, etc. shall record and retain the name and address (in the case of a juridical person, the name and address) of the consignee of the product pertaining to the implanted medical device.

Article 50 Deletion

(Articles, etc. of Product Recipient)

Article 51 (1) a manufacturer, etc. may, in connection with the goods, etc. (including intellectual property, information, etc. for which the product recipient holds ownership rights) of the goods, etc. of the product recipient that are used or provided for the purpose of incorporating them into the products, etc. Identify, verify, protect, and It must be protected.

(2) where the articles, etc. set forth in the preceding paragraph are lost or damaged, or when the articles, etc. set forth in the preceding paragraph are found to be unsuitable for use, the manufacturer, etc. shall report the contents to the product recipient, and

You must make a record and keep it.

(Retention of Products)

Article 52 (1) a manufacturer, etc. shall maintain conformity (identification, Handling, packaging, storage and protection) The procedure shall be written. However, with regard to products pertaining to limited general medical devices, this shall be limited to the duration of the business in which the manufacturer, etc. is responsible for the said products.

(2) in order to protect products or component parts, etc. from alteration, contamination or damage during the period from manufacture to distribution, a manufacturer, etc. shall take any of the following measures:

Specify the specifications of the packaging or packaging necessary to protect the product, and use the said packaging or packaging.

二 Document the requirements pertaining to special conditions for maintaining conformity of the product (limited to cases where the product or its component parts, etc. cannot be maintained by packaging or packaging). Of the system.

(3) when the special conditions set forth in item (II) of the preceding paragraph are required, the manufacturer, etc. shall manage such conditions and record them. However, this shall not apply to products and component parts, etc. pertaining to limited general medical devices.

(Management of Equipment and Equipment)

Article 53 (1) a manufacturer, etc. shall clarify the monitoring and measurement necessary for demonstrating the conformity of a product to the product requirements, and the equipment and instruments for such monitoring and measurement.

2 The manufacturer, etc. shall document procedures for the monitoring and measurement set forth in the preceding paragraph in a manner that is feasible and consistent with the requirements for such monitoring and measurement.

3 Where necessary to ensure the appropriateness of the results of the monitoring and measurement, the manufacturer, etc. shall ensure that the monitoring and measurement equipment and instruments conform to the following conditions:

— It must be calibrated or verified at predetermined intervals or in a manner that allows traceability to the measurement standard prior to use. However, if the standard does not exist, the basis for the calibration or verification shall be recorded.

二 Necessary adjustments or readjustments have been made and records of these have been prepared and maintained.

三 The status of the calibration must be identified so that the status of the calibration can be clearly identified.

四 It must be protected from actions that invalidate the monitoring and measurement results.

(V) it is protected from damage and deterioration during handling, maintenance and storage.

4 The manufacturer, etc. shall specify the contents of the calibration and verification

in the procedure manual and carry out the calibration and verification in accordance with the said procedure manual.

5 Where it is found that the monitoring and measurement equipment and instruments do not conform to the monitoring and measurement requirements, the manufacturer, etc. shall evaluate and record the appropriateness of the results of the previous monitoring and measurement.

6 In the case referred to in the preceding paragraph, the manufacturer, etc. shall take appropriate measures for the equipment and instruments for the monitoring and measurement and the products affected by the non-conformity set forth in the preceding paragraph.

(7) the manufacturer, etc. shall prepare and keep records of the results of calibration and verification of equipment and instruments for monitoring and measurement.

(8) in cases where a manufacturer, etc. uses software for monitoring and measurement, the manufacturer, etc. shall document the validation procedure pertaining to the application of said software.

9 When using the software set forth in the preceding paragraph for the first time for monitoring or measurement, or when changing the software or its application, the manufacturer, etc. shall perform validation in advance. However, if it is possible to indicate a justifiable reason for not requiring validation prior to a change in the software or its application, it shall be sufficient to validate the software after a change in the software or its application.

10 The manufacturer, etc. shall assume risks associated with the use of software for monitoring and measurement (including the effects of the use of such software on the functions, performance and safety of medical devices, etc. pertaining to the product). The software shall be validated and re-validated as appropriate.

11 The manufacturer, etc. shall record the results and conclusions of the validation prescribed in paragraph (9) (in cases where necessary measures have been taken based on said results and conclusions, such records shall be included) A record of the must be created and retained.

Section 6 Measurement, Analysis and Improvement

(Measurement, Analysis and Improvement)

Article 54 (1) a manufacturer, etc. (excluding a limited Type 3 Medical Device manufacturer and Seller) The same shall apply in the following paragraph and the following Article.) The monitoring, measurement, analysis and improvement necessary for the following operations (referred to as "monitoring, etc." in the following paragraph): A plan shall be formulated and implemented for the process concerned.

- Products (excluding products pertaining to limited general medical devices) To demonstrate the suitability of the.

二 Ensure the conformity of the quality control supervisory system.

三 To maintain the effectiveness of the quality control supervisory system.

2 The manufacturer, etc. shall, in the plan set forth in the preceding paragraph, provide the method of monitoring, etc. applicable to the process prescribed in the preceding paragraph (including statistical methods). And the scope of application of the method shall be stipulated.

(Opinions of Product Recipients)

Article 55 (1) as part of the measurement of the implementation status of the quality control and supervision system, the manufacturer, etc. shall collect and monitor information on whether it conforms to the requirements of the product recipient.

2 The manufacturer, etc. shall document the methods for obtaining and utilizing the information set forth in the preceding paragraph.

3 A mechanism for collecting opinions from product recipients (including a mechanism for collecting data from manufacturing processes) in order to use process input information for product realization and improvement processes, and process input information for risk management to use for monitoring product requirements. Procedures shall be documented.

4 The manufacturer, etc. shall make the information collected pursuant to the provision of Article 68-2-6, paragraph (1) of the Act a part of the mechanism for collecting opinions set forth in the preceding paragraph by reviewing the knowledge gained after the shipment of the product, such as information collected pursuant to the provision of Article 68-2-6, paragraph (1) of the Act.

(Complaint Processing)

Article 55-2 (1) a manufacturer, etc. shall take steps necessary for processing a complaint without delay (including requirements and responsibilities pertaining to implementation of the matters listed below): Must be documented.

Information acquisition and recording

二 Determine if the information from the product recipient is a complaint

(III) complaint investigation

四 Evaluation of the necessity of reporting based on the provisions of Article 68-10, paragraph (1) of the Act and Article 68-11 of the Act

五 Actions taken against the product concerned

六 Correction (means a measure to remove a found non-conformity). The same shall apply hereinafter.) Or assess the need for corrective action

2 If the manufacturer, etc. decides not to investigate the complaint of a product recipient, the manufacturer, etc. shall identify the reason and document the reason.

3 The manufacturer shall document all corrections and corrective actions taken in the handling of the complaint.

4 If, as a result of the investigation of the complaint, the business of all persons other than those involved in the process, including the manufacturer, etc., is related to the complaint of the product recipient, the relevant information shall be communicated to each other with the concerned parties.

5 The manufacturer, etc. shall prepare and retain records pertaining to the processing of complaints.

(Report to the Minister of Health, Labour and Welfare, etc.)

Article 55-3 (1) a manufacturer, etc. shall document procedures pertaining to reports pursuant to the provisions of Article 68-10, paragraph (1) of the Act and Article 68-11 of the Act.

(2) the manufacturer, etc. shall prepare and retain a record of the report pertaining to the provisions of the preceding paragraph.

(Internal Audit)

Article 56 (1) a manufacturer, etc. shall conduct an internal audit at predetermined intervals in order to clarify whether the quality control and supervision system conforms to the following requirements:

一 Implementation guidelines, provisions of laws and regulations, etc., and the relevant quality management supervision system (in the case of products pertaining to limited general medical devices, excluding the product realization plan) It conforms to the requirements related to the above.

二 Implemented and maintained effectively.

(2) the manufacturer, etc. shall document the responsibility for planning, implementation, recording, and audit results of internal audits and the procedures pertaining to these requirements.

(3) the manufacturer, etc. shall formulate an internal audit implementation plan, taking into consideration the status and importance of the processes and areas subject to internal audits and the results of previous audits.

4 Manufacturers, etc. shall specify and record the criteria, scope, frequency and method of internal audits.

5 A manufacturer, etc. shall be a member who conducts internal audits (hereinafter referred to as "internal auditors"). Objectivity and fairness shall be ensured in the selection and implementation of internal audits.

6 Manufacturers, etc. (excluding limited Type III medical device manufacturers and sellers) The Company shall not have an internal auditor conduct an internal audit of its own business.

7 The manufacturer, etc. shall conduct internal audits and the results thereof (including clarification of the processes and areas audited). A record of the must be created and retained.

8 The manufacturer, etc. shall have the responsible person responsible for the area of internal audit take all corrective and corrective actions necessary to eliminate the discovered nonconformity and the cause of the nonconformity without delay, conduct verification of such corrective actions, and report the results thereof.

(Monitoring and Measurement of Process)

Article 57 (1) a manufacturer, etc. shall monitor each process pertaining to the quality control and supervision system in an appropriate manner, and when it is necessary to conduct a quantitative evaluation in the monitoring of said process, he/she shall make measurements.

2 Manufacturers and distributors, etc. (excluding limited type 3 medical device

manufacturers and distributors) The same shall apply in the following paragraph.) With regard to the method of monitoring set forth in the preceding paragraph, the Process shall be able to demonstrate that it can obtain the results set forth in the plan set forth in paragraph (1) of Article 14.

3 Where the manufacturer, etc. is unable to obtain the results set forth in the plan set forth in Article 14, paragraph (1), the manufacturer, etc. shall, in the case where it is unable to obtain the results set forth in the plan set forth in Article 14, paragraph (1), make a product (excluding products pertaining to limited general medical devices) Modifications and corrective actions shall be taken to ensure conformity. However, this shall not apply in cases where there is a justifiable reason for not taking corrective measures.

(Monitoring and Measurement of Products)

Article 58 (1) a manufacturer, etc. shall monitor and measure the characteristics of a product in order to verify that the product conforms to the product requirements.

2 Manufacturers, etc. (excluding limited Type III medical device manufacturers and sellers) The shall establish an implementation procedure for monitoring and measurement set forth in the preceding paragraph and a procedure manual for such monitoring and measurement, and shall carry out such monitoring and measurement at the appropriate stage of the process pertaining to product realization in accordance with said implementation procedure and procedure manual.

3 The manufacturer, etc. shall prepare and retain records that serve as evidence of conformity with the criteria for deciding whether or not to ship.

4 (In cases where a manufacturer, etc. other than a limited Type III medical device manufacturer or seller uses equipment and instruments for the monitoring and measurement necessary for demonstrating conformity to the criteria for deciding whether to ship, etc., the manufacturer, etc. shall include a record identifying said equipment and instruments.) Must be created and stored.

5 The manufacturer, etc. shall not grant permission to proceed to the next stage of the process, decide to ship, or provide services until the monitoring and measurement in accordance with the procedure and procedure set forth in paragraph (2) has been completed without hindrance.

(Requirements specific to Implanting Medical Devices)

Article 59 (1) a manufacturer, etc. (excluding a limited Type 3 Medical Device manufacturer and Seller) The following Article through Article 60 to Article 60 (excluding Article 60-3, paragraph (2)) The same for.) Products pertaining to implantable medical devices (excluding products pertaining to limited general medical devices) The same shall apply in the following Article.) A record shall be prepared to identify the members who performed all tests or inspections related to the product.

(Management of nonconforming Products)

Article 60 (1) a manufacturer, etc. may, in the event that a product that does not conform to the product requirements (hereinafter referred to as a "nonconforming product") This shall be identified and controlled to ensure that unintended use, operation or

shipment is prevented.

2 The manufacturer, etc. shall identify the nonconforming product, document the nonconforming information, isolate the nonconforming product, and evaluate the nonconforming product (including assessing the need for investigation and evaluating the need for notification to the outside party responsible for the nonconforming). Procedures should be documented with respect to the management of the measures and the responsibilities and powers associated therewith.

