



Dr. Tim Hsu, G.M. of HMD BioMedical Inc.(left). is awarded by Mr. Bill Lin (right), G.M. of TÜV SÜD Taiwan

HMD BioMedical Inc. is committed to the development of medical device products, such as blood glucose monitoring system, since 2000.

Its medical equipment quality management system was rigorously reviewed and approved by

Written by BS

TÜV SÜD, and was awarded the first MDSAP medical equipment single audit program certificate in Taiwan.

Leading the industry to meet the requirements of international quality management standards, HMD BioMedical enhances the competitiveness of Taiwan's medical device industry in the international market.

By organizing the management of the MDSAP system, HMD BioMedical ensure the stability of the quality of supply chain production and strengthen the risk assessment and safety management level.

Passing TÜV SÜD audit, HMD BioMedical won the MDSAP certificate, achieving the international level of quality management standards to provide customers with high quality, revealing its determination of medical device products.

The Medical Device Single Audit Program (MDSAP) is a proposal presented by the International Medical Device Regulators Forum (IMDRF). It is expected that a single audit can be used to achieve regulatory requirements in multiple countries. The integration of resources verified by laws and regulations will increase the efficiency and flexibility of management, speed up the introduction of medical products to the international market, and reduce the time and cost that medical equipment manufacturers are struggling with to meet the requirements of national laws and regulations.

The regulatory authorities currently involved in MDSAP include:

1. Australian Medical Supplies Agency (TGA)

2. Brazilian National Health Surveillance Agency (ANVISA)

3. Health Canada

4. U.S. Food and Drug Administration (FDA)

5. Ministry of Health, Labour and Welfare, Japan/MHLW/PMDA

TÜV SÜD, originating from Germany, which has always been rigorous in quality, has a professional team in the field of medical equipment, and it is also one of the few units that have MDSAP auditor qualifications. TÜV SÜD can provide customers with a complete MDSAP verification process, covering ISO 13485 medical equipment quality management system and all the specific requests made by the competent authorities participating in MDSAP.

Written by BS

About HMD BioMedical Inc.

Established in 2000 by Dr. Tim Hsu, HMD BioMedical is committed to the development of medical biotechnology and solutions in the field of human health and health care. Devoted in the manufacturing research and development of blood glucose monitoring system, HMD BioMedical is dedicated to provide safe and reliable products to help diabetes families lead a better life and improve the service quality of medical care professionals.

