Criteria for reprocessed single-use medical devices

(July 31, 2017)
(MHLW Ministerial Announcement No. 261)

In accordance with provisions in Article 42, Paragraph 2 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 1960), the Standards for reprocessed single-use medical devices shall be established as follows and applied from July 31, 2017.

Standards for reprocessed single-use medical devices

1 Definition
  1 The term “recyclable components” refers to components that constitute the whole or a part of a single-use medical device used at a medical institution; and are supplied for reprocessing.
  2 The term “replacement components” refers to components that constitute reprocessed single-use medical devices and are newly manufactured.
  3 The term “serial number, etc.” refers to a unique number or code or other symbols to identify individual reprocessed single-use medical devices.

2 Scope of application
  The concerned standards shall be applied to reprocessed single-use medical devices specified in Article 114-8, Item 4 of the Ministerial Ordinance for Enforcement of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (MHW Ordinance No. 1 of 1961).

3 Shape and structure
  1 Recyclable components
    (1) Recyclable components must have such shape and structure that microbial pathogen and other pathogenic agents will be inactivated or removed by validated methods in the manufacturing process.
  2 Replacement components
    (1) Replacement components must have the shape and structure equivalent to those of the components of the original medical device.
  3 Reprocessed single-use medical devices
    (1) A reprocessed single-use medical device must have the shape and structure equivalent to those of the original medical device.

4 Performance and safety
  1 Raw materials (recyclable components and replacement components)
    (1) Recyclable components must be ones used at a medical institution in Japan.

(2) Recyclable components must be ones that have not come in contact with the brain, spinal cord, dura mater, cerebral ganglion, spinal ganglion, retina, or optic nerve.

(3) Recyclable components must be ones that have not been implanted in the human body.

(4) Recyclable components must be ones that have not been used for treatment or examination in patients with Class I Infectious Disease, Class II Infectious Disease, Class III Infectious Disease, Class IV Infectious Disease, Novel Influenza Infection, Designated Infectious Disease, or New Infectious Disease specified in Article 6 of the "Law on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases" (Law No. 114 of 1998), or those specified in Article 8, Paragraphs 1 to 3 of the above law.

(5) Recyclable components must be ones received from medical institutions by a marketing authorization holder of reprocessed single-use medical devices as specified in the approval document issued upon marketing approval of the reprocessed single-use medical devices (hereinafter referred to as "approval document").

(6) Recyclable components must be ones that have been separately stored to avoid damage, deterioration, or contamination with microbial pathogen and other pathogenic agents that cannot be inactivated or removed in the manufacturing process.

(7) Recyclable components must be ones that have been confirmed to meet items listed in (5) and (6) appropriately by the marketing authorization holders of reprocessed single-use medical devices or special approval holders of foreign manufactured medical devices (hereinafter referred to as "marketing authorization holders, etc.").

(8) Recyclable components must be ones that have been confirmed to be free from contamination with microbial pathogen and other pathogenic agents that cannot be inactivated or removed in the manufacturing process by appropriate examinations in light of the latest knowledge about infectious diseases.

(9) Recyclable components must be ones that have not undergone reprocessing runs more than specified in the approval document of the reprocessed single-use medical device.

(10) Recyclable components must be placed in dedicated well-closed containers, which are designed to avoid damage, deterioration, or contamination with microbial pathogen and other pathogenic agents that cannot be inactivated or removed in the manufacturing process, and then the containers in a well-closed condition must be received from medical institutions for transportation by the marketing authorization holder of the reprocessed single-use medical devices.

(11) Recyclable components and replacement components must have the quality, performance, and safety as specified in the approval document.

(12) Recyclable components and replacement components must meet requirements for ensuring the quality, performance, and safety, as specified in the approval document, in addition to Items listed in (1) to (11).

2 Performance and safety (recyclable components, replacement components and reprocessed single-use medical devices)

(1) Recyclable components

A Recyclable components must have the quality, performance, and safety required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices in consideration of potential decreases in characteristics and performance due to the reprocessing.

B Recyclable components must be ones that meet the following requirements.

(A) Marketing authorization holders, etc. of reprocessed single-use medical devices shall continuously check the original medical devices for any change to the raw materials or another change that may affect the quality, efficacy, and safety of the reprocessed single-use medical devices. In the case where the concerned change occurs, changes to the reprocessing method for the recyclable components and other actions shall be made, as required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices.