3 The manufacturer, etc. shall make a record of all measures taken in the management of nonconforming products (including the content of the nonconformity, the investigation and evaluation of the nonconforming products, and the reasons for taking such measures). Must be created and stored.

(Measures for nonconforming Products before Shipping)

Article 60-2 (1) a manufacturer, etc. shall dispose of nonconforming products by any- or more of the following methods:

一 To take steps to eliminate any nonconformities found.

二 To take measures to prevent its intended use or operation.

三 Permission to use or operate, permission to proceed to the next stage of the process, or a decision to ship under special employment.

2 If a nonconforming product does not conform to the provisions of laws and regulations, the manufacturer, etc. shall not dispose of the nonconforming product through special adoption.

3 When a manufacturer, etc. has specially adopted a nonconforming product, the manufacturer, etc. shall prepare and retain a record identifying the person who has authorized the special adoption.

4 The manufacturer, etc. shall record all measures taken with regard to the nonconforming product prior to shipment (including the details of the nonconforming product, the investigation and evaluation of the nonconforming product, and the reason for taking such measures). And keep them.

(Treatment of nonconforming Products after Shipment)

Article 60-3 (1) where a manufacturer, etc. discovers a nonconforming product after the service of the product to the product recipient or after the use or operation of the medical device, etc. pertaining to the said product, he/she shall take appropriate measures against the impact or possible impact of the nonconformity.

2 The manufacturer, etc. shall document the procedures for issuing and implementing notices pertaining to nonconforming products, and shall be able to implement such procedures at any time.

3 The manufacturer, etc. shall prepare and retain the records pertaining to the preceding two paragraphs.

(Remanufacture)

Article 60-4 (1) when it is necessary to remanufacture a product, a manufacturer, etc. shall establish a procedure manual for remanufacturing, taking into account adverse effects on the product, and remanufacture it in accordance with said

procedure manual. In this case, the manufacturer, etc. shall carry out the approval procedure in the same manner as the ordinary procedure manual when issuing said procedure manual.

2 The manufacturer, etc. shall reverify the remanufactured product in order to demonstrate its conformity to the applicable criteria and the provisions of laws and regulations.

3 The manufacturer, etc. shall prepare and keep records of the remanufactured products.

(Data Analysis)

Article 61 (1) in order to demonstrate the appropriateness, validity and effectiveness of the quality control supervision system, the manufacturer, etc. shall, after clarifying appropriate data, prepare procedures for collecting and analyzing said data (appropriate methods for conducting said collection and analysis (including statistical methods and the scope of application thereof). Includes the steps to determine the .) Must be documented.

2 In analyzing the data, the manufacturer, etc. shall, when analyzing the data obtained from the results of monitoring and measurement and data from other relevant information sources (excluding item (vi) when there is a justifiable reason): Including the information listed in the above.) Must be used.

- The opinions of the recipient of the product

(II) conformity to product requirements

三 Characteristics and trends of processes and products (including those that serve as the starting point for improvement)

(IV) Suppliers, etc. of purchased Goods, etc.

(V) Audits

六 Records of incidental service operations (limited to incidental service operations for products for which incidental services are provided)

3 If a manufacturer, etc. cannot demonstrate the appropriateness, validity and effectiveness of the quality control supervision system through analysis of the data, the manufacturer, etc. shall utilize the results of such analysis as process input information for improvement.

4 The manufacturer, etc. shall prepare and retain records pertaining to the results of the analysis of the data. However, this shall not apply to products pertaining to limited general medical devices.

(Improvement)

Article 62 (1) a manufacturer, etc. (excluding a limited Type 3 Medical Device manufacturer) Is based on its quality policy, quality targets, audit results, post-market monitoring, Through the analysis of data, corrective measures, preventive measures, and inspections of management supervisors, the functions, performance and safety of medical devices, etc. according to the intended use, and the appropriateness of the quality management supervision system on an ongoing basis. All matters that need to be changed in order to maintain validity and effectiveness must be clarified, and such

changes must be implemented.

(Corrective Measures)

Article 63 (1) the manufacturer, etc. shall, in accordance with the impact of the discovered nonconformity, take all corrective measures necessary to prevent the reoccurrence of said nonconformity without delay.

(2) a manufacturer, etc. shall document procedures pertaining to corrective measures that establish necessary requirements with respect to the following matters:

Non-conformity (including complaints from product recipients) Review

二 Identify the cause of the nonconformance

三 Assessment of the need for action to ensure that non-conformities do not recur

(IV) Formulation of a plan pertaining to the necessary corrective measures, recording the contents of said corrective measures, and implementation of said corrective measures (in the case of changes to said corrective measures, including updating said plans and records).

(V) Verification of the adverse effects of corrective measures on the function, performance, and safety according to the conformity to the provisions of laws and regulations, etc. or the intended use of medical devices, etc.

(VI) when corrective measures have been taken, review the effectiveness of the corrective measures

(3) where a manufacturer, etc. has conducted an investigation concerning the Corrective Measures, he/she shall prepare and retain a record pertaining to the results of said investigation and the Corrective Measures.

(Preventive Measures)

Article 64 (1) a manufacturer, etc. (excluding a limited Type 3 Medical Device manufacturer and Seller) Hereinafter the same shall apply in this Article and the following Article) In light of the effects of possible problems, the shall identify and take appropriate precautions to prevent the occurrence of such problems.

2 The manufacturer, etc. shall document procedures pertaining to preventive measures that establish the necessary requirements for the following matters:

(I) Identification of possible nonconformity and the cause thereof

(II) Evaluation of the necessity of preventive measures

(III) Formulation of a plan pertaining to the necessary preventive measures, recording the contents of said preventive measures, and implementation of said preventive measures (including the renewal of said plans and records in the case of changes to said preventive measures).

四 Verification of the adverse effects of preventive measures on the function, performance, and safety in accordance with the conformity of laws and regulations or the intended use of medical devices, etc.

五 If preventive measures are taken, review the effectiveness of the preventive measures

3 In cases where a manufacturer, etc. has conducted an investigation concerning the preventive measures, he/she shall prepare and retain a record pertaining to the

results of said investigation and preventive measures.

Chapter III additional requirements for manufacturing and quality control of medical devices, etc.

Article 65 Deletion

(Additional Requirements for Quality Control and Supervision Systems)

Article 66 (1) in addition to the provisions of Chapter II, a manufacturer, etc. may, in addition to the provisions of Chapter III to Chapter V-2 (limited to the provisions to be applied pursuant to the provisions of Article 3). Hereinafter the same shall apply in this Article.) The Company shall establish, document, implement, and maintain the effectiveness of a quality management supervisory system.

2 In addition to the provisions of Chapter II, the manufacturer, etc. shall control and supervise the process in accordance with the provisions of chapters III through V-2.

3 In addition to the matters listed in the items of Article 6, the manufacturer, etc. shall state in the quality control supervision document the procedures and records prescribed in chapters III to V-2.

(Retention period for Quality Control and Supervision Documents)

Article 67 (1) the period for which a manufacturer, etc. retains a quality control supervision document or a copy thereof pursuant to the provision of Article 8, paragraph (4) shall be the period listed in the following items (five years for those pertaining to education and training) from the date of abolition of said quality control supervision document: However, with regard to the quality control supervision document used for the manufacture or test inspection of the product, it is sufficient to keep the quality control supervision document available for use for the period prescribed in the following Article.

- 15 years (the effective period or the expiration period of use of said product (hereinafter simply referred to as the "effective period") for products pertaining to specified maintenance management medical devices. If the period by adding one year to the valid period is longer than 15 years, the period by adding one year to the valid period)

(II) for products pertaining to medical devices, etc. other than specified maintenance management, five years (if the effective period of the product plus one year is longer than five years, the effective period of the product plus one year);

(Retention period for Records)

Article 68 (1) the manufacturer, etc. shall retain the records prescribed in Article 9, paragraph (1) or this Chapter for the period listed in the following items (five years for those pertaining to education and training) from the date of preparation:

- For products pertaining to medical devices under specified maintenance management, 15 years (if the effective period of said products plus years is longer than 15 years, the effective period of said products plus one year)

(II) for products pertaining to medical devices, etc. other than specified maintenance management, five years (if the effective period of the product plus one year is longer

than five years, the effective period of the product plus one year);

(Report of defects, etc.)

Article 69 (1) a manufacturer, etc. shall prepare all facilities and related manufacturing facilities registered pursuant to the provisions of Article 23-2-3, paragraph (1) of the Act or Article 23-2-4, paragraph (1) of the Act (hereinafter referred to as "registered manufacturing facilities"). In the event that said facility and related registered manufacturing facilities come to know the matters listed in each item of Article 228-20, paragraph (1) and each item of paragraph (2) of the Ordinance for Enforcement, the procedures for having said manufacturer/seller, etc. notify said matters shall be documented.

(Relationship with Post-Manufacturing Safety Management Standards)

Article 70 (1) where a manufacturer, etc. engages in the business concerning post-sales safety management of medical devices, etc. pertaining to products, in addition to the provisions of this Ministerial Ordinance, the manufacturer, etc. shall, in addition to the provisions of this Ministerial Ordinance, carry out the business concerning pharmaceutical products, quasi-drugs, cosmetics, Ministerial Ordinance on Standards for Post-Manufacturing Safety Management of Medical Devices and Regenerative Medicine Products (Ordinance of the Ministry of Health, Labour and Welfare No. 135 of 2004) Hereinafter referred to as the "post-manufacturing and sales safety management standards") You must comply with the provisions of the .

(Business of General Manufacturing and Sales Manager of Medical Devices, etc.)

Article 70 - (1) a manufacturer or seller shall carry out the business listed in the following items as a general manufacturing and sales manager of medical devices, etc. prescribed in Article 23-2-14, paragraph (2) of the Act (hereinafter referred to as a "general manufacturing and sales manager of medical devices, etc."): It must be done.

Supervise and be responsible for decisions on the shipment of products and other operations related to manufacturing control and quality control.

二 When it is found necessary for the fair and appropriate performance of the business, state the necessary opinion in writing to the manufacturer, the management supervisor, or any other person responsible for the business, and retain a copy of the opinion for five years.

三 Supervising the Domestic Quality Business Operation Manager prescribed in paragraph (1) of the following Article (excluding cases where the Medical Device General Manufacturing and Sales Manager concurrently serves as the Domestic Quality Business Operation Manager pursuant to the provisions of the following paragraph) Of the system.

(IV) a Management Representative and a Domestic Quality Business Operation Representative prescribed in paragraph (1) of the following Article (in the case of a limited Type III medical device manufacturer and seller, excluding the Management Representative); To respect the opinions of the.

(V) Departments related to production control or quality control and the general

safety management department prescribed in Article 4, paragraph (1) of the post-production and sales safety management standard (referred to as the "general safety management department" in paragraph (2), item (ix) of the following Article) To work closely with.

(2) a general manufacturing and sales manager of medical devices, etc. may concurrently act as a management supervisor or manager, or a domestic quality business operation manager prescribed in paragraph (1) of the following Article.

(Domestic Quality Business Operations Manager)

Article 72 (1) a manufacturer shall conduct business to control the quality of domestic products in accordance with the provisions of this Ministerial Ordinance (hereinafter referred to as "quality control business"). A domestic quality business operation manager who satisfies the following requirements shall be appointed at facilities located in Japan as the person responsible for the quality business operation.

You are responsible for quality assurance at the manufacturer.

二　A person must have engaged in quality control services or other similar services for three years or longer.

三　A person who has the ability to properly and smoothly carry out quality control operations in Japan.

四 A person who does not belong to a department related to the sale of medical devices, etc., or who has no risk of interfering with the proper and smooth performance of quality control operations in Japan.

(2) a manufacturer shall have a Domestic Quality Business Operation Manager perform the following services based on the Procedures, etc. prepared pursuant to the provisions of this Ministerial Ordinance:

- To supervise quality control operations in Japan.

二　To confirm that quality control operations in Japan are carried out appropriately and smoothly.

