This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail.

Tentative translation of MHLW MO 1 for Remanufactured Single-Use Devices

Regulations for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
(MHW Ordinance No. 1, 1961)

(Matters to be observed by marketing authorization holders of medical devices or *in vitro* diagnostics)

Article 114-54 Matters to be observed by marketing authorization holders of medical devices or *in vitro* diagnostics specified in Paragraph 1, Article 23-2-15 of the Act are as follows.

[4] A person with bacteriological knowledge shall be appointed as an assistant to the Marketing Supervisor-general of medical devices, etc. if none of the Marketing Supervisor-general of medical devices, etc., Domestic Quality Operation Manager, and Safety Management Supervisor of medical devices, etc. of a marketing authorization holder of biological products (limited to medical devices) or re-manufactured single-use medical devices has bacteriological knowledge.

[9] Marketing authorization holders of re-manufactured single-use medical devices shall continuously check for any changes in raw materials of the original medical devices (single-use medical devices intended for re-manufacturing, which have not been re-manufactured yet; the same shall apply hereinafter) and any of the other changes that may affect the quality, effectiveness, and safety of re-manufactured single-use medical devices and take necessary measures, such as changes in design, to ensure the quality, effectiveness, and safety of re-manufactured single-use medical devices if such changes occur.

[10] Marketing authorization holders of re-manufactured single-use medical devices shall continuously collect information on malfunctions and recalls of the original medical devices and other information on the quality, effectiveness, and safety of the devices, examine the impact on the quality, effectiveness, and safety of the re-manufactured single-use medical devices based on the collected information, and take measures necessary to prevent the occurrence or spread of hazards to the public health and hygiene.

[11] Marketing authorization holders of re-manufactured single-use medical devices shall promptly provide the following information to marketing authorization holders of original medical devices, emergency approval holders of foreign manufactured medical devices, etc., or foreign manufacturers of designated specially-controlled medical devices, etc.

A. Approval under Paragraph 1 or Paragraph 15, Article 23-2-5 of the Act for re-manufactured single-use medical devices (cases where a designated marketing

authorization holder of foreign manufactured medical devices, etc. is provided with information under Item 1, Paragraph 1, Article 114-76 for re-manufactured single-use medical devices) if granted

B. Information on disposal, recall, discontinuation of marketing, provision of information, and other necessary measures taken for re-manufactured single-use medical devices due to quality-related reasons, etc. (excluding cases where the conduct of such measures is obviously attributable to re-manufacturing of the re-manufactured single-use medical devices) if implemented

C. Information on planning and implementation of disposal, recall, discontinuation of marketing, revision of precautions, etc. (matters listed in each item of Paragraph 2, Article 63-2 of the Act or information on precautions, etc. specified in Paragraph 2, Article 68-2 of the Act) or other safety assurance measures considered to require provision of information to marketing authorization holders of original medical devices, emergency approval holders of foreign manufactured medical devices, etc., or foreign manufacturers of designated specially-controlled medical devices, etc. as well as safety management information examined in planning

[12] When marketing authorization holders of re-manufactured single-use medical devices transport single-use medical devices used in medical institutions, which have not been cleaned and sterilized yet (excluding transportation by a vessel or airplane; the same shall apply hereinafter in this item), the following items shall be met.

A. When transporting, enclose devices in containers.

B. The containers specified in the preceding item shall meet the following criteria.

(1) They can be handled easily and safely.

(2) There is no risk of cracking and damage, etc. due to vibration and changes in temperature and internal pressure, etc. expected during transportation.

(3) Measures, such as attaching a seal that does not break easily, are taken to prevent the containers from being opened without a reason.

(4) The containers shall have sufficient strength and water resistance not to cause leakage of the contents.

(5) When they are used repeatedly, it shall be easy to remove contamination by microorganisms, etc. which may be pathogenic.

(6) The containers shall be labeled to indicate that single-use medical devices used in medical institutions are enclosed.

C. Loading of cargoes onto vehicles, etc. shall be done so that safety will not be compromised by movement, turnover, and falling, etc. during transportation.

D. They shall be separated from the other cargoes during transportation to prevent them from being mixed with the other cargoes.

E. A document that describes a method for handling cargoes, measures to be taken in the event of an accident, and other matters to be considered for transportation shall be carried out.

F. If any contamination by microorganisms, etc. that may be pathogenic is caused by cargoes, the spread of the contamination should be promptly prevented, and decontamination should be performed.

G. The date and method of transportation, consignee or consignor, and person who carries out the transportation, shall be recorded. The records should be retained for 5 years.

H. When transportation is outsourced to a third party, the third party shall carry out the transportation by a method conforming to the following matters.

(1) Do not subcontract.

(2) A contract acceptor shall transport by a method conforming to the matters described in A to G. In addition, necessary matters for this shall be arranged and retained in writing.

(Matters to be observed by manufacturers of medical devices)

Article 114-54-2 Regarding matters to be observed by manufacturers of medical devices specified in Paragraph 3, Article 23-2-15 of the Act (including cases where it is applied mutatis mutandis pursuant to Article 23-2-19 of the Act), if the Medical Device Responsible Engineer Manager at a manufacturing site that manufactures re-manufactured single-use medical devices (excluding manufacturing sites related to manufacturing processes specified in E, Item 4, Paragraph 1, Article 114-8) is not a physician or has no bacteriological knowledge or expertise in sterilization of medical devices, a physician or person with such knowledge shall be appointed as an assistant to the Medical Device Responsible Engineer Manager.