

Total Lab Solutions



Technical Bulletin
ISO13485 Registration

SANYO was granted medical device QMS standard ISO13485 registration.

In April 2008, SANYO Biomedical QMS (Quality Management System) products have been certified with ISO13485, the requirements for a comprehensive management system for the design and manufacturing of medical devices.

Achieving the ISO 13485 registration mark is an important milestone that will greatly increase our position in medical and clinical markets worldwide. This is in addition to our supplementary requirements of ISO 9001 and 14001*, which are the standards for QMS and Environmental management systems.

Very few competitors have been granted ISO 13485 certification yet, demonstrating SANYO's superior Quality Management and regulations meet the strict international standard for medical device manufacturers, validating SANYO biomedical products' high quality. Please note that ISO13485 does not applied for all of SANYO Biomedical products. (Details are below).

ISO 13485 for Tega SANYO Industry Co.,Ltd. The quality management system of **MLS-3751/3781/3750/3780**, which are related to medical purposes, were already granted **ISO 13485 & ISO 9001** (Certification Organization: TUV).

The **ISO 9001** application of QMS of **MLS-3751L/3781L** (not suitable for medical usage) has been submitted and the registration is expected to be approved by this summer (Certification Organization: JIA).



ISO Certificate Copy Insurance

When you need a copy of the ISO 13485 certification please inform the SANYO Japan HQ of purpose of use and submittal information. Then an official certification copy with serial number can be issued. This is the same procedure for ISO 9001. Failure to follow this procedure may result in the registration being extinguished if the certifying organization finds unauthorized usage of ISO certifications.

** Not applicable to Autoclaves (MLS). MLS products have their own regulatory requirements since they are from different manufacturing facility.*

ISO 13485 for Gunma factory

The quality management system of SANYO Electric Co.,Ltd. Biomedical department applicable to design, development, manufacturing, post delivery activities of 3 product categories.

3 product categories should be clarified as:

- Preservation related products (**MDFs, MPRs, MBRs**)
- Incubation related equipment (**MCOs, MIRs, MLRs, MCOK**)
- Sterilization and drying related equipments (**MOVs**)

Certification Organization	NQA
Registration Number	24438
Registration Date	11th Apr 2008
Valid date	11th July 2011



Certification of Registration

