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Management System Certificate

Certificate No.:
245706-2017-AQ-JPN-NA-PS Rev. 2.0

Project No.:
PRJC-497731-2014-MS-C-JPN

Initial Certification Date:
09 OCTOBER 2014

Valid Until:
09 OCTOBER 2020

This is to certify that the management system of:

FUJIMORI KOGYO CO., LTD.

Life Science Business

1-23-7 Nishi-Shinjuku, Shinjuku-ku, Tokyo 160-0023, Japan

With sites as listed overleaf.

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

- (1) Design, Development and Manufacture of Packing Materials for Medical Use.**
- (2) Design, Development, Manufacture, Distribution and Marketing of Chips and Accessories for Blood Coagulation Testing for In-vitro Diagnostic Use.**
- (3) Distribution and Marketing of the Medical Devices and Sterilized Blood Collection Tubes for Blood Coagulation Testing for In-vitro Diagnostic Use.**

Place and Date:
Høvik, 27 November 2018



For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



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Site Name	Address	Site Scope
FUJIMORI KOGYO CO., LTD. Head Office	1-23-7 Nishi-Shinjuku, Shinjuku-ku, Tokyo 160- 0023, Japan	(1) Design and Development, Distribution and Marketing of Chips and Accessories for Blood Coagulation Testing for In-vitro Diagnostic Use. (2) Distribution and Marketing of the Medical Devices and Sterilized Blood Collection Tubes for Blood Coagulation Testing for In-vitro Diagnostic Use.
FUJIMORI KOGYO CO., LTD. Mie Plant	3889-1, Gitchobo, Takinohara, Nabari City, Mie Pref. 518-0411, Japan	(1) Design, Development and Manufacture of Packing Material for Medical Use. (2) Manufacture of Chips and Accessories for Blood Coagulation Testing for In-vitro Diagnostic Use.

End of Certificate