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## Tentative translation of MHLW MA 261

### ○ Standards for Re-manufactured Single-use Medical Devices

(July 31, 2017)

(Ministerial Announcement No. 261 of the Ministry of Health, Labour and Welfare)

Based on the provisions of Paragraph 2, Article 42 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960), the Standards for Re-manufactured Single-use Medical Devices were established as follows and implemented starting from July 31, 2017.

#### Standards for Re-manufactured Single-use Medical Devices

##### Part 1 Definitions

- 1 A "recycled part" is the whole or part of a single-use medical device, which is used at a medical institution and provided for re-manufacturing.
- 2 A "replacement part" means a newly manufactured part constituting a re-manufactured single-use medical device.
- 3 A "serial number, etc." means a unique number, symbol, or other sign to identify an individual re-manufactured single-use medical device.

##### Part 2 Scope

These standards apply to re-manufactured single-use medical devices specified in Item 4, Article 114-8 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (MHW Ordinance No. 1, 1961).

##### Part 3 Shape and structure

- 1 Recycled parts
  - (1) The shape and structure of recycled parts shall be able to inactivate or remove pathogenic microorganisms and other disease-causing agents by validated methods during remanufacturing processes.
- 2 Replacement parts
  - (1) The shape and structure of replacement parts shall be equivalent to those of the original medical device.
- 3 Re-manufactured single-use medical devices
  - (1) The shape and structure of re-manufactured single-use medical devices shall be equivalent to those of the original medical device.

##### Part 4 Performance and safety

- 1 Raw materials (recycled and replacement parts)
  - (1) Recycled parts shall have been used at medical institutions in Japan.
  - (2) Recycled parts shall not come into contact with the brain, spinal cord, dura mater, cerebral ganglion, spinal ganglion, retina, or optic nerve.
  - (3) Recycled parts shall not be implanted in the human body.
  - (4) Recycled parts shall not be used for treatment and testing, etc. of patients with Class I, II, III, or IV infection, infection such as pandemic influenza, designated infection, or new infectious disease specified in Article 6 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998) or persons specified in Paragraphs 1 to 3, Article 8 of the said Act.
  - (5) Recycled parts shall be received from a medical institution by a marketing authorization holder of re-manufactured single-use medical devices in accordance with the method described in an approval certificate issued at the time of marketing

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- approval of a re-manufactured single-use medical device (hereinafter referred to as "approval certificate").
- (6) Recycled parts shall be stored separately at a medical institution to prevent them from being damaged, deteriorated, or contaminated by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.
  - (7) For recycled parts, marketing authorization holders of re-manufactured single-use medical devices or emergency approval holders of foreign manufactured medical devices, etc. (hereinafter referred to as "marketing authorization holders, etc.") shall confirm that the matters listed in (5) and (6) have been performed appropriately.
  - (8) Recycled parts shall be examined appropriately in light of the latest findings on infectious diseases to confirm that they are not contaminated by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.
  - (9) Recycled parts shall not be provided for re-manufacturing more than the number of times specified in an approval certificate of a re-manufactured single-use medical device manufactured using the parts.
  - (10) Recycled parts shall be received from medical institutions and transported by a marketing authorization holder of re-manufactured single-use medical devices in a sealed, dedicated container designed to prevent breakage, deterioration, or contamination by pathogenic microorganisms or other causes of diseases that cannot be inactivated or removed in the manufacturing process.
  - (11) Recycled parts and replacement parts shall have the quality, performance, and safety described in an approval certificate.
  - (12) In addition to the items from (1) to (11), the requirements for securing the quality, performance, and safety of recycled parts and replacement parts described in an approval certificate shall be met.
- 2 Performance and safety (recycled parts, replacement parts, and re-manufactured single-use medical devices)
- (1) Recycled parts
    - A Recycled parts shall have the quality, performance, and safety required to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices in consideration of deterioration, etc. in characteristics and performance, which may occur due to re-manufacturing.
    - B Recycled parts shall satisfy the following requirements.
      - (a) Marketing authorization holders, etc. of re-manufactured single-use medical devices continuously check the presence or absence of changes in raw materials of the original medical device and other changes that may affect the quality, efficacy, and safety of re-manufactured single-use medical devices, and if such changes occur, measures, such as changes in the re-manufacturing method of recycled parts, necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices have been taken.
      - (b) Information on defects and recalls of the original medical device and other information on the quality, efficacy, and safety have been continuously collected by a marketing authorization holder, etc. of re-manufactured single-use medical devices, and based on the collected information, changes in the re-manufacturing method of recycled parts necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices and other measures have been taken.
  - (2) Replacement parts
    - A Replacement parts shall have the quality, performance, and safety required to ensure the quality, efficacy, and safety of re-manufactured single-use medical

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devices.

