Establishment of Minimum Requirements for Reprocessed Single-use Medical Devices

Reprocessing of single-use medical devices (SUDs) is defined as the process of collecting, disassembling, cleaning and reassembling used SUDs to distribute as subsequent SUDs.
The Minimum Requirements for Reprocessed SUDs (R-SUDs) will be established as follows;

• SUDs which can be reprocessed shall be limited to be the ones used in healthcare facilities in Japan.

• Maximum number of times SUDs can be reprocessed shall be verified.

• The disease-causing agents shall be removed or eliminated from R-SUDs by the validated processes.

• Quality, efficacy and safety of R-SUDs shall be designed and verified to be equivalent to the original SUDs.

• Changes (e.g. materials) of the original SUDs shall be monitored to maintain quality, efficacy and safety of R-SUDs.

• Each R-SUDs shall be labeled with the unique ID to ensure traceability.

• Any other necessary provisions to secure quality, efficacy and safety of R-SUDs.