

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: FUJIMORI KOGYO CO., LTD.
Medical Device Business
1-1-1 Koishikawa,
Bunkyo-ku,
Tokyo
112-0002
Japan

藤森工業株式会社
医療機器事業
〒112-0002
東京都
文京区
小石川一丁目1番1号

Holds Certificate No: MD 741700


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

Design and development, Manufacture and Distribution of Chips and Accessories (Reservoir Set and Sterilized Blood Collection Tubes) for In Vitro Diagnostic Medical Device (Haemostasis Testing)

Manufacture and Distribution of In Vitro Diagnostic Medical Device (Haemostasis Testing)

体外診断用医療機器（凝固検査）に用いる凝固検査用チップ及び付属品（リザーバーセット及び滅菌済み採血管）の設計開発、製造及び販売
体外診断用医療機器（凝固検査）の製造及び販売

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-06-29

Latest Revision Date: 2023-09-26

Effective Date: 2023-10-10

Expiry Date: 2026-10-09

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Location

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東京都
文京区
小石川一丁目1番1号

Registered Activities

Design and development, Distribution of Chips and Accessories (Reservoir Set and Sterilized Blood Collection Tubes) for In Vitro Diagnostic Medical Device (Haemostasis Testing)
Manufacture and Distribution of In Vitro Diagnostic Medical Device (Haemostasis Testing)
体外診断用医療機器（凝固検査）に用いる凝固検査用チップ及び付属品（リザーバーセット及び滅菌済み採血管）の設計開発及び販売
体外診断用医療機器（凝固検査）の製造及び販売

Mie Plant
3889-1 Gitchobo, Takinohara,
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Mie
518-0411
Japan
三重事業所
〒518-0411
三重県
名張市
滝之原字義丁坊3889-1

Manufacture of Chips for In Vitro Diagnostic Medical Device (Haemostasis Testing)
Manufacture (Packaging) of Accessories (Reservoir Set and Sterilized Blood Collection Tubes) for In Vitro Diagnostic Medical Devices (Haemostasis Testing)
体外診断用医療機器（凝固検査）に用いる凝固検査用チップの製造
体外診断用医療機器（凝固検査）用付属品（リザーバーセット及び滅菌済み採血管）の製造（梱包）

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