1. Revision Status

Revision Level	Date Issued	Remarks	App'd
Revision 1	March 6, 1998	First Release based on ISO 9001 (1994) Standard	MA
Revision 2	August 28, 1998	Revised release after full Implementation of Quality System	MA
Revision 3	November 17, 1998	Revised release after Desk Audit by SGS	MA
Revision 4	January 15, 2001	Inclusion of Training manager, revised Design Review to include Marketing Executive, new Training Director and personnel Changes	JWD
Revision 4.1	March 4, 2004	Post Audit revision of Quality Control QSP Section 4.10 to alter Sampling Policy and related QC and Process Control procedures	JWD
Revision 4.2	May 18, 2004	Inclusion of CMDR and ISO 13488	JWD
Revision 5.0	August 9, 2004	Responsibility and Organizational change, Integration of ISO 13488 and CMDR, expansion of statistical analysis, increased distinction between component and Kit QA, interdepartmental SOP's.	JWD
Revision 6.0	August 9, 2005	Integration of ISO 13485:2003 and Risk-Management in accordance with ISO 14971:2000	JWD
Revision 6.1	September 12, 2008	CE Marking, Outsourcing 6.3, Output-Input Definition & Use, Plan-Do-Check-Act Management Review	JWD
Revision 6.2	April 13, 2009	Instrument Process Control QSP-09-02 added; Servicing QSP-19-01 revised.	JWD
Revision 6.3	August 1, 2011	Adoption of ISO14971:2007 Standard; Name Change	

2. Company Profile

Infrared Laboratory Systems (ILS) is engaged in the research, development, manufacture, sales and service of *in vitro* diagnostic reagents and automation for use in clinical chemistry and cytology worldwide. The ILS quality system is a continuation of the Synermed International Inc. Quality System and all ILS personnel, equipment and facilities were conducting these activites for Synermed International prior to August 1, 2011. Synermed filed and received 510(k) approval to market the first of its products in the United States in 1990 and had continued to add to the product line with new chemistry methodologies. As of August 2005, Synermed has filed submissions with the FDA and has received 510(k) clearance to market over 40 *in vitro* diagnostic chemistry methodologies and instruments. Those 510(k) clearances and all Synermed quality records are now the property of Infrared Laboratory Systems. ILS was 88% owned by Synermed International Inc. Shareholders at the time of the quality system transfer.

ILS has U.S. and certain foreign rights to the Synermed® trade mark and manufactures Synermed® brand products.

The chemistry products manufactured by ILS are unique in the marketplace in that only a few other companies manufactures a line of liquid-stable, ready-to-use reagents. The ILS products also include reagents that utilize chromophores that can be read spectrophotometrically in the near infrared. The advantage of reading in the near-infrared is that there is less interference from serum chromatic substances such as hemoglobin, lipemia and bilirubin. In addition, ILS products have been tested and proven to provide accurate results in serum from patients containing hemoglobin-based blood substitutes.

ILS's Synermed® brand instrument products are being marketed in the U.S.. The instruments optimally utilize the ILS Synermed® brand near-infrared reagents and provide customers with more accurate results in a cost-effective manner.

ILS is developing cytology products for general cytology use and has extended the cytology development to include automation and gynecologic use of the cytology reagents in non-U.S. markets.

ILS uses its best efforts to comply with all FDA requirements as established by law and by the Quality System Regulations of 1996: 21 CFR 820. In addition, Synermed operates under the quality system as defined by ISO13485:2003 EC IVDMDD and CMDR to be able to meet the needs of its customers throughout the world. A systematic, information based Risk-Management program has been implemented in accordance with ISO 14971:2007.

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