三 For products to be distributed in Japan, the decision to ship to the market shall be made for each lot (in the case of medical devices, etc. that do not constitute a lot, by serial number or manufacturing symbol), the results thereof and the record of the shipment to the market such as the destination of the shipment shall be made (in the case of having a person designated beforehand to decide whether to ship to the market pursuant to the provisions of the next paragraph, the appropriate decision shall be made). Of the system.

(IV) where there is a change in the manufacturing method, test and inspection method, etc. that may affect the quality of the product distributed in Japan, the information pertaining to said change shall be collected from Japan and overseas; and If the change is likely to have a significant impact on the quality of the product, the person in charge of management (in the case of a domestic quality business operation manager of a limited type 3 medical device manufacturer, the person in charge of management and supervision. The same shall apply in the following item to item (vii).) Report in writing to the person responsible for the overall manufacturing and sales of medical devices, etc. so that necessary and appropriate

measures are taken.

(V) with regard to products distributed in Japan, information on the quality, etc. of said products (including information on poor quality or likely to be poor quality); In addition, when such information is obtained, it shall be promptly reported in writing to the person responsible for management and the person responsible for general manufacturing and sales of medical devices, etc., and recorded so that necessary and appropriate measures shall be taken.

(VI) carrying out the following business activities when collecting products distributed in Japan:

(A) to properly dispose of recovered medical devices, etc. after storing them separately for a certain period of time.

(B) to prepare a record stating the contents of the collection and report it in writing to the manager and the general manufacturing and sales manager of medical devices, etc.

七 In addition to what is listed in item (iv) to the preceding item, when it is deemed necessary for the performance of quality control services in Japan, a document shall be sent to the person responsible for the management and the person responsible for the overall manufacturing and sales of medical devices, etc.

To be reported.

(C) in implementing the Quality Control Services in Japan, as necessary, a manufacturer or a foreign manufacturer, seller, pharmacy organizer of a medical device, etc. pertaining to the registered manufacturing facilities concerned; To communicate or give instructions in writing to the organizers of hospitals and clinics and other related persons.

(IX) providing the information on safety measures prescribed in paragraph (2) of Article 2 of the Post-Manufacturing and Sales Safety Management Standards in writing to the Safety Management Headquarters without delay;

(3) the decision to ship to the market prescribed in item (III) of the preceding paragraph shall be made by a person designated in advance by the Domestic Quality Business Operation Manager (person of the Quality Assurance Department or registered manufacturing facility (limited to those that ship to the market). (Limited to a person who has the ability to perform said business appropriately and smoothly) You can go to .

4 A person who has made a decision to ship to the market pursuant to the provisions of the preceding paragraph shall prepare a record of the result and the shipment to the market, such as the destination of the shipment, and shall report it in writing to the Domestic Quality Business Operations Manager.

5 Domestic Quality Operations Managers may also serve as Management Managers.

(Other Matters to be observed)

Article 72-2 (1) in order not to obstruct the collection of information pursuant to the provisions of paragraph (2), items (iv) and (v) of the preceding Article, a manufacturer shall establish the necessary system taking into account the relationship with the business conducted pursuant to the provisions of Article 55, and shall make

arrangements and document the necessary and sufficient matters with the relevant facilities and registered manufacturing facilities.

(2) a manufacturer shall document procedures concerning the following matters:

Processing of notifications from medical device repairers

(II) ensuring quality at the seller or lender of medical devices

(III) Processing notices from sellers or lenders of used goods

(Business of appointed Overseas manufacturer of Medical Devices, etc.)

Article 72-3 (1) a person who has obtained approval for special provisions for medical devices manufactured in a foreign country shall have a designated manufacturer and seller of medical devices manufactured in a foreign country perform the following services among the services performed pursuant to the provisions of this Ministerial Ordinance:

Business conducted pursuant to the provisions of Article 7 that is related to domestic business

二 Business conducted pursuant to the provisions of Article 17 that is related to domestic business

三 Business conducted pursuant to the provisions of Article 29 that is related to domestic business

四 Business conducted pursuant to the provisions of Article 43 that is related to domestic business

五 Business conducted pursuant to the provisions of Article 48 and Article 49 pertaining to domestic business

六 Business conducted pursuant to the provisions of Articles 55 and 55-2, which is related to domestic business

(VII) among operations conducted pursuant to the provisions of Articles 60 to 60-4, those related to domestic operations

(C) Collection and processing pertaining to products in Japan

(IX) Work related to post-manufacturing and sales safety management pertaining to products in Japan

(X) Business to make necessary reports to supervisors and managers of persons who have obtained special approval for foreign manufacturing medical devices, etc., and other relevant persons with regard to the business conducted as a designated manufacturer and seller of foreign manufacturing medical devices, etc., and to make necessary cooperation with persons who have obtained special approval for foreign manufacturing medical devices, etc. in order to properly carry out said business

(XI) Management of documents and records relating to the business conducted as an appointed manufacturer and seller of medical devices, etc. in foreign countries

(2) the provisions of the preceding paragraph shall apply mutatis mutandis to a foreign designated manufacturer of highly controlled medical devices, etc. In this case, the term "appointed foreign manufacturer and seller of medical devices" shall be deemed to be replaced with "appointed foreign manufacturer and seller of high-level controlled medical devices."

(3) Articles 70 to the preceding Article inclusive (excluding Article 72, paragraph (5))

with regard to an appointed foreign manufacturer of medical devices, etc. or an appointed foreign designated manufacturer and seller of highly controlled medical devices, etc. The provisions of the preceding paragraph shall apply mutatis mutandis. In this case, the seventh In Article, paragraph (1), item (I), the term "other" shall be deemed to be replaced with "other

In item (II) of the same paragraph, "designated foreign manufacturer of medical devices, etc. or designated foreign manufacturer of highly controlled medical devices, etc." and in item (iv) of the same paragraph, "designated foreign manufacturer of medical devices, etc. or designated foreign manufacturer of highly controlled medical devices, etc." and "designated foreign manufacturer and seller of highly controlled medical devices, etc." in item (iv) of the same paragraph shall be deemed to be deemed to be replaced with "the following Article, paragraph (paragraph, paragraph, paragraph (paragraph (1). Excluding the manager.) The terms "and conditions" in paragraph (2) of the same Article shall be deemed to be replaced with "the opinion of the management supervisor or manager responsible or paragraph (1) of the following Article" and "so" in paragraph (1) of Article 72 shall be deemed to be replaced with "the appointed foreign manufacturer of medical devices, etc. or the appointed foreign designated manufacturer and seller of highly controlled medical devices, etc." in paragraph (4) of Article. The same shall apply in the following item to item (vii).) The term "manager and manager responsible for manufacturing and sales of medical devices" in items (v), (vi) and (vii) of the same paragraph shall be deemed to be replaced with "manager responsible for manufacturing and sales of medical devices, etc." and the term "manager responsible for manufacturing and sales of medical devices, etc." in items (v), (vi) and (vii) of the same paragraph shall be deemed to be replaced with "manager.

Chapter IV Manufacturing control and quality control of biologically derived medical devices, etc.

(Basis of Business Operations at Manufacturing Sites of manufacturer and Seller of specified Biological-derived Medical Devices, etc.)

Article 73 Medical devices, etc. that are products derived from specified organisms, medical devices and cellular tissue medical devices designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 43, paragraph (2) of the Act (hereinafter referred to as "medical devices derived from specified organisms, etc." in this Chapter) (Hereinafter referred to as "manufacturer and distributor, etc. of specified Bio-derived Medical Devices, etc.") In the case of a manufacturing facility where the said product is manufactured (excluding a manufacturing facility where only packaging, labeling, storage, or design is carried out), Hereinafter the same shall apply in this chapter.) The following requirements must be satisfied as a business operation foundation.

Equipment for supplying distilled water, etc. necessary for the manufacture of products shall be provided to foreign substances or microorganisms (including viruses). Hereinafter the same shall apply in this Chapter and Chapter VI) The

structure must be necessary to prevent contamination of distilled water, etc.

(II) a work place (meaning a place where manufacturing work is carried out); Hereinafter the same shall apply in this Chapter through Chapter 6.) Shall conform to the following provisions:

(A) the working room or work control area shall have a structure and equipment capable of maintaining and managing the appropriate temperature, humidity and degree of cleanliness according to the manufacturing process.

Mouth the work room where the weighing work of raw materials or materials or the cleaning work of containers are carried out shall have a tightly closed structure for dust prevention.

(C) the working room for drying or sterilizing the container after cleaning shall be dedicated. However, this shall not apply to cases where there is no risk of contamination of the container after cleaning.

(II) a clean area (meaning a work site where weighing and preparation work of component parts, etc. are carried out, and where the products, etc. after washing come into contact with air in the work site); Hereinafter the same shall apply in this Chapter and Chapter VI) And sterile areas (where sterilized products, components, etc., or sterilized containers come into contact with air, places where containers are blocked, and places where sterile operations such as aseptic tests are performed.) Hereinafter the same shall apply in this chapter.) Shall conform to the following provisions.

(1) The surfaces of ceilings, walls and floors shall be smooth, crack-free and free from dust.

(2) Drainage equipment shall be of adequate construction to prevent contamination by hazardous drainage.

(E) not to install drainage outlets in the clean area. However, this shall not apply in cases where the following provisions are met and it is deemed unavoidable.

(1) The drainage outlet shall have a trap that is easy to clean and a device to prevent the backflow of drainage.

(2) The trap must be of a structure that allows disinfection to be carried out.

(3) The floor grooves are shallow and easy to clean, and through drainage outlets, the production area (culture, (2) "places where extraction and purification work, weighing and preparation work of component parts, etc., cleaning and drying work of containers, clogging and packing work of containers, and places where changing work is carried out) You are connected to the outside of the .

The sterile area shall conform to the following provisions:

(1) Do not install drainage outlets.

(2) Do not install a sink.

(B) areas where tests using animals or microorganisms are conducted and areas where animal tissues or microorganisms are not necessary for the manufacture of products related to medical devices derived from specified organisms are clearly distinguished from other areas where the products are manufactured, and

air treatment systems are separated.

(H) the area where the aseptic operation is carried out shall provide clean air treated by filters and have the structure and equipment necessary for carrying out appropriate differential pressure control.

(I) the area where pathogenic microorganisms, etc. are handled shall have the structure and equipment necessary for carrying out appropriate negative pressure control.

(J) an area that handles infectious microorganisms, etc. shall have facilities for cleaning, disinfection and sterilization of the equipment used in said area, and facilities for the treatment of waste liquid, etc.

(K) to provide the following facilities in a room clearly distinguished from others: However, equipment that is deemed not necessary for the manufacture of the product is excluded, depending on the type of product, manufacturing method, etc.

(1) Microbial storage facilities

(2) Equipment for managing animals used for manufacturing or testing after microbial inoculation

(3) Equipment for processing animals used for manufacturing or testing

(4) Equipment for transplanting microorganisms into culture media

(5) Equipment for culturing microorganisms

(6) Equipment for collecting, inactivating, and sterilizing cultured microorganisms

(7) Equipment to disinfect instruments, etc. used for manufacturing or test inspections

(L) the surfaces of ceilings, walls and floors of rooms having the facilities listed in (2) to (4) and (6) shall be of a structure capable of cleaning and disinfection.

Rooms equipped with facilities listed in Wal (4) and (6) and rooms equipped with facilities for conducting aseptic tests among the facilities necessary for test and inspection of products, etc. shall satisfy the following requirements.

(1) The room must be sterile. However, this shall not apply to the case where facilities with functions capable of performing aseptic operation without hindrance depending on the type of product, manufacturing method, etc. are installed in the said working room.

(2) The sterile room referred to in (1) shall have a dedicated front room attached to it, and shall have a structure that normally allows entry and exit of the working room only through the front room, and the entrance and exit of the front room shall not be directly facing the outdoors.

