



SEKISUI

SEKISUI MEDICAL CO.,LTD.

1-3 Nihombashi 2-chome, Chuo-ku,
Tokyo 103-0027 Japan

Date: May 16, 2017

Certificate

We, SEKISUI MEDICAL CO., LTD. located at 1-3 Nihonbashi 2-chome, Chuo-ku, Tokyo 103-0027, certify that the attached document, ISO13485:2003& ENISO13485:2012 the Certificate of Registration issued by BSI, is true and correct. The attached document is the firm copies of the original.

Hiroshi Ogura

HIROSHI OGURA

Leader, ASIA Sales Promotion Group,

Senior Manager

International Business Department

Diagnostics Division

SEKISUI MEDICAL CO.,LTD.



SAO Y BẢN CHÍNH



Lê Kim Vân Anh
**GIÁM ĐỐC
LÊ KIM VÂN ANH**



COPY



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that: SEKISUI MEDICAL CO., LTD.
Head Office
1-3, Nihonbashi 2-chome,
Chuo-ku,
Tokyo
103-0027
Japan

積水メディカル株式会社
本社
〒103-0027
東京都
中央区
日本橋二丁目1番3号

Holds Certificate No: MD 525659

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Please see scope page.

For and on behalf of BSI:


Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 2008/01/16

Latest Revision Date: 2017/02/06

Effective Date: 2017/01/16

Expiry Date: 2019/02/28

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...making excellence a habit.

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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 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: MD 525659

Registered Scope:

Design, Development and Manufacture and Customer Services of in-vitro diagnostics (hematology, biochemistry, immunology, infectious disease, TDM, others and, control sera and standards), HbA1c column, HbA1c eluent and sampling devices for in-vitro diagnostic tests.

Control of Design and Development, and Manufacture of Medical Devices for in-vitro diagnostic.

Customer Services of Medical Devices for in-vitro diagnostic.

Design, Development and Customer Services of Medical Devices (blood collection tubes, serum/plasma separating gel and blood clotting accelerant).

体外検査薬（血液学的検査用、生化学的検査用、免疫学的検査用、感染症検査用、及び血中薬物濃度検査用、その他の各試薬ならびに管理用血清・標準液）、HbA1c カラム、HbA1c 溶離液、体外検査用の試料採取用具の設計・開発、製造及び顧客サービス

体外診断用医療機器の設計・開発の管理及び製造

体外診断用医療機器の顧客サービス

検査用具（採血管、分離剤、凝固促進剤）、の設計・開発及び顧客サービス

Original Registration Date: 2008/01/16

Latest Revision Date: 2017/02/06

Effective Date: 2017/01/16

Expiry Date: 2019/02/28

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Location	Registered Activities
SEKISUI MEDICAL CO., LTD. Head Office 1-3, Nihonbashj 2-chome, Chuo-ku, Tokyo 103-0027 Japan 積水メディカル株式会社 本社 〒103-0027 東京都 中央区 日本橋二丁目1番3号	Design, Development and Customer Services of Medical Devices (blood collection tubes, serum/plasma separating gel and blood clotting accelerant), HbA1c column and HbA1c eluent. Design, Development and Manufacture and Customer Services of in-vitro diagnostics (hematology, biochemistry, immunology, infectious disease, TDM, others and, control sera and standards), HbA1c column, HbA1c eluent and sampling devices for in-vitro diagnostic tests. Control of Design and Development, and Manufacture of Medical Devices for in-vitro diagnostic. Customer Services of Medical Devices for in-vitro diagnostic. Design, Development and Customer Services of Medical Devices (blood collection tubes, serum/plasma separating gel and blood clotting accelerant). 体外検査薬（血液学的検査用、生化学的検査用、免疫学的検査用、感染症検査用、及び血中薬物濃度検査用、その他の各試薬ならびに管理用血清・標準液）、HbA1c カラム、HbA1c 溶離液、体外検査用の試料採取用具の設計・開発、製造及び顧客サービス 体外診断用医療機器の設計・開発の管理及び製造 体外診断用医療機器の顧客サービス 検査用具（採血管、分離剤、凝固促進剤）、の設計・開発及び顧客サービス
SEKISUI MEDICAL CO., LTD. Tsukuba Plant 3-1, Koyodai 3-chome, Ryugasaki-shi, Ibaraki 301-0852 Japan 積水メディカル株式会社 つくば工場 〒301-0852 茨城県 龍ヶ崎市 向陽台三丁目3番1号	Manufacture of in-vitro diagnostics (hematology, biochemistry, immunology, infectious disease, TDM, others and, control sera and standards), HbA1c column, HbA1c eluent and sampling devices for in-vitro diagnostic tests. Manufacture of Medical Devices for in-vitro diagnostic. 体外検査薬（血液学的検査用、生化学的検査用、免疫学的検査用、感染症検査用、及び血中薬物濃度検査用、その他の各試薬ならびに管理用血清・標準液）、HbA1c カラム、HbA1c 溶離液、体外検査用の試料採取用具の製造 体外診断用医療機器の製造

Original Registration Date: 2008/01/16

Effective Date: 2017/01/16

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