SD BIOSENSOR

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Subject : Notice that ISO9001 can be replaced by ISO13485.

Dear valued customers,

We, SD Biosensor, Inc., would like to inform you that ISO9001 can be replaced by our certified ISO13485. Please refer to the following for related additional explanations.

ISO13485 is a stand-alone QMS standard, derived from the internationally recognized and accepted *ISO9000 quality management standard series. ISO13485 adapts the ISO 9001 process-based model for a regulated medical device manufacturing environment. While ISO13485 is based on the ISO9001 process model concepts of Plan, Do, Check, Act, it is designed for regulatory compliance. Thus It is more prescriptive in nature and requires a more thoroughly documented quality management system.

ISO 13485 was written to support medical device manufacturers in designing quality management systems that establish and maintain the effectiveness of their processes. It ensures the consistent design, development, production, installation, and delivery of medical devices that are safe for their intended purpose.

**ISO9000 is a model for quality management and quality assurance set by the International Standardization Organization (ISO), and includes ISO9001, ISO9002, ISO9003, ISO9004, etc.*

We will continue our efforts to comply with high quality management standards and to maintain a consistent high quality management system to ensure customer's satisfaction and product safety.

Sincerely,

Geun-Kuk Song
QMR
SD BIOSENSOR, Inc.