In addition to the facilities listed in (K), a person shall have the following facilities:

(1) Equipment necessary for the care and management of animals used for manufacturing or testing

(2) Equipment for preparing culture media and its dilution solution

(3) Equipment necessary for cleaning, drying, sterilizing and retaining pipes of instruments, containers, etc. used for manufacturing or test inspection

(4) Container blockage equipment

(5) Equipment for the proper treatment of animal carcasses and other sewage and the purification of sewage

(O) the storage facility shall be equipped with a constant temperature device, self-recorded thermometer and other necessary instruments. The evening air treatment system shall conform to the following provisions:

(1) It must have an appropriate structure to prevent contamination of products, etc. by microorganisms.

(2) When handling pathogenic microorganisms, etc., it must have an appropriate structure to prevent the spread of the air of the microorganisms, etc.

(3) The air discharged from the area where pathogenic microorganisms are handled shall be discharged after the microorganisms are removed by a high-performance air filter.

(4) A structure that does not recirculate the air discharged from the work room where pathogenic microorganisms may leak. However, this shall not apply when such microorganisms have been sufficiently removed by the structure prescribed in (3) and it is deemed unavoidable to recirculate them.

(5) Separate system for each work room, if necessary.

(Re) the piping, valve and vent filter shall have a structure that can be easily cleaned or sterilized according to the purpose of use.

(D) to be equipped with the following test and inspection equipment: However, this shall not apply when the said test and inspection is conducted at its own risk using another testing and inspection organization such as the manufacturer and seller of the specified organism medical device, etc., and it is recognized that there is no hindrance to the said test and inspection.

(1) When it is necessary to conduct a sealing inspection, equipment and instruments for sealing inspection

(2) Equipment and equipment for foreign body inspection

(3) Equipment and instruments for physical and chemical testing of products, manufacturing substances and materials

(4) Sterility testing equipment and equipment

(5) When it is necessary to conduct a pyrogenic substance test, equipment and equipment for the pyrogenic substance test

(6) Biological testing equipment and equipment where it is necessary to conduct biological testing

三 The work station for products pertaining to cell tissue medical devices shall conform to the following provisions:

(A) the area for receiving raw materials or materials, processing and storing products, etc. shall be separated from other areas where products pertaining to cell tissue medical equipment are manufactured.

The area for receiving raw materials or materials, processing and storage of products, etc. shall have the structure and facilities necessary for these.

(IV) the area where the production of products made from human blood or plasma as raw materials or materials is carried out shall be clearly separated from other areas, and shall have special facilities and instruments for the production thereof. However, this shall not apply to the manufacturing process after the process of inactivating or removing the virus.

五 Animals used for manufacturing or testing (donor animals (meaning animals that provide cells or tissues as raw materials or materials for cell tissue medical devices) Hereinafter the same shall apply in this chapter.) Includes. Hereinafter referred to as "used animals") The facilities under management shall conform to the following provisions.

(A) the area for inspecting the animal to be used shall be isolated from other areas. To have a storage facility for feed that is not likely to be infiltrated by mouth pests.

(C) the applicant shall have a breeding room for the animals used for manufacturing and a breeding room for the animals used for test and inspection.

(II) the animal room for use shall have a separate air treatment system from the other areas. However, this shall not apply to animals for which it is deemed appropriate to keep them outdoors.

(E) when inoculating an animal to be used with antigens, etc., it shall have an inoculation room separate from the autopsy room of the animal.

(Documents pertaining to Production Control and Quality Control)

Article 74 (1) a manufacturer, etc. of products pertaining to biological medical devices, etc. (hereinafter referred to as a "manufacturer, etc.") When handling products pertaining to biologically derived medical devices, etc., the following matters shall be stated in the Product Standard Manual in addition to what is provided for in Article 7-2:

Name, essence and properties, composition, content and other standards of substances obtained from persons, animals, plants or microorganisms used as component parts, etc.

二 Standards for animals to be used (including breeding and management methods)

三 Other required items

(Process Control)

Article 75 (1) when handling products pertaining to biogenic medical devices, etc., in addition to the work set forth in the preceding Article, a manufacturer and seller of biogenic medical devices, etc. shall appropriately manage the work related to process control of products pertaining to biogenic medical devices, etc. listed below, based on Product Standard Documents. The procedure must be written.

(I) having a person designated in advance in accordance with the contents of the business perform the following business:

(A) Biological-derived raw materials (organisms used in the manufacture of biological-derived medical devices, etc. (excluding plants)) contained in products, etc. in the manufacturing process; This means raw materials or materials derived from. The same shall apply hereinafter. ○), microorganisms, etc., shall take

necessary measures to prevent contamination by raw materials, materials, products, etc. that have not been inactivated or removed.

(B) when biochemical technologies such as fermentation are used in the manufacturing process, measurement shall be made continuously on matters necessary for the management of the manufacturing process such as temperature and hydrogen ion index.

(C) when a column chromatograph device, etc. is used in the manufacturing process, to take necessary measures to prevent contamination of said device by microorganisms, etc., and to measure endotoxin as necessary.

(II) in the case where a culture method in which culture medium is continuously supplied in a culture tank and culture medium is continuously discharged in a culture tank is used in the manufacturing process, necessary measures shall be taken to maintain the culture conditions in said culture tank during the culture period.

(E) in the following cases, to conduct the validation, prepare and retain a record of the validation:

(1) When the manufacturing facility commences the manufacture of products related to bio-derived medical devices, etc.

(2) When there is a change in the manufacturing procedure, etc. that has a significant impact on the quality of products related to biologically derived medical devices, etc.

(3) Other cases where it is deemed necessary to properly carry out manufacturing control and quality control of products related to biologically derived medical devices, etc.

To restrict access to the work site by persons other than those engaged in manufacturing operations as much as possible. (B) Hygiene management of members shall be carried out in accordance with the following provisions.

(1) Access to clean or sterile areas where work is actually being carried out shall be restricted as far as possible.

(2) The members engaged in the manufacturing work shall be assigned to the animals used (excluding those actually used in the manufacturing process). Do not engage in the work pertaining to the management of the

(H) to carry out hygiene management for members working in clean or sterile areas pursuant to the following provisions:

(1) Personnel engaged in manufacturing work shall be required to wear disinfected work clothes, work clothes, work caps and work masks.

(2) To conduct regular medical examinations of members to confirm that they are not suffering from diseases that may contaminate products, etc. with microorganisms.

(3) Health conditions (including cases where members have skin or hair infections or colds, injuries, or symptoms such as diarrhea or fever of unknown cause) that may contaminate products with microorganisms. The same shall apply hereinafter) In such cases, the applicant must submit a declaration.

(I) animals used (limited to those used for manufacturing); Hereinafter the same

shall apply in this item.) In addition to keeping the animals under proper management at all times, health observation shall be conducted to prevent the use of animals suffering from infectious diseases or other animals that are not suitable for use.

(J) All articles contaminated by microorganisms (limited to those contaminated in the process of manufacture); The carcasses of the animal being used shall be treated in such a way that there is no risk of causing problems with health and hygiene.

(K) to prepare and preserve records pertaining to the following matters concerning the handling of strains of microorganisms used for production:

(1) The name of the microorganism and the number given to each container

(2) Date of acquisition and name and address of the other party (in the case of a juridical person, name and address)

(3) Biological properties and date of inspection

(4) Passaging status

(L) to confirm that biological raw materials are appropriate in light of product standard documents for said products, and to prepare and preserve records pertaining to the results thereof;

(M) with regard to biologically derived raw materials used in the manufacture of biologically derived medical devices, etc., prepare a record of matters that must be recorded pursuant to the provisions of the Minister of Health, Labour and Welfare, and store such records, or businesses, etc. that collect raw materials or materials that fall under the biologically derived raw materials (hereinafter referred to as "raw material extractors, etc.") By concluding an agreement with the relevant raw material extraction company, etc., it shall be appropriately stored.

(II) to prepare and retain the records set forth in (e), (I) and (h) of the preceding item for each lot.

(2) in cases where a manufacturer or seller, etc. handles products pertaining to cell tissue medical devices, in addition to the work set forth in the preceding paragraph, the manufacturer or seller of biologically derived medical devices, etc. shall appropriately manage the work related to process control of products pertaining to the following cell tissue medical devices at the manufacturer of said products, based on the Product Standard. The procedure must be documented.

(I) having a person designated in advance in accordance with the contents of the business perform the following business:

(A) different donors (persons who provide cells or tissues that are raw materials or materials for cell tissue medical devices (excluding those pertaining to the body of a brain-dead person prescribed in Article 6, paragraph (2) of the Act on Organ transplantation (Act No. 104 of 1997)); It refers to. Hereinafter the same shall apply in this chapter.) When handling cells or tissues collected from donor animals, the necessary measures shall be taken to prevent confusion and cross-contamination of such cells or tissues.

At the time of acceptance, it shall be confirmed that the cells or tissues that will be used as raw materials or materials are appropriate in light of the Product Standard of the said product by means of the records pertaining to the following matters, and shall prepare records pertaining to the results thereof.

(1) The place of business where the said cell or tissue was collected

(2) The date on which the cell or tissue was collected

(3) If the cells or tissues are of human origin, donor screening (with regard to the donor, make a diagnosis through interviews, tests, etc., and ask whether the donor is sufficiently qualified to provide cells or tissues to be used as raw materials or materials for products related to cell tissue medical devices; It means to be judged by inspection, etc.) The status of the

(4) In cases where such cells or tissues are related to animals, the status of acceptance of donor animals and donor screening (which means conducting test testing and breeding management of donor animals to determine whether they are sufficiently qualified to provide cells or tissues as raw materials or materials for products related to cell tissue medical devices through such testing and breeding management). The status of the

(5) The process of collecting the cells or tissues

(6) In addition to what is listed in (1) to (5), necessary matters concerning ensuring the quality of products related to cell tissue medical devices

(VIII) in the case of collecting raw materials or material cells or tissues from donor animals, to take necessary measures to prevent contamination of microorganisms, etc. in the process of collection, and to prepare a record of said measures.

(II) when a member falls under any of the following, not to have said member engage in the work in a clean or sterile area:

(1) When the product is in a health condition that may contaminate the product with microorganisms

(2) When handling microorganisms, etc. that may contaminate cells or tissues immediately prior to the collection or processing of cells or tissues

(E) for each product, the name of the place of business to which the product is shipped, the date of shipment, and the lot shall be identified, and the record shall be prepared.

To take necessary measures to ensure the quality of the product and to create a record of such measures.

(G) to prepare a record concerning care management after acceptance of donor animals.

(II) in the case of records set forth in (b), (c) and (b) and (b) of the preceding item, for each lot, and in the case of records set forth in (e) of the same item, for each product; Keep this.

(3) a manufacturer or seller of biological medical devices, etc. shall keep the records set forth in the preceding two paragraphs in such a way that it can properly confirm a series of records ranging from the records pertaining to the biological source raw

materials used in the manufacture to the records pertaining to the products manufactured using said biological source raw materials.

(Test Inspection)

Article 76 (1) when dealing with products pertaining to biogenic medical devices, etc., the manufacturer and seller of biogenic medical devices, etc. shall, in addition to the work set forth in the preceding Article, appropriately manage the work pertaining to test and inspection of products pertaining to the following biogenic medical devices, etc. at the manufacturing facilities of said products, based on Product Standard Documents. The procedure must be documented.

In order to prevent sample confusion and cross-contamination, specimens should be classified by appropriate identification and labeling.

二 Tests and inspections that are important for quality control and cannot be carried out on final products should be carried out at an appropriate stage in the manufacturing process.

三 Animals to be used (limited to those used for test and inspection). Hereinafter the same shall apply in this item.) In addition to keeping the animals under proper management at all times, when using them, they should not use animals suffering from infectious diseases or other animals that are not suitable for use by observing their health.

四 All articles contaminated by microorganisms (limited to those contaminated during the test process). The carcasses of the used animals shall be treated in such a way that there is no risk of causing health and hygiene problems.

