(Appendix)

Outline of the draft Partial Amendment of the Ministerial Order for the Standard of Manufacturing Control and Quality Control for Medical Devices and In vitro Diagnostic Pharmaceutical Products

1. The Ministerial Order for the Standard of Manufacturing Control and Quality Control for Medical Devices and In vitro Diagnostic Pharmaceutical Products

The relevant international standard (ISO 13485) to structural management mechanism ensuring product quality (Quality Management System) of medical devices and in vitro diagnostic pharmaceutical products (hereinafter referred to as the "medical devices, etc.") has been established by the International Organization for Standardization (ISO).

In Japan, according to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the Ministerial Order for the Standard of Manufacturing Control and Quality Control for Medical Devices and In vitro Diagnostic Pharmaceutical Products (the ministerial order No.169 of MHLW, 2004, (hereinafter referred to as the "QMS Ministerial Order") has been established with regard to quality management system for medical devices.

2. The summary of this amendment

The QMS Ministerial Order will be amended in accordance with the amendment of the international standard (ISO 13485).

This amendment includes “requirement for Quality Management System to establish clearly the degree of management etc. in accordance to product risks”, “requirement for validation when any software be initially utilized or changed within Quality Management System” and so on.