Attachment 4

Application for Handling of Reusable manually-operated pulmonary resuscitator, etc.

(1) Scope of application
“Reusable manually-operated pulmonary resuscitator” and “Single-use manually-operated pulmonary resuscitator” prescribed in Appendix 1-4 of the Ministerial notification No.112 shall be Reusable manually-operated pulmonary resuscitator and Single-use manually-operated pulmonary resuscitator prescribed as No.777 and 779 in Appendix 1 regarding specially controlled medical devices, controlled medical devices, and general medical devices designated by the Minister of Health, Labour and Welfare (MHLW Ministerial Notification No.298 dated 2004) pursuant to the provision of Art.2, para.5 to 7 of "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics". However, the reusable products and products for single use shall not be treated as a single product.

(2) Primary endpoints to assess the substantial equivalence to a legally marketed predicate device and their criteria
Based on the contents detailed below, assess the substantial equivalence to a legally marketed predicate device. In that case, the standards, etc. applied to the legally marketed predicate device (refer to (3) List of applicable standards, etc. in order to conform with the essential principles) shall be used.

① Shape and precision of cone connectors
Evaluate the shape and precision of cone connectors if the device has cone connectors. (See, for example, item 4 “Metal cone connectors” or item 5 “Cone connector made from material other than metals” in JIS T 7201-2-1: 1999 “Inhalational anaesthesia systems – Anaesthetic and respiratory equipment – Conical connectors – Part 2-1 Cones and sockets.”)

② Oxygen supply and inspired oxygen concentration
Evaluate the oxygen supply and inspired oxygen concentration required for operator-powered resuscitators. (See, for example, “6.1 R) Supplementary oxygen and delivered oxygen concentration” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)
Tidal volume
Evaluate the tidal volume required for operator-powered resuscitators. (See, for example, “6.7.1 R) Minimum delivered volume (V_{del})” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Inspiratory and expiratory resistance
Evaluate the inspiratory and expiratory resistance required for operator-powered resuscitators. (See, for example, “6.2 R) Expiratory resistance/6.3 R) Inspiratory resistance” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Expiratory positive pressure when adding high flow rate oxygen
Evaluate the patient valve malfunction required for operator-powered resuscitators. (See, for example, “6.4 R) Patient valve malfunction” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Dead space volume
Evaluate the dead space volume required for operator-powered resuscitators. (See, for example, “6.6 R) Resuscitator dead space and rebreathing” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Pressure controllability
Evaluate the pressure limitation system required for operator-powered resuscitators. (See, for example, “6.7.2 R) Pressure limitation” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Tolerance to mechanical shock
Evaluate the tolerance to mechanical shock required for operator-powered resuscitators. (See, for example, “5.4.1 R) Drop test” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Tolerance to immersion
Evaluate the tolerance to immersion required for operator-powered resuscitators.
(See, for example, “5.5 Immersion in water” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Normal operation under expected conditions

(a) Patient valve function after contamination with vomitus
Evaluate the patient valve function after contamination with vomitus for operator-powered resuscitators. (See, for example, “5.3 R) Patient valve function after contamination with vomitus” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

(b) Performance under use and storage conditions and the storage and operating conditions
Evaluate performance under the use and storage conditions required for operator-powered resuscitators. (See, for example, “7.1 Storage/7.2 R) Operating conditions” of ISO 10651-4: 2002 “Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators.”)

Maximum pressure of PEEP valve
Evaluate to determine if the maximum value of added PEEP pressure is substantially equivalent to that of approved (certified) products if the device has a PEEP valve.

(3) List of applicable standards, etc. in order to conform with the essential principles
In regards to conformity with certification standards, applicable standards, etc. to explain compliance with essential principles are as follows. Conformity with the requirements of the standards, etc. shall be demonstrated when demonstrating compliance with essential principles. In addition, if conformity with these standards, etc. cannot be demonstrated, one can demonstrate compliance with essential principles with adequate justification for any deviation from the standards.

Standards to be used to assess the substantial equivalence
• JIS T 7201-2-1, Inhalational anaesthesia systems – Anaesthetic and respiratory equipment – Conical connectors – Part 2-1 Cones and sockets
• ISO 10651-4, Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators
Others

- ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes
- JIS Q 13485, Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 14971, Medical devices – Application of risk management to medical devices
- JIS T 14971, Medical devices – Application of risk management to medical devices
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- JIS T 0993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- HPB/GAD Notification No. 0914001 and PFSB/SD Notification No. 0914001 dated September 14, 2007 “Voluntary Recall of Operator-Powered Resuscitators (Request)”
- PFSB/SD Notification No. 0326-3, by the Director of Safety Division, Pharmaceutical and Food Safety Bureau, MHLW, dated March 26, 2013 “Self-Check, etc. of Package Inserts, etc. of Reusable Operator-Powered Resuscitators”