(V) to create and preserve records pertaining to the following matters concerning the handling of strains of microorganisms used for test inspections:

(A) the name of the microorganism and the number attached to each container

The date of the acquisition and the name and address of the other party (in the case of a juridical person, the name and address)

(VIII) the biological properties and the date of the inspection

The status of two passaging cultures

六 For products pertaining to specified biologically-derived medical devices, etc., for each lot (with regard to products pertaining to medical devices, etc. which are specified biologically-derived products, etc. that do not constitute a lot, the biologically-derived raw materials used in their manufacture shall be The product shall be stored under appropriate storage conditions for an appropriate period from the date of manufacture as a reference product in quantities at least twice the amount required for the prescribed test and inspection (for each serial number of the product or lot of the biogenic raw material) (if the medical device to which the product is manufactured is a medical device, etc. derived from a specified biogenic product, 10 years shall be added to the effective period). However, this shall not apply to products pertaining to medical devices, etc., which are specified biologically derived products that do not constitute lot, and products pertaining to medical devices or cell tissue medical devices designated by the Minister of Health,

Labour and Welfare pursuant to the provisions of Article 43, paragraph (2) of the Act that do not constitute lot, or products derived from medical devices, etc., which are specified biologically derived products, etc. After the expiration of the validity period of the product plus one year, The storage of biogenic raw materials used in the manufacture of the product can be substituted for the storage of the product.

(2) in cases where a manufacturer or seller of biologically derived medical devices, etc. handles products pertaining to cell tissue medical devices, in addition to the work set forth in the preceding paragraph, the manufacturer or seller of biologically derived medical devices, etc. shall appropriately manage the work pertaining to the test and inspection of products pertaining to the cell tissue medical devices listed in the following items at the manufacturer of said products based on the Product Standard. The procedure must be established and documented.

To have a person designated in advance perform tests and inspections at the time of acceptance of donor animals and other necessary work according to the nature of the work.

(II) Prepare and retain records pertaining to the operations set forth in the preceding item;

(3) a manufacturer or seller of biological medical devices, etc. shall keep the records set forth in the preceding two paragraphs in such a way that it can properly confirm a series of records ranging from the records pertaining to the biological source raw materials used in the manufacture to the records pertaining to the products manufactured using said biological source raw materials.

(Education and Training)

Article 77 (1) where a manufacturer or seller of biological medical devices, etc. deals with products pertaining to biological medical devices, etc., he/she shall, in addition to the business prescribed in Article 23, document the following business procedures:

(I) to provide education and training related to microbiology, medicine, veterinary medicine, etc. to members engaged in the manufacture or test inspection of products pertaining to biogenic medical devices, etc.

(II) Education and training on measures necessary to prevent contamination by microorganisms shall be provided to members engaged in work in sterile areas and areas handling pathogenic microorganisms.

(2) a manufacturer or seller of biogenic medical devices, etc. shall prepare and retain records pertaining to the education and training set forth in the preceding paragraph.

(Management of Documents and Records)

Article 78 (1) a manufacturer or seller of biological medical devices, etc. shall retain at least a part of the documents prescribed in this Chapter or copies thereof for the period listed in the following items (five years in the case of those pertaining to education and training) from the date of abolition of said documents: However, with regard to documents used for the manufacture or test inspection of a product, it shall be sufficient to keep such documents available for use during the storage of the records pertaining to the product prescribed in the following paragraph.

Raw materials (raw materials or materials used in manufacturing (including those used in manufacturing processes) from medical devices, etc. or human blood that are products derived from specified organisms The same shall apply hereinafter.) It is the origin of the name. The same shall apply hereinafter.) In the case of products pertaining to biologically derived medical devices, etc. manufactured, the effective period plus 30 years

(II) Biological Medical Devices, etc. (excluding those listed in the preceding item) In the case of the product concerned, the period in which 10 years is added to the effective period

(2) a manufacturer or seller of biological medical devices, etc. shall retain the records prescribed in this Chapter for the period listed in item (I) or item (II) of the preceding paragraph (five years in the case of those pertaining to education and training) from the date of preparation.

(Special Provisions on Retention of Records)

Article 79 Notwithstanding the provisions of this Chapter, a manufacturer or seller of biologically derived medical devices, etc. may, with regard to products pertaining to biologically derived medical devices, etc. designated by the Minister of Health, Labour and Welfare, record the records prescribed in this Chapter for the period designated by the Minister of Health, Labour and Welfare, It must be kept. Provided, however, that this shall not apply to cases where the said raw material extractor, etc. shall appropriately store the said raw material for the relevant period by concluding an agreement with the raw material extractor, etc.

Chapter V Production control and quality control of in vitro diagnostic reagents

(Infrastructure for Business Operations of registered Manufacturing Facilities of Radioactive in Vitro Diagnostics)

Article 80 (1) a manufacturer, etc. of a product pertaining to a radioactive in vitro diagnostic reagents shall be appointed as a registered manufacturing facility (excluding a registered manufacturing facility that only designs the product) that manufactures said product. Hereinafter the same shall apply in this chapter.) The following requirements (for registered manufacturing facilities that only package, labeling or storing containers or envelopes prescribed in the proviso of Article 2, paragraph (3), item (I) of the Ordinance for the Manufacture and Handling of Radiopharmaceuticals, the provisions concerning the working room in item (e) and item (iv)) shall be applied to the In the case where the said test and inspection is carried out at its own risk using other test and inspection facilities or other test and inspection bodies of said registered manufacturing facility, and where it is found that there is no hindrance, excluding the provisions concerning the test and inspection rooms of item (II) (e) and item (iv) (II))) Must be fulfilled.

It must be located in a place where there is little risk of landslides and flooding.

(II) the work station of the product pertaining to the in vitro diagnostic reagents shall conform to the following provisions:

(A) the facilities shall be clearly distinguished from other facilities.

Mouth the main structural part, etc. is a fire-resistant structure or a non-combustible material (meaning a non-combustible material prescribed in Article 2, item (ix) of the Building Standards Act (Act No. 201 of 1950)). The same shall apply hereinafter.) Being built in ..

(VIII) that shielding walls and other shielding devices necessary to keep the following doses below the dose limit specified by the Minister of Health, Labour and Welfare shall be provided:

(1) The dose of radiation that a person may be exposed to at any time in a registered manufacturing facility where the person is in constant access

(2) Dose of radiation at the boundary of the registered manufacturing site and in the area where people live within the registered manufacturing site

(II) to have only one entrance/exit where people can enter and exit at all times.

(E) working rooms and test laboratories conforming to the following provisions (including animal testing rooms in the case of animal testing): The same shall apply hereinafter.) Having a ..

(1) Internal walls, floors and other radioactive materials (meaning radioactive materials prescribed in item (II) of Article 1 of the Ordinance on Manufacture and Handling of Radiopharmaceuticals). The same shall apply hereinafter) The parts which may be contaminated by the shall have a structure with few gaps such as protrusions, indentations and joints of finishing materials.

(2) The surface surfaces of internal walls, floors and other areas which may be contaminated by radioactive materials should be smooth, difficult for gases or liquids to penetrate, and Made of materials that are resistant to corrosion.

(3) A waste container that is capable of safely transporting and disposing of radioactive material or material contaminated by radioactive material that is not likely to be scattered, leaked, stained out, or flowed out.

(4) A device to prevent the spread of radioactive substances in gaseous form, such as a hood or glove box, or air contaminated by radioactive substances shall be provided in connection with the exhaust equipment.

A contamination inspection room that conforms to the following provisions (meaning a room that inspects and removes contamination by radioactive substances on the human body or on the surface of work clothes, footwear, protective equipment, etc.) The same shall apply hereinafter) Having a .. However, this shall not apply when handling radioactive materials in quantities or concentrations less than those specified by the Minister of Health, Labour and Welfare.

(1) It shall be located near the entrance and exit of the work place where people always come and go, and in the most suitable place for inspection and removal of contamination by radioactive materials.

(2) (E) to conform to the provisions of (1) and (2) of paragraph (e).

(3) Cleaning equipment and changing facilities shall be provided, and radiometers for contamination inspection and equipment necessary for decontamination shall be provided.

(4) The drainage pipe of the cleaning equipment specified in (3) shall be connected to the drainage equipment.

三 To have storage facilities conforming to the following provisions:

(A) the main structure, etc. shall be fire-resistant, and a storage room with fire doors or a storage box with fire-resistant structure shall be provided at the opening thereof.

(6) a shielding wall or other shielding object that conforms to the standards set forth in (8) of the preceding item shall be provided.

(VIII) to have one entrance or exit where people can come and go at all times.

(II) a door, a lid, or any other closing device or apparatus shall be installed on the part that leads to the outside.

(E) to have a locked facility or apparatus for storing radiopharmaceuticals separately from other materials.

A container for containing radioactive material that conforms to the following provisions shall be provided.

(1) Containers containing radioactive materials that may contaminate the air outside the containers shall have an airtight structure.

(2) Containers for liquid-like radioactive materials must have a structure that prevents liquid from spilling and a material that prevents liquid from permeating.

(3) For containers containing liquid or solid radioactive material that are likely to cause cracks, breakages, or other accidents, a receptacle, absorbent or other equipment or apparatus to prevent the spread of contamination by radioactive material shall be provided.

四 To have disposal facilities conforming to the following provisions.

(A) the facilities shall be clearly distinguished from other facilities.

The main structure, etc. of the mouth shall be fire-resistant or made of non-combustible materials. (C) a shielding wall or other shielding object that conforms to the standards set forth in item (II) (viii) shall be provided.

(II) to have exhaust equipment conforming to the following provisions: However, when handling radioactive materials in quantities or concentrations less than those specified by the Minister of Health, Labour and Welfare, or when installing exhaust equipment significantly interferes with the purpose of use or is difficult due to the nature of the work, and when there is no risk of emitting radioactive materials in gaseous form or contaminating the air with radioactive materials This is not the case.

(1) It must have the ability to limit the concentration of radioactive substances in the exhaust at the exhaust outlet to the concentration limit specified by the Minister of Health, Labour and Welfare, or by establishing an exhaust monitoring system to monitor the concentration of radioactive substances in the exhaust, the boundary of the registered manufacturing facility (if measures are taken to prevent people from entering the area adjacent to the boundary of the registered manufacturing facility without reason, the boundary of the area shall be considered. Hereinafter the same shall apply in

this item.) To have the ability to limit the concentration of radioactive substances in the air outside the above to the concentration limit specified by the Minister of Health, Labour and Welfare. However, this shall not apply to cases where it is extremely difficult to install an exhaust system with such capability, and where the approval of the Minister of Health, Labour and Welfare has been obtained for the exhaust system to have the ability to limit the dose exposure to persons outside the boundary of the registered manufacturing facility to less than the dose limit specified by the Minister of Health, Labour and Welfare.

(2) It has a structure that prevents gas from leaking and a material that is resistant to corrosion.

(3) In the event of a failure, equipment shall be provided that can rapidly prevent the spread of air contaminated by radioactive materials.

(4) Work room, test room, or disposal room (including treatment for solidification (including solidification) with concrete or other solidifying material after incineration of radioactive material or material contaminated by radioactive material, the residue is carried out from the incinerator, or solidified by concrete or other solidifying material. The same shall apply hereinafter) This refers to the room in which the work is carried out. The same shall apply hereinafter) It must have the ability to limit the concentration of radioactive substances in the air to below the concentration limit specified by the Minister of Health, Labour and Welfare.

(E) when purifying or draining liquid radioactive material or liquid contaminated by radioactive material, to have drainage facilities conforming to the following provisions:

(1) Having the ability to limit the concentration of radioactive substances in the effluent at the drainage outlet to below the concentration limit specified by the Minister of Health, Labour and Welfare, or having the ability to reduce the concentration of radioactive substances in the effluent at the boundary of the registered manufacturing facility to below the concentration limit specified by the Minister of Health, Labour and Welfare by establishing a wastewater monitoring facility and monitoring the concentration of radioactive substances in the effluent. However, this shall not apply to cases where it is extremely difficult to install drainage facilities with such capability, and where approval has been obtained from the Minister of Health, Labour and Welfare that the drainage facilities have the ability to limit the dose exposure to people outside the boundaries of the registered manufacturing facilities to less than the dose limit specified by the Minister of Health, Labour and Welfare.

(2) It has a structure that prevents drainage fluid from leaking, and uses materials that prevent drainage fluid from penetrating and are resistant to corrosion.

