

Tentative translation of MHLW MO 169 revised in 2021, Chapter 5-2

(Note)

- 1) This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail.
- 2) The requirements of MHLW MO 169 are applied to both the Marketing Authorization Holder and the person operating the Registered Manufacturing Site. In this document the requirements are stipulated as the requirements for the Marketing Authorization Holder. Meanwhile, when they are applied to the Registered Manufacturing Site, the requirements must be paraphrased, as appropriate.

(Definition)

Article 2

27. The term, "re-manufactured single-use medical devices," in this MHLW Ordinance means medical devices for single use (medical devices that can be used only once; hereinafter the same), which have been re-manufactured (inspection, disassembly, cleaning, sterilization, and other necessary processing for the purpose of newly manufacturing and marketing single-use medical devices after use; hereinafter the same).

28. In this Ordinance, "recycled parts" refer to all or part of single-use medical devices used in medical institutions among parts, etc. specified in Paragraph 3 and are supplied for re-manufacturing.

(Scope of application)

Article 3

4. Marketing authorization holders, etc. shall implement manufacturing control and quality control for products related to re-manufactured single-use medical devices in accordance with the provisions of Chapter 2 and Chapter 3 as well as the provisions of Chapter 5-2.

Chapter 5-2. Manufacturing control and quality control of re-manufactured single-use medical devices

(Infrastructure for operation at a registered manufacturing site of a marketing authorization holder, etc. of re-manufactured single-use medical devices)

Article 81-2 Marketing authorization holders, etc. of products related to re-manufactured single-use medical devices (hereinafter referred to as "marketing authorization holders, etc. of re-manufactured single-use medical devices") shall meet the following requirements as an infrastructure for operation at a registered manufacturing site (excluding registered manufacturing sites that only design in the manufacturing process or store finished products in Japan; the same shall apply hereinafter in this chapter) that manufactures the products.

[1] Work areas shall conform to the following requirements.

B. Re-manufacturing clean areas (work areas where recycled parts are exposed to the air in the work areas after pathogenic microorganisms and other causes of diseases are inactivated or removed; the same shall apply in this chapter) shall have a drainage facility conforming to the following requirements.

(1) The facility shall have an appropriate structure to prevent contamination by harmful drainage.

(2) The facility shall have a structure that can be easily cleaned or disinfected

B. There should be facilities listed below. This shall not apply if it is considered obviously unnecessary.

(1) Areas where recycled parts contaminated by pathogenic microorganisms or other causes of diseases are handled: Facilities for cleaning, drying, and sterilization of recycled parts, facilities for cleaning, disinfection, and sterilization of apparatuses used in the areas, and facilities for treatment of waste fluids, etc.

(2) Facilities necessary for cleaning, disinfection, drying, and storage (including drainage facilities to prevent contamination by harmful drainage) of transportation containers (containers for transporting single-use medical devices used in medical institutions, which have not been cleaned or sterilized; the same shall apply hereinafter in this chapter)

C. The following testing facilities and apparatuses are provided. This does not apply to cases where testing is performed by using other testing institutions of a marketing authorization holder, etc. of re-manufactured single-use medical devices on their own responsibility without any problem.

(1) Facilities and apparatuses to verify that recycled parts which have undergone inactivation or removal of pathogenic microorganisms and other causes of diseases are not contaminated by the microorganisms

(2) Other facilities and apparatuses necessary for testing

[2] Areas, where recycled parts contaminated by pathogenic microorganisms or other causes of diseases are handled, shall be clearly separated from the other areas and have dedicated facilities and apparatuses to conduct the manufacturing. In the manufacturing process after the process to inactivate or remove pathogenic microorganisms and other causes of diseases, there should be facilities and apparatuses necessary for manufacturing.

(Process control)

Article 81-2-2 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall, when handling products related to re-manufactured single-use medical devices, appropriately control the following operations related to process control of products related to re-manufactured single-use medical devices based on a product master formula and establish/document procedures of the operations.

[1] Instruct a person designated beforehand to conduct the following operations according to the details of the operations.

A. Marketing authorization holders, etc. of re-manufactured single-use medical devices shall

evaluate and select medical institutions as suppliers of recycled parts that meet the following requirements.

(1) A system for supplying recycled parts conforming to the standards specified by the Minister of Health, Labour and Welfare has been established.

(2) Recycled parts are stored separately so that they are not damaged, deteriorated, or contaminated by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.

B. For reusing transportation containers used when marketing authorization holders, etc. of re-manufactured single-use medical devices receive recycled parts contaminated by pathogenic microorganisms or other causes of diseases, the transportation containers should be cleaned and disinfected where necessary.

C. Take necessary measures to prevent contamination by recycled parts that have not undergone inactivation or removal when pathogenic microorganisms or other causes of diseases adhering to the recycled parts are inactivated or removed in the manufacturing process.

