

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

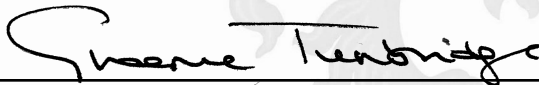
アイ・エル・ジャパン株式会社
〒108-0073
東京都
港区
三田1-3-30
三田神田ビル

Holds Certificate No: **MD 580919**

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

Please see scope page.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2012-12-17

Latest Revision Date: 2026-02-27

Effective Date: 2024-12-17

Expiry Date: 2027-12-16

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 580919**

Registered Scope:

Manufacturer, packaging / labeling / storage and distribution of in vitro diagnostics of clinical chemistry, haemostasis and immunochemistry
Manufacturer, packaging / labeling / storage, distribution and repair of automatic analytical equipment for in vitro diagnostic use of blood, clinical chemistry, haemostasis and immunochemistry
Manufacture, packaging / labeling / storage and distribution of disposable automatic lancet
Manufacture, packaging / labeling / storage and distribution of haematology coagulation analyser
体外診断用医薬品(生化学関連、凝固関連、免疫化学関連)の製造、包装・表示・保管、販売
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)の製造、包装・表示・保管、販売、修理
単回使用自動ランセットの製造、包装・表示・保管、販売
血液凝固分析装置の製造、包装・表示・保管、販売



Original Registration Date: 2012-12-17

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Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsi-global.com/ClientDirectory or Telephone 045-414-3022.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
Japan Headquarters: Ocean Gate Minato Mirai 3F, 3-7-1 Minato Mirai, Nishi-ku, Yokohama, Kanagawa, 220-0012, Japan. Tel: +81 45 414 3020
A Member of the BSI Group of Companies.

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Location

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1-3-30 Mita,
Minato-ku,
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108-0073
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アイ・エル・ジャパン株式会社
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〒143-0006
東京都
大田区
平和島6-5-1
物流ビルC棟

Registered Activities

Manufacture, packaging / labeling / storage and distribution of in vitro diagnostics of clinical chemistry, haemostasis and immunochemistry
Manufacture, distribution and repair of automatic analytical equipment for in vitro diagnostic use of blood, clinical chemistry, haemostasis and immunochemistry
Manufacture, packaging / labeling / storage and distribution of disposable automatic lancet
Manufacture, packaging / labeling / storage and distribution of haematology coagulation analyser
体外診断用医薬品(生化学関連、凝固関連、免疫化学関連)の製造、包装・表示・保管、販売
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)の製造、販売、修理
単回使用自動ランセットの製造、包装・表示・保管、販売
血液凝固分析装置の製造、包装・表示・保管、販売

Packaging / labeling / storage, distribution and repair of automatic analytical equipment for in vitro diagnostic use of blood, clinical chemistry, haemostasis and immunochemistry
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)の包装・表示・保管、販売、修理

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