



## MSI PROJECT PROFILE

ISO 14001:2004 Implementation | St. Jude Medical

### About St. Jude Medical

ISO14001:2004, St. Jude Medical Irvine, California) MSI serving since 2010

St. Jude Medical is a leading manufacturer of medical devices and is also ISO 13485 certified



“St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient.”

**-Company Vision**

### Results/Timeline

- Registered in October 2009
- Internal Audit training & Management Review completed August 2009
- EMS Aspect Identification completed June 2009
- System Audit July 2009

### MSI's Turnkey Approach

ISO14001:2004, St. Jude Medical (Irvine, California) Since 2010

Before the ISO registration, SurePath™:

- Reviewed the procedures and reflected the processes and practices performed by each department.
- Guided St. Jude Medical EMS processes in reaching program milestones with 100% on-time completion
- Guided the establishment of the EMS Policy and Objectives.
- Coached through the development of the required process procedures and Environmental Manual by interviewing employees in their related functions.
- Trained personnel for ISO 14001:2008 Overview, as well as EMS process implementations and internal auditing.
- Identified Environmental Aspects and Pollution Prevention Programs.
- Coached Corrective and Preventive Actions on processes found to be nonconforming.
- Showed required material/data samples for Management Review meeting.





## Documentation

Environmental Documented Procedures coached through development for St. Jude Medical:

- EMS Manual
- Environmental Legal & Other Requirements
- EHS Objectives & Targets & Action Plan
- Resource Management
- Communications
- EHS Document Control
- Operation Control
- Emergency response
- Monitoring and Measurement
- Evaluation of Compliance
- Nonconformance & Corrective & Preventive Action

**“It is St. Jude Medical’s policy is committed to a sustainable future and recognizes that our products and people interact with a finite environment. It is our commitment to be proactive stewards of the environment to protect current and future generations.**

*St. Jude Medical Environmental Policy*



**MSI COMPETITION SENSITIVE**



Management Systems International, LLC

*Management Systems International (MSI) systematically implements Environmental Management Systems (EMS), ensuring your company continuously meets the globally recognized ISO 14001 international standard.*

*“St. Jude Medical wanted its EMS program in line with its ISO 13485 system and to bring all employees at the Irvine site on board with the Environmental Programs”*

Diana Procter, MSI President

*Company info found at [www.sjm.com](http://www.sjm.com)*