(3) The wastewater septic tank shall have a structure capable of collecting wastewater or a structure capable of measuring the concentration of

radioactive substances in the wastewater, and shall be equipped with a device to regulate the outflow of wastewater.

(4) The opening at the top of the wastewater septic tank must have a lid or be surrounded by a fence or other equipment to prevent unauthorized entry.

In the case of incineration of radioactive material or material contaminated by radioactive material, a waste working room conforming to the provisions of (1), (2) and (4) of (e) of item (II), a contamination inspection room conforming to the provisions of (1) to (3) of item (II), and an incinerator conforming to the following provisions.

(1) It must have a structure that prevents gas from leaking and that prevents ash from dispersing.

(2) It must be connected to the exhaust system.

(3) The discharge port for incineration residue should be connected to the disposal room.

(B) in the case of solidifying radioactive material or material contaminated by radioactive material with concrete or other solidifying material, the exhaust equipment conforming to the provisions of 2, (e) of item (II), the disposal working room conforming to the provisions of (1), (2) and (4) of item (II), from (1) to (II) To have a contamination inspection room that conforms to the provisions of 3. And solidification treatment facilities that conform to the following provisions.

(1) Radioactive materials or materials contaminated by radioactive materials are not likely to leak or spill, and the structure is unlikely to allow dust to disperse.

(2) Materials that are difficult to penetrate liquids and that are resistant to corrosion are used.

(H) when storing and disposing radioactive material or material contaminated by radioactive material, to have storage and disposal facilities conforming to the following provisions:

(1) The structure must be compartmentalized from the outside.

(2) Doors, lids, and other parts that connect to the outside shall be equipped with a key or other equipment for closing.

(3) Containers conforming to the provisions of the preceding item (limited to those of fire-resistant structure) Must be equipped with.

(V) a fence or other equipment to prevent persons from entering the control area prescribed in Article 1, item (III) of the Ordinance on the Manufacture and Handling of Radiopharmaceuticals shall be provided at the boundary of the control area prescribed in Article 1, item (III) of the Ordinance on the Manufacture and Handling of Radiopharmaceuticals.

(2) the Minister of Health, Labour and Welfare may rescind the said approval when the exhaust equipment or drainage equipment for which the approval set forth in item (iv), 2. 1. Or e. 1. Of the preceding paragraph has been obtained and is no longer deemed to have the capability to pertain to said approval.

(3) in cases where handling only radioactive substances in quantities or concentrations

not exceeding those specified by the Minister of Health, Labour and Welfare, the provisions of item (I), item (II), (b) to (e) inclusive, item (III), (a) to (II) and (III), item (iv) and item (v) of the preceding paragraph shall Not applicable.

(Observance of regulations for Manufacture and Handling of Radioactive in Vitro Diagnostics)

Article 81 (1) in addition to what is provided for in the preceding Article, a manufacturer or seller, etc. of products pertaining to in vitro diagnostics shall confirm that the registered manufacturing facility is conducting its business based on the provisions of the regulations for the manufacture and handling of radiopharmaceuticals.

Chapter V-2 Manufacturing control and quality control of remanufactured single-use medical devices

Article 81-2 (basis of Business Operation at registered Manufacture of remanufacturing Single-use Medical Device manufacturers, etc.) a manufacturer or seller, etc. of products pertaining to remanufacturing Single-use Medical Device (hereinafter referred to as "manufacturer or seller of remanufacturing Single-use Medical Device, etc.") (3) a registered manufacturing facility that manufactures such products (excluding a registered manufacturing facility that only designs or stores the final product in Japan within the manufacturing process) shall be a registered manufacturing facility that manufactures such products (excluding a registered manufacturing facility that only stores the final product in Japan). The same shall apply hereinafter in this chapter.) The following requirements must be met as the foundation for business operations.

— The work station shall conform to the following:

(A) Remanufacturing clean area (meaning a place in a work place where remanufactured parts in which pathogenic microorganisms and other causes of diseases are inactivated or removed are exposed to air within the work site); The same shall apply hereinafter in this chapter.) To have drainage facilities conforming to the following provisions:

(1) They are of suitable construction to prevent contamination from harmful drainage.

(2) It should be of a structure that can be easily cleaned or disinfected.

(B) to have the following facilities: However, this shall not apply if it is clearly recognized that it is not necessary.

(1) For areas that handle recycled parts contaminated with pathogenic microorganisms or other causes of disease, equipment for cleaning, drying and sterilization of recycled parts, equipment for cleaning, disinfection and sterilization of equipment used in the area, and equipment for the treatment of waste liquids, etc.

(2) Transport containers (means containers for transporting single-use medical devices used in medical institutions that have not been cleaned or sterilized. The same shall apply hereinafter in this chapter.) Equipment necessary for cleaning, disinfection, drying and storage of the , including

drainage equipment to prevent contamination by hazardous wastewater.

(VIII) to be equipped with the following test and inspection equipment: However, this shall not apply in cases where such test and inspection is conducted at the person's own responsibility by using another testing and inspection organization such as the manufacturer and seller of the remanufacturing single-use medical device, and it is recognized that there is no hindrance to the said test and inspection.

(1) Equipment and equipment to verify that regenerated parts that have been inactivated or removed from pathogenic microorganisms or other causes of diseases are not contaminated by such microorganisms

(2) Other equipment and equipment necessary for test and inspection

二 Areas that handle recycled parts contaminated with pathogenic microorganisms or other causes of disease must be clearly distinguished from other areas and have special facilities and equipment for the production of such parts. In addition, in the manufacturing process after the inactivation or removal of pathogenic microorganisms and other causes of disease, the equipment and equipment necessary for manufacturing shall be provided.

(Process Control)

Article 81-2-2 (1) when handling products pertaining to remanufactured single-use medical devices, a manufacturer or seller of remanufactured single-use medical devices, etc. shall appropriately manage the work related to process control of the products pertaining to the following remanufactured single-use medical devices, and shall document the procedures thereof, based on Product Standards:

(I) having a person designated in advance in accordance with the contents of the business perform the following business:

(A) a manufacturer and seller of remanufacturing single-use medical devices, etc. shall evaluate and select a medical institution that is a supplier of regenerative parts that conforms to the following provisions:

(1) A system for supplying remanufactured parts that conform to the standards specified by the Minister of Health, Labour and Welfare is in place.

(2) Separate remanufactured parts so that they are not damaged, deteriorated, or contaminated with pathogenic microorganisms or other disease-causing substances that cannot be inactivated or removed in the manufacturing process

Stored.

Reproduction of remanufactured parts contaminated with oral pathogenic microorganisms or other causes of disease Single-use when reusing transport containers used by medical device manufacturers and distributors, etc., clean and disinfect the transport containers as necessary.

(C) in the case of inactivating or removing pathogenic microorganisms or other causes of disease that have adhered to the Recycled Parts in the manufacturing process, to take necessary measures to prevent contamination by the Recycled Parts that have not been inactivated or removed.

(II) in the case of handling more than one remanufactured part, to take necessary measures to prevent confusion between remanufactured parts or between remanufactured parts and component parts other than remanufactured parts, etc. and cross contamination with pathogenic microorganisms or other causes of disease.

(E) when the manufacturing equipment, etc. is contaminated by recycled parts to which pathogenic microorganisms or other causes of disease are attached in the manufacturing process, to take necessary measures to remove the contamination.

In the following cases, validation of the cleaning process and other necessary validations shall be performed, and a record thereof shall be created and stored.

(1) When the manufacturing facility commences the manufacture of products related to remanufactured single-use medical devices

(2) When there is a change in the manufacturing procedure, etc. that has a significant impact on the quality of the product related to the remanufactured single-use medical device

(3) There is a change in the quality, performance or specifications of the prototype medical device

(4) Other cases where it is deemed necessary to properly carry out manufacturing control and quality control of products related to remanufactured single-use medical devices

(B) to restrict access to the remanufacturing clean area by persons other than those who engage in work in the remanufacturing clean area as much as possible.

(H) not to allow remanufactured parts with pathogenic microorganisms or other causes of diseases to be brought into the remanufacturing clean area.

(I) with regard to component parts, etc. used in the manufacture of remanufacturing single-use medical devices, the relevant component parts, etc. shall be confirmed to be appropriate in light of the product standard documents of said products, and records related to the results shall be remanufactured. Serial numbers, etc. (meaning unique numbers, symbols or other codes used to identify individual remanufacturing single-use medical devices). The same shall apply hereinafter) To be created and stored.

(J) with regard to recycled parts, a record of matters that must be recorded shall be prepared and retained by the Minister of Health, Labour and Welfare pursuant to the provisions of the Minister of Health, Labour and Welfare.

(II) the name of the place of business to which the product is shipped and the date of shipment shall be identified for each serial number, etc. of the remanufactured single-use medical device, and the record thereof shall be prepared and retained.

(2) a remanufacturing single-use medical device manufacturer, etc. shall keep the records set forth in the preceding paragraph for each serial number, etc. in such a way that it is possible to properly confirm a series of records ranging from the records pertaining to the remanufactured parts used in the manufacture to the records pertaining to the products manufactured using said remanufactured parts.

(Test Inspection)

Article 81-2-3 (1) in cases where a manufacturer or seller of remanufactured single-use medical devices, etc. handles products pertaining to remanufactured single-use medical devices, in addition to the work prescribed in the preceding Article, the manufacturer or seller of remanufactured single-use medical devices shall, in order to prevent the mixing of specimens and cross-contamination at the manufacturing facilities of the said products, based on the Product Standards, Work related to testing and testing of component parts, etc. and products related to remanufactured single-use medical devices, such as classifying specimens by appropriate identification and labeling, shall be appropriately managed and the procedures shall be documented.

(Education and Training)

Article 81-2-4 (1) when handling products pertaining to remanufactured single-use medical devices, the manufacturer or seller of remanufactured single-use medical devices, etc. shall, in addition to the work prescribed in Article 23, provide microbiology, Procedures for education and training in medicine, veterinary medicine, etc. shall be documented.

(2) a manufacturer or seller of remanufacturing single-use medical devices, etc. shall prepare and retain records pertaining to the education and training set forth in the preceding paragraph.

(Management of Documents and Records)

Article 81-2-5 (1) a remanufacturing single-use medical device manufacturer, etc. shall retain at least a part of the document or a copy thereof provided for in this Chapter for a period of at least five years (five years in the case of education and training) added to the valid period of the product pertaining to the remanufactured single-use medical device from the date of abolition of said document. However, with regard to documents used for the manufacture or test inspection of a product, it shall be sufficient to keep such documents available for use during the storage of the records pertaining to the product prescribed in the following paragraph.

(2) a manufacturer or seller of remanufacturing single-use medical devices, etc. shall retain the records prescribed in this Chapter for a period of five years (five years in the case of education and training) added to the valid period of products pertaining to remanufactured single-use medical devices from the date of preparation.

(Ensuring Traceability of Products pertaining to remanufactured Single-use Medical Devices)

Article 81-2-6 (1) where there is a risk that a product pertaining to a remanufactured single-use medical device will no longer conform to the product requirements due to component parts, etc. or working environment conditions, a manufacturer or seller of remanufactured single-use medical device, etc. shall ensure traceability of records pertaining to all such component parts, etc. and working environment conditions.

(2) a manufacturer or seller of remanufactured single-use medical devices, etc. shall, in order to ensure traceability of products pertaining to remanufactured single-use medical devices after shipment, establish a seller, etc. (meaning a seller or a lender

of highly controlled medical devices or controlled medical devices) that handle such products. The same shall apply in the following paragraph.) The Company shall have the record of the distribution of such products be made and retained.

(3) the records set forth in the preceding paragraph shall be obtained in cases where a remanufacturing single-use medical device manufacturer, etc. has undergone an investigation pursuant to the provisions of Article 20-2-5, paragraph (7) or (9) or paragraph (2) of Article 23-2-6-2, paragraph (4) of the Act, an investigation pursuant to the provisions of Article 23-2-2-2-2-2-2-2-2-2, paragraph (4, paragraph (4) of the Act, or paragraph (4) of the Act, or paragraph (4) of the Act, or paragraph (4) of the Act, When requested by the prefectural governor or the Implementer of the Conformity Survey of Medical Devices, etc. prescribed in Article 37-23 of the Order, the seller, etc. shall keep it so that the seller, etc. can present it.