D. When handling multiple recycled parts, take measures necessary to prevent mix-up among recycled parts and among recycled parts and parts, etc. other than the recycled parts as well as cross-contamination by pathogenic microorganisms and other causes of diseases.

E. If manufacturing facilities, etc. are contaminated by recycled parts, to which pathogenic microorganisms or other causes of diseases have adhered, in the manufacturing process, take necessary measures to remove such contamination.

F. In the following cases, perform validation of cleaning process and other necessary validation, and prepare and retain the records.

(1) When manufacturing of products related to re-manufactured single-use medical devices is newly started at the manufacturing site

(2) When there is a change in manufacturing procedures, etc., which has a significant impact on the quality of products related to re-manufactured single-use medical devices

(3) When there are any changes in the quality, performance, or specifications of the original medical device

(4) Other cases where it is deemed necessary to appropriately conduct manufacturing control and quality control for products related to re-manufactured single-use medical devices

G. Restrict entry of persons other than those engaged in operations in a re-manufacturing clean area to the re-manufacturing clean area as much as possible.

H. Do not bring recycled parts with pathogenic microorganisms or other causes of diseases into a re-manufacturing clean area.

I. For parts, etc. used for manufacturing of re-manufactured single-use medical devices, verify that the parts, etc. are appropriate based on a product master formula of the products, and prepare/retain records of the results for each serial number, etc. (unique numbers, symbols, and other signs to identify individual re-manufactured single-use medical devices; the same shall apply hereinafter) of re-manufactured single-use medical devices.

J. For recycled parts, prepare and retain records of matters to be recorded pursuant to the provisions specified by the Minister of Health, Labour and Welfare.

[2] Know the name of a business office to which products are released and date of release for each serial number, etc. of re-manufactured single-use medical devices, and prepare/retain the records.

2. Marketing authorization holders, etc. of re-manufactured single-use medical devices shall store records of the preceding paragraph for each serial number, etc. so that a series of records from recycled parts used in manufacturing to products manufactured by using the recycled parts can be checked appropriately.

(Testing)

Article 81-2-3 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall, when handling products related to re-manufactured single-use medical devices, appropriately control operations related to testing of parts, etc. and products related to re-manufactured single-use medical devices by appropriate identification labeling of samples for separation to prevent mix-up and cross-contamination of samples at a manufacturing site of the products based on a product master formula and establish/document procedures of the operations in addition to the operations of the previous article.

(Education and training)

Article 81-2-4 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall, when handling products related to re-manufactured single-use medical devices, establish and implement procedures for education and training related to microbiology, medicine, and veterinary medicine, etc. for members engaged in manufacturing or testing of the products in addition to the operations specified in Article 23 and document the procedures.

2. Marketing authorization holders, etc. of re-manufactured single-use medical devices, etc. shall prepare and retain records on the education and training in the preceding paragraph.

(Management of documents and records)

Article 81-2-5 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall retain documents specified in this chapter or at least one copy of the documents for a period of the shelf life of products related to re-manufactured single-use medical devices plus 5 years (5 years for those related to education and training) from the date of abolition of the documents. However, for documents used for manufacturing or testing of products, it is enough to store those documents so that they can be used during storage of records related to the products specified in the following paragraph.

2. Marketing authorization holders, etc. of re-manufactured single-use medical devices shall retain records specified in this chapter for a period of the shelf life of products related to re-manufactured single-use medical devices plus 5 years from the date of preparation (5 years for those related to education and training).

(Ensuring traceability of products related to re-manufactured single-use medical devices)
Article 81-2-6 Marketing authorization holders, etc. of re-manufactured single-use medical devices shall secure the traceability of records related to all of parts, etc. and conditions of work environment if there is a risk that products related to re-manufactured single-use medical devices may not conform to product requirements depending on the parts, etc. or conditions of work environment.

2. In order to ensure the traceability of products related to re-manufactured single-use medical devices after release, marketing authorization holders, etc. of re-manufactured single-use medical devices shall instruct distributors, etc. handling such products (distributors or loaners of specially-controlled medical devices or controlled medical devices; the same shall apply in the following paragraph) to prepare and retain records of distribution of the products concerned.

3. If marketing authorization holders, etc. of re-manufactured single-use medical devices have received an inspection pursuant to the provisions of Paragraph 6 or Paragraph 8, Article 23-2-5 of the Act or on-spot inspection, etc. pursuant to the provisions of Paragraph 1 or Paragraph 4, Article 69 of the Act for the said products and if it is requested by the Minister of Health, Labour and Welfare, prefectural governor, or implementer of compliance inspection of medical devices, etc. stipulated in Article 37-23 of the MHLW Ordinance, distributors, etc. shall be instructed to retain the records of the preceding paragraph so that the records can be presented.