(B) Marketing authorization holders, etc. of reprocessed single-use medical devices shall continuously collect information about malfunctions and recalls of the original medical devices and the other information about the quality, efficacy, and safety, and reprocessed single-use medical devices shall be ones in which changes to the reprocessing method related to recyclable components and other actions have been made based on the collected information, as required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices.

(2) Replacement components

A Replacement components must have the quality, performance, and safety required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices.

B Replacement components must be ones that meet the following requirements.

(A) Marketing authorization holders, etc. of reprocessed single-use medical devices shall continuously check the original medical devices for any change to the raw materials or another change that may affect the quality, efficacy, and safety of the reprocessed single-use medical devices. In the case where the concerned change occurs, changes to the design for the replacement components and other actions shall be made, as required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices.

(B) Marketing authorization holders, etc. of reprocessed single-use medical devices shall continuously collect information about malfunctions and recalls of the original medical devices and the other information about the quality, efficacy, and safety, and reprocessed single-use medical devices shall be ones in which changes to design related to replacement components and other actions have been made based on the collected information, as required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices.

(3) Reprocessed single-use medical devices

A The intended use or indication of the reprocessed single-use medical device shall not be beyond that of the original medical device.

B Reprocessed single-use medical devices must have the quality, efficacy, and safety equivalent to those of the original medical device in consideration of potential decreases in characteristics and performance due to the reprocessing.

C Reprocessed single-use medical devices must be ones that meet the following requirements.

(A) Marketing authorization holders, etc. of reprocessed single-use medical devices shall continuously check the original medical devices for any change to the raw materials or another change that may affect the quality, efficacy, and safety of the product. In the case where the concerned change occurs, changes to the design and other actions shall be made, as required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices.

(B) Marketing authorization holders, etc. of reprocessed single-use medical devices shall continuously collect information about malfunctions and recalls of the original medical devices and the other information about the quality, efficacy, and safety, and reprocessed single-use medical devices shall be ones in which changes to design and other actions have been made based on the collected information, as required to ensure the quality, efficacy, and safety of the reprocessed single-use medical devices.

5 Manufacturing process

(1) Recyclable components must be reprocessed by the validated methods to ensure that microbial pathogen and other pathogenic agents are inactivated or removed.

(2) Reprocessed single-use medical devices must be reprocessed to ensure the quality, efficacy, and safety equivalent to those of the original medical device.

6 Labeling, etc.

1 Labeling items on medical devices

(1) Reprocessed single-use medical devices must indicate the serial number, etc. on their body to ensure traceability (state that can trace history, application, or location, hereinafter the same) of the items specified in 6. 3 (2).

(2) Reprocessed single-use medical devices must indicate the status of a reprocessed product by an appropriate method, for instance, by placing the word “reprocessed” on the body, to prevent mix-up with the original medical device.

2 Items indicated on immediate containers

(1) The word of “reprocessed” must be indicated on immediate containers or immediate wrappers of reprocessed single-use medical devices.

(2) Documents attached to reprocessed single-use medical devices must include information on the following items.

A Word “Reprocessed”

B Name of 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 or corporate name of the marketing authorization holder of the original medical device; name or corporate name of the special approval holder of foreign manufactured medical devices and appointed marketing authorization holder of foreign manufactured medical devices; or name or corporate name of foreign manufacturer of designated specially controlled medical devices and appointed marketing authorization holder of foreign manufactured designated specially controlled medical devices

3 Records and retention

(1) The following items on recyclable components must be recorded, and the records must be retained.

A Name and location of the medical institution in which the single-use-medical device supplied for reprocessing was used

B Date when the marketing authorization holder of reprocessed single-use medical devices received recyclable components from the medical institution

C Serial number, etc. of the recyclable component that has been reprocessed if applicable

D Number of reprocessing runs the recyclable component has undergone

E Assessment results on conformity to the items in 4. 1 (1) to (12)

F Information necessary for ensuring the quality, performance, and safety of the recyclable component other than ones listed in A to E

(2) For reprocessed single-use medical devices, records on recyclable components, tests, manufacture, operation environment conditions, and distribution must be appropriated prepared and retained to ensure traceability of these items.