Chapter VI Application mutatis mutandis to manufacturers, etc. of Medical Devices, etc.

(Manufacturing Control and Quality Control by manufacturers of Medical Devices, etc. for Export)

Article 82 (1) with regard to the manufacturing control and quality control of products by a manufacturer of products pertaining to medical devices, etc. for export set forth in Article 80, paragraph (2) of the Act, chapters II and III (excluding paragraphs (2) and (3) of Article 49 and Articles 69 to 72-3) of the Act. "Biological Medical Devices"

In addition to these provisions, the provisions of Chapter IV for manufacturers of products, the provisions of Chapter V for manufacturers of products pertaining to in vitro diagnostic drugs, and the provisions of Chapter V for manufacturers of products pertaining to remanufactured single-use medical devices, in addition to these provisions for manufacturers of products pertaining to remanufactured single-use medical devices, Chapter V-2 (excluding paragraphs (2) and (3) of Article 81-2-6)). The provisions of the Law shall apply mutatis mutandis. In this case, the terms listed in the middle column of the provisions listed in the left column of the following table shall be replaced with the terms listed in the right column of the same table.

Article 5-2, item (I)	Each facility and its department	Each department in the manufacturing facility
Article 5-5, paragraph (2)	You have to manage it. However, among general medical devices, medical devices other than those designated by the Minister of Health, Labour and Welfare as those requiring care in production control or quality control (hereinafter referred to as "limited general medical devices") In this regard, it shall be sufficient if the method of control of the process set forth in the preceding paragraph is clearly stipulated in the quality control supervision system	You have to manage it
Article 5-5, paragraph (3)	(2). However, this shall not apply to processes pertaining to limited general medical devices	It must be specified in the document
Article 5-6, paragraph (1)	Manufacturer, etc. (a manufacturer or distributor of limited type 3 medical devices (meaning a manufacturer or distributor who manufactures and sells limited general medical devices only) The same shall apply hereinafter.) Except for. Hereinafter the same shall apply in this Article.)	Manufacturer, etc.
Article 6	Matters (excluding item (I) for a limited Type 3 Medical Device manufacturer and Seller)	Matters
Article 6, item (iv)	Each facility	MFG
Article 10	Business (limited to the business listed in items (I) and (v) in the case of a management supervisor of a limited Type 3 medical device manufacturer)	Business
	(Hereinafter referred to as "Product Recipient Requirements") (Limited to the provisions of laws and regulations, etc. in the case of a Management Supervisor of a Limited Type 3 Medical Device	(Hereinafter referred to as "Product Recipient

	manufacturer)	Requirements")
	To all facilities	In the manufacturing plant
Article 11	Supervisors (excluding supervisors of limited Type 3 medical device manufacturers) The same shall apply in the following Article to Article 14, Article 106, Article 18 and Article 19)	Supervisor

Article 12, item (iv)	To all facilities	In the manufacturing plant
Article 13, paragraph (1)	Each facility	MFG
Article 15, paragraph 1	All facilities	MFG
Article 16, paragraph (2), item (III)	All facilities	The entire manufacturing facility
Article 17	Within and between facilities	MFG
Article 19, item (vi)	Products (excluding products pertaining to limited general medical devices)	Product
Article 20	Matters (excluding the matters listed in item (II) for products pertaining to limited general medical devices)	Matters
Item (II) of Article 20	Product recipient requirements (limited to the provisions of laws and regulations, etc. in the case of a limited type 3 medical device manufacturer and seller)	Product Recipient Requirements
Article 23	Business (excluding the business listed in item (III) for a limited Type 3 Medical Device manufacturer and Seller)	Business
Article 24, paragraph (1)	Must be documented. However, it shall be sufficient for a limited Type 3 medical device manufacturer to clarify, secure, and maintain the following operational foundations necessary to achieve compliance with the product requirements	I have to document it I don't
Article 24, paragraph (1), item (I)	Each facility	MFG
Article 24, paragraph (2)	Must be documented. However, for a limited type 3 medical device manufacturer and distributor, it shall be sufficient to establish appropriate operation of the maintenance work and to document it	I have to document it I don't
Article 25, paragraph (1)	Products (excluding products pertaining to limited general medical devices). Hereinafter the same shall apply in this Article to Article 36-2.)	Product
Article 28,	Each facility	MFG

paragraph (2)		

No. 5		
Article 37, paragraph (2)	Standards should be established and suppliers should be evaluated and selected in accordance with those standards. However, in the case of a limited Type III medical device manufacturer and seller, the purchase goods, etc. shall be transferred to the process or final product (meaning products other than intermediate products) pertaining to the subsequent realization of the product. It shall be sufficient to establish standards pertaining to the evaluation of suppliers of such purchased goods, etc., and to evaluate such suppliers in accordance with such standards	We have to set standards You can't
Article 37, paragraph 3	Reevaluation (for suppliers of purchased goods, etc. of products pertaining to limited general medical devices, reevaluation)	Re-evaluate
Article 37, paragraph (6)	In the case of a limited Type 3 medical device manufacturer and distributor, it shall be limited to the records pertaining to the evaluation set forth in paragraph (2) and the results of the reevaluation set forth in paragraph (3)	Include records
Article 38, paragraph (4)	It must be kept. However, this shall not apply to products pertaining to limited general medical devices	It must be kept
Article 40, paragraph (1)	Products (excluding products pertaining to limited general medical devices). The same shall apply in paragraph (3))	Product
Article 40, paragraph (1), item (vi)	To the market	From the manufacturer concerned
Article 40, paragraph (2)	It must be kept. However, with regard to products pertaining to limited general medical devices, it shall be sufficient to create a record for each lot of the product so that the quantity manufactured and the quantity decided to be shipped can be identified, and keep this record	It must be kept
Paragraph (1) of Article 41	Products (excluding products pertaining to limited general medical devices). Hereinafter the same shall apply in this Article to Article 5" 1 inclusive and Article 53)	Product
Article 42, paragraph	Handle	Manufacturing

(1)		
Article 44 and Article 46	Handle	Manufacturing

Article 52, paragraph (1)	Until distribution (in the case of a limited Type III Medical Device manufacturer, during the business under his/her responsibility)	Until distribution
	Must be documented. However, with regard to products pertaining to limited general medical devices, this shall be limited to the duration of the business in which the manufacturer, etc. is responsible for the said products	I have to document it I don't
Article 52, paragraph (3)	It must be recorded. However, this shall not apply to products and component parts, etc. pertaining to limited general medical devices	It must be recorded
Article 54, paragraph (1), item (I)	Products (excluding products pertaining to limited general medical devices)	Product
Article 55, paragraph (1)	Self	MFG
Article 55, paragraph (4)	Information collected pursuant to the provisions of Article 68-2, paragraph (1) of the Act	From the factory
Article 55-2, paragraph (1), item (iv)	Report based on the provisions of Article 68-10, paragraph (1) of the Act and Article 68-11 of the Act	If it is required to notify the regulatory authorities of the country or region to which the product is exported of information about a product defect, such notification
Article 55-3, paragraph (1)	Report based on the provisions of Article 68-10, paragraph (1) of the Act and Article 68-11 of the Act	If it is required to notify the regulatory authorities of the country or region to which the product is exported of information about a product defect, such notification
Article 56, paragraph (1), item (I)	Quality control supervision system (for products pertaining to limited general medical devices, excluding product realization plans)	Quality Control Supervision System MU
Article 57,	Products (excluding products pertaining to limited	Product

paragraph (3)	general medical devices)	

Article 58, paragraph (4)	Records (in cases where a manufacturer or seller, etc. other than a limited Type 3 medical device manufacturer has used equipment and apparatus for the monitoring and measurement necessary for demonstrating conformity to the criteria for deciding whether to ship or not, etc., records identifying said equipment and apparatus shall be included.)	Record
Article 59	Products (excluding products pertaining to limited general medical devices). The same shall apply in the following Article.)	Product
Article 61, paragraph (4)	It must be kept. However, this shall not apply to products pertaining to limited general medical devices	It must be kept
Thirteenth Article	Manufacturers and distributors of medical devices derived from specified organisms	Manufacturer of specified organisms for export medical equipment
Article 74 and Article 75, paragraph (1)	Manufacturers and distributors of biologically derived medical devices, etc.	Manufacturer of biologically derived medical equipment for export
	Handle	Manufacturing
Article 75, paragraph (2)	Manufacturers and distributors of biologically derived medical devices, etc.	Manufacturer of biologically derived medical equipment for export
	Handle the product	Make the product
Article 75, paragraph (3)	Manufacturers and distributors of biologically derived medical devices, etc.	Manufacturer of biologically derived medical equipment for export
Article 76, paragraphs (1) and (2)	Manufacturers and distributors of biologically derived medical devices, etc.	Manufacturer of biologically derived medical equipment for export
	Handle	Manufacturing
Article 76, paragraph 3	Manufacturers and distributors of biologically derived medical devices, etc.	Manufacturer of biologically derived medical equipment for export
Article 77, paragraph	Manufacturers and distributors of biologically derived medical devices, etc.	Manufacturer of biologically derived

(1)		medical equipment for export
	Handle	Manufacturing
Article 77, paragraph (2), Article 718 and	Manufacturers and distributors of biologically derived medical devices, etc.	Manufacturer of biologically derived medical equipment for export

Article 709		
Article 81-2	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export
Article 81-2-2, paragraph (1)	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export
	Handle the product	Make the product
Article 81-2-2, paragraph (2)	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export
Article 81-2-2	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export
	Handle	Manufacturing
Article 81-2-4, paragraph (1)	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export
	Handle	Manufacturing
Article 81-2-4, paragraph (2)	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export
Article 81-2-5	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export
Article 81-2-6, paragraph (1)	Manufacturers and distributors of remanufacturing single-use medical devices, etc.	Manufacturer of remanufactured single use medical devices for export

(Manufacturing Control and Quality Control by manufacturers, etc. pertaining to registered Manufacturing Facilities)

Article 83 (1) in cases where a place of business that has been outsourced to a manufacturer, etc. or another registered manufacturer, or a place of business that supplies purchased Goods, etc. to a manufacturer, etc. or another registered

manufacturer is a registered manufacturer, a manufacturer or a foreign manufacturer of medical devices, etc. (hereinafter referred to as "manufacturer, etc. pertaining to a registered manufacturer, etc.") Chapter II to Chapter V-2 inclusive (excluding Article 19, item (III), Article 49, paragraphs (2) and (3), Articles 69 to 72-3 inclusive, and Article 8 "1-2-6, paragraphs (2) and (3))) with regard to the production control and quality control of products. The provisions of the preceding paragraph shall apply mutatis mutandis. However, in light of the processes carried out by the registered manufacturer for the product, provisions that are deemed inappropriate to be applied to the quality control supervision system may not be applied to the quality control supervision system. In this case, the manufacturer, etc. pertaining to the registered manufacturing facility shall state that effect in the Quality Control and Supervision System Standard for the said product.

