

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: I.L.Japan Co., Ltd.
Mita-Kanda Bldg.,
1-3-30 Mita,
Minato-ku,
Tokyo
108-0073
Japan

アイ・エル・ジャパン株式会社
〒108-0073
東京都
港区
三田1-3-30
三田神田ビル

Holds Certificate No: MD 580919

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development and manufacturer of in vitro diagnostics of clinical chemistry, haemostasis and immunochemistry
Design, development and manufacturer of automatic analytical equipment for in vitro diagnostic use of blood, clinical chemistry, haemostasis and immunochemistry
体外診断用医薬品(生化学関連、凝固関連、免疫化学関連)の設計・開発及び製造
体外診断用自動分析装置(血液、生化学関連、凝固関連、免疫化学関連)の設計・開発及び製造

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-12-17

Latest Revision Date: 2021-12-06

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