B Replacement parts shall satisfy the following requirements.

(a) Marketing authorization holders, etc. of re-manufactured single-use medical devices continuously check the presence or absence of changes in raw materials of the original medical device and other changes that may affect the quality, efficacy, and safety of re-manufactured single-use medical devices, and if such changes occur, measures, such as changes in the design of replacement parts, necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices have been taken.

(b) Information on defects and recalls of the original medical device and other information on the quality, efficacy, and safety have been continuously collected by a marketing authorization holder, etc. of re-manufactured single-use medical devices, and based on the collected information, changes in the design of replacement parts necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices and other measures have been taken.

(3) Re-manufactured single-use medical devices

A The intended use or effects of re-manufactured single-use medical devices shall not exceed the scope of the intended use or effects of the original medical device.

B Re-manufactured single-use medical devices shall have the quality, efficacy, and safety equivalent to those of the original medical device in consideration of deterioration, etc. in characteristics and performance, which may occur due to re-manufacturing.

C Re-manufactured single-use medical devices shall satisfy the following requirements.

(a) Marketing authorization holders, etc. of re-manufactured single-use medical devices continuously check the presence or absence of changes in raw materials of the original medical device and other changes that may affect the quality, efficacy, and safety of products, and if such changes occur, measures, such as changes in the design, necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices have been taken.

(b) Information on defects and recalls of the original medical device and other information on the quality, efficacy, and safety have been continuously collected by a marketing authorization holder, etc. of re-manufactured single-use medical devices, and based on the collected information, changes in the design necessary to ensure the quality, efficacy, and safety of re-manufactured single-use medical devices and other measures have been taken.

#### Part 5 Manufacturing method

(1) Recycled parts shall be re-manufactured so that pathogenic microorganisms and other causes of diseases can be inactivated or removed by validated methods.

(2) Re-manufactured single-use medical devices shall be re-manufactured to have the quality, efficacy, and safety equivalent to those of the original medical device.

#### Part 6 Labeling, etc.

##### 1 Labeling on medical devices

(1) For re-manufactured single-use medical devices, a serial number, etc. shall be assigned and indicated on the main body to secure the traceability (history, application, or location; the same shall apply hereinafter) to the matters specified in 3 (2) of Part 6.

(2) Re-manufactured single-use medical devices shall be identifiable as re-manufactured devices by an appropriate method, such as indicating "re-manufactured" on the body, to prevent confusion with the original medical device.

##### 2 Information shown on immediate containers, etc.

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- (1) "Re-manufactured" shall be indicated on an immediate container or wrapper of a re-manufactured single-use medical device.
  - (2) Information, such as precautions for re-manufactured single-use medical devices, or documents attached to the re-manufactured single-use medical devices shall include the following information.
    - A Word, "re-manufactured"
    - B Name of the original medical device
    - C Approval number and date of approval of the original medical device, certification number and date of certification of the original medical device, or notification number and date of notification of the original medical device
    - D Name of the marketing authorization holder of the original medical device, names of the emergency approval holder of foreign manufactured medical devices, etc. and designated marketing authorization holder of foreign manufactured medical devices, etc., or names of the foreign manufacturer of designated specially controlled medical devices and designated marketing authorization holder of designated foreign manufactured specially controlled medical devices
- 3 Records and storage
- (1) The following items related to recycled parts shall be recorded and stored.
    - A Name and address of a medical institution where single-use medical devices used for re-manufacturing were used
    - B Date on which a marketing authorization holder of re-manufactured single-use medical devices received recycled parts from a medical institution
    - C Serial numbers, etc. of recycled parts if they have already been re-manufactured
    - D Number of times that recycled parts were re-manufactured
    - E Results of confirmation of compliance with the matters listed in 1 (1) to (12) of Part 4
    - F Matters necessary for ensuring the quality, performance, and safety of recycled parts in addition to those listed in A through E
  - (2) For re-manufactured single-use medical devices, the traceability shall be ensured by properly preparing and retaining records of recycled parts, inspections, manufacturing, work environment conditions, and distribution.