(2) in the case referred to in the preceding paragraph, Article 5-6, Article 6, Article 7, paragraph (2), Article 8, paragraph (3), Article 10, Article 11, Article 21, item (II), Article 23, Article 24, Article 25, paragraph (1), Article 37, paragraphs (2) and (6), Article 38, paragraph (4), Article 40, paragraph (1), Article 41, paragraph (1), Article 50, paragraph (1), Article 54, paragraph (1), Article 56, paragraph (6), Article 57, paragraph (2), Article 58, paragraphs (2) and (4), In Article 59, Article 62 and Article 64, paragraph (1), the term "qualified third-class medical device manufacturer, etc." means "qualified third-class medical device manufacturer, etc."; in the provisions of Articles 73 to 79, the term "biogenic medical device manufacturer, etc." means "manufacturer, etc. of biogenic medical device, etc." means "manufacturer, etc. of biogenic medical device, etc."; and "manufacturer, etc., reuse, etc.," In Article 5-6, paragraph (1), "a manufacturer who manufactures and sells" shall be deemed to be replaced with "a manufacturer, etc. pertaining to the registered manufacturing facility that manufactures." "Handling" in paragraph (1) of Article 42 means "manufacturing", "handling" in Article 44 and Article 46 means "manufacturing", and "information collected pursuant to the provision of paragraph (1) of Article 68-2 of the Act" in paragraph (4) of Article 55 means "from the registered factory" and paragraphs (1) and (4) of Article 55-2" of Article 55 of the Act "Report based on the provisions of Article 228-20, paragraph (1) and Article 74, paragraph (2) of the Ordinance for Enforcement" means "notification", "report" in paragraph (2) of the same Article and "manufacturer, etc. of specified biogenic medical devices, etc." in Article 73 means "notification" and "manufacturer, etc. of specified biogenic medical devices, etc." in Article 73. The term "handle" in Article 76, paragraphs (1) and (2), Article 77, paragraph (1), Article 81-2-2 and Article 81-2-4, paragraph (1) shall be deemed to be replaced with "manufacture."

(Management by manufacturer, etc.)

Article 84 (1) where a manufacturer, etc. pertaining to a registered manufacturing facility outsources the necessary processes pursuant to the provision of Article 5-5 as applied mutatis mutandis pursuant to the preceding Article, or where the place of business of a supplier of purchased goods is a registered manufacturing facility, the manufacturer, etc. shall make necessary confirmation that the outsourcing or the

management of said supplier is being carried out appropriately.

Supplementary Provisions

(Effective Date)

Article 1 this Ministerial Ordinance shall come into effect as of April 1, 2005.

(Transitional Measures)

Article 2 the Ordinance on Manufacturing Control and Quality Control of Medical Devices (Ordinance of the Ministry of Health, Labour and Welfare No. 40 of 1995) shall cease to be effective only on March 31, 2005. However, the provisions of the Supplementary Provisions of the Pharmaceutical Affairs Act and the Act for Partial Revision of the blood Collection and blood Donation Business Control Act (Act No. 96 of 2002) or the Cabinet Order on Establishment of relevant Cabinet Orders accompanying the enforcement of the Pharmaceutical Affairs Act and the Act for Partial Revision of the blood Collection and blood Donation Business Control Act (Cabinet Order No. 535 of 2003) are deemed to have been approved under Article 13 of the preceding paragraph 3 of the preceding Article 14 of the Act.

Article 3 the Ordinance on Import and Sales Control and Quality Control of Medical Devices (Ordinance of the Ministry of Health, Labour and Welfare No. 63 of 1999) shall cease to be effective only on March 31, 2005.

Article 4 for a period of two years from the date of enforcement of this Ministerial Ordinance, section 3 of Chapter II (excluding Article 15) Section 5 (Article 26(5) and (6), Articles 27 to 36 inclusive, Article 37(4) and (5), Article 4"1, Article 45 (excluding the part pertaining to the sterilization process) , Article 47, Article 50 and Article 5 "limited to Article 1") And section 6 (limited to Article 57, Article 6 "1 and Article 64) (Including cases where these provisions are applied mutatis mutandis in Chapter V) The provisions of the may not apply.

Supplementary Provisions (Ordinance of the Ministry of Health, Labour and Welfare No. 87, July 3, 2010 ○) Extract

(Effective Date)

Article 1 this Ministerial Ordinance shall enact the Act for Partial Revision of the Pharmaceutical Affairs Act, etc. (hereinafter referred to as the "Revising Act"). This shall come into effect as of the date of enforcement of the Act (November 25, 2014).

(Transitional Measures accompanying Partial Revision of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and in-Vitro Diagnostics)

Article 10 (1) Medical devices that have received approval under Article 14 or Article 19-2 of the Old Pharmaceutical Affairs Act or approval under Article 23-2 of the Old Pharmaceutical Affairs Act prior to the enforcement of this Ministerial Ordinance (Cabinet Order No. 269 of 2016) (Article 63 of the Supplementary Provisions of the Revising Act or the Act for Partial Revision of the Pharmaceutical Affairs Act, etc.) Hereinafter referred to as "Revised Cabinet Order" in this paragraph) (Including those

approved under Article 14 or Article 19-2 of the Old Pharmaceutical Affairs Act or those approved under Article 23-2 of the Old Pharmaceutical Affairs Act for which the provisions then in force shall remain applicable pursuant to the provisions of Article 18) (For medical devices that have obtained approval under Article 14 or Article 19-2 of the Old Pharmaceutical Affairs Act or approval under Article 23-2 of the Old Pharmaceutical Affairs Act for which the provisions then in force shall remain applicable pursuant to the provisions of Article 63 of the Supplementary Provisions of the Revised Act or Article 18 of the Revised Cabinet Order, or approval under Article 23-2 of the Old Pharmaceutical Affairs Act, Those that fall under the category of medical devices other than those specified by the Minister of Health, Labour and Welfare as prescribed in Article 4, paragraph (1) of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and in-Vitro Diagnostics prior to the revision pursuant to the provisions of Article 9 (excluding those approved by the Minister of Health, Labour and Welfare as medical devices capable of controlling design and development). And Article 23 of the former Pharmaceutical Affairs Act for which the approval under Article 14 or Article 19-2 of the former Pharmaceutical Affairs Act or the approval under Article 23-2 of the former Pharmaceutical Affairs Act was obtained at the time of the enforcement of this Ministerial Ordinance (excluding the approval under Article 14 or Article 19-2 of the former Pharmaceutical Affairs Act or the approval under Article 18 of the revised Cabinet Order for in vitro diagnostic products for which the development of the former Pharmaceutical Affairs Act can still be approved or for non-labor). Ministerial Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and in Vitro Diagnostics Revised pursuant to the provisions of Article 9 (referred to as the "Ordinance of the Ministry of Manufacturing Control, etc. of New Medical Devices" in the following paragraph) The provisions of Articles 30 to 36 shall not apply.

(2) Article 72, paragraph (1) (limited to the part pertaining to item (II)) of the Ordinance on the Standards for Manufacturing Control, etc. of New Medical Devices with respect to Domestic Quality Business Operation Managers of manufacturers and distributors who manufacture and sell programmed medical devices only. With regard to the application of this provision, a person who has completed the Program Special Training Course for Medical Devices shall be deemed to have been engaged in quality control services or other similar services for three years or more until January 24, 2020.

Supplementary Provisions (Ordinance of the Ministry of Health, Labour and Welfare No. 12 (c) of January 2009)

This Ministerial Ordinance shall come into effect as of the date of promulgation.

Supplementary Provisions (Ordinance of the Ministry of Health, Labour and Welfare No. 84 of July 31, 2009) Extract

(Effective Date)

Article 1 this Ministerial Ordinance shall come into effect as of the date of

promulgation.

Supplementary Provisions (Ordinance of the Ministry of Health, Labour and Welfare No. 1-4, January 24, 2009)

This Ministerial Ordinance shall come into effect as of the date of promulgation.

Supplementary Provisions (August 31, 2020, Ordinance of the Ministry of Health, Labour and Welfare No. 155) Extract

(Effective Date)

Article 1 this Ministerial Ordinance shall come into effect as of the date of enforcement (September 1, 2020) of the Act for Partial Revision of the Act on Securing the Quality, Effectiveness and Safety of Pharmaceuticals, Medical Devices, etc. (Act No. 63 of 2019).

Supplementary Provisions (Ordinance of the Ministry of Health, Labour and Welfare, January 29, 2021, No. 15) Extract

(Effective Date)

Article 1 this Ministerial Ordinance shall stipulate the Act for Partial Revision of the Act on Securing the Quality, Effectiveness and Safety of Pharmaceuticals, Medical Devices, etc. (hereinafter referred to as the "Revised Act"). It shall come into effect as of the date of enforcement of the provisions prescribed in Article 1, item (II) of the Supplementary Provisions (August 1, 2021).

Supplementary Provisions (Ordinance of the Ministry of Health, Labour and Welfare, March 26, 2021, No. 6 〇) Extract

(Effective Date)

Article 1 this Ministerial Ordinance shall come into effect as of the date of promulgation.

(Transitional Measures)

Article 2 Notwithstanding these provisions, the provisions then in force shall remain applicable until the day on which three years have elapsed from the date of enforcement of this Ministerial Ordinance with regard to the application of the provisions of the Ministerial Ordinance concerning the Standards for Manufacturing Control and Quality Control of Medical Devices and in Vitro Diagnostics revised by this Ministerial Ordinance.

(2) related to the enforcement of the Act for Partial Revision of the Pharmaceutical Affairs Act, etc. and the Act for Partial Revision of the Pharmaceutical Affairs Act, etc. Ministerial Ordinance on the Maintenance, etc. of the relevant Ministerial Ordinance accompanying the enforcement of the Cabinet Order on the Maintenance, etc. of the Cabinet Order and Transitional Measures

(Ordinance of the Ministry of Health, Labour and Welfare No. 87 of 2014.) Hereinafter referred to as "Revised Ministerial Ordinance" in this paragraph) The Act for Partial

Revision of the Pharmaceutical Affairs Act, etc. (Act No. 84 of 2013. Less than or equal "Revision Law") The Pharmaceutical Affairs Act prior to the revision by the provisions of Article 1 (Act No. 145 of 1960. Hereinafter referred to as the "former Pharmaceutical Affairs Law.") Medical devices approved under Article 14 or Article 19-2 or certified under Article 23-2 of the former Pharmaceutical Affairs Act (Cabinet Order on Development, etc. and Transitional Measures of relevant Cabinet Orders accompanying the enforcement of the Act for Revising Article 63 of the Supplementary Provisions of the Revising Act or the Act for Revising Part of the Pharmaceutical Affairs Act, etc. (Cabinet Order No. 269 of 2008). Hereinafter referred to as "Revised Cabinet Order" in this paragraph) (Including those approved under Article 14 or Article 19-2 of the Old Pharmaceutical Affairs Act or those approved under Article 23-2 of the Old Pharmaceutical Affairs Act for which the provisions then in force shall remain applicable pursuant to the provisions of Article 18) In the case of medical devices that have obtained approval under Article 14 or Article 19-2 of the Old Pharmaceutical Affairs Act or approval under Article 23-2 of the Old Pharmaceutical Affairs Act for which the provisions then in force shall remain applicable pursuant to the provisions of Article 63 of the Supplementary Provisions of the Revised Act or Article 18 of the Revised Cabinet Order, or approval under Article 23-2 of the Old Pharmaceutical Affairs Act A medical device other than a medical device specified by the Minister of Health, Labour and Welfare as prescribed in Article 4, paragraph (1) of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and in-Vitro Diagnostics prior to the revision pursuant to Article 9 of the Revised Ministerial Ordinance (excluding those approved by the Minister of Health, Labour and Welfare as medical devices capable of controlling design and development). And in vitro diagnostic drugs that have received approval under Article 14 or Article 19-2 of the Old Pharmaceutical Affairs Act or approval under Article 23-2 of the Old Pharmaceutical Affairs Act at the time of enforcement of the revised Ministerial Ordinance (including approval under Article 14 or Article 19-2 of the Old Pharmaceutical Affairs Act, or approval under Article 23 of the Old Pharmaceutical Affairs Act that can be approved for development of pharmaceuticals other than those approved by the Minister of Health and Labour). The provisions of Articles 30 to 36-2 of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and in Vitro Diagnostics amended by this Ministerial Ordinance shall not apply.

Supplementary Provisions (○ Ordinance of the Ministry of Health, Labour and Welfare No. 84 of may 2, 2022) Extract

(Effective Date)

(1) this Ministerial Ordinance shall come into effect as of the date of promulgation of the Act for Partial Revision of the Act on Securing Quality, Effectiveness and Safety of Pharmaceuticals, Medical Devices, etc. (Act No. 47 of 1992).

Supplementary Provisions (Ordinance of the Ministry of Health, Labour and

Welfare No. 12 (c) of September 13, 1992)

This Ministerial Ordinance shall come into effect as of December 1, 1992.