



Sagami Rubber Industries Co., Ltd.

2-1, Moto-cho, Atsugi-shi, Kanagawa-ken
243-0002, Japan

Tel: +81-46-221-2311, Fax: +81-46-221-2315

To Whom It May Concern,

2025-07-31

ISO 13485 Certificate

The undersigned hereby certifies that the attached documents are true copies of the original
Certificate of Registration for ISO 13485:2016 issued to Sagami Industries Co., Ltd. by BSI Group
Japan (Certificate No. MD 81433).

Sincerely yours,

Signature:

Satoshi ARIMA

Assistant General Manager, Quality Assurance Department

Sagami Rubber Industries Co., Ltd.

Date:

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Sagami Rubber Industries Co., Ltd.
2-1 Moto-cho,
Atsugi-Shi,
Kanagawa
243-0002
Japan

相模ゴム工業株式会社
〒243-0002
神奈川県
厚木市
元町2-1

Holds Certificate No: MD 81433

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

Design / Development, Manufacture and Distribution of Natural Rubber Latex Condoms and Natural Rubber Latex Ultrasound Probe Covers.

天然ゴムラテックス製コンドーム及び天然ゴムラテックス製超音波診断用プローブカバーの設計・開発、製造及び販売

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2004-01-29

Latest Revision Date: 2024-02-06

Effective Date: 2024-04-09

Expiry Date: 2027-04-08

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...making excellence a habit.™

Certificate No: MD 81433

Location

Registered Activities

Sagami Rubber Industries Co., Ltd.
2-1 Moto-cho,
Atsugi-Shi,
Kanagawa
243-0002
Japan
相模ゴム工業株式会社
〒243-0002
神奈川県
厚木市
元町2-1

Design / Development and Manufacture of Natural Rubber Latex Condoms and Natural Rubber Latex Ultrasound Probe Covers.
天然ゴムラテックス製コンドーム及び天然ゴムラテックス製超音波診断用プローブカバーの設計・開発、製造

Sagami Rubber Industries Co., Ltd.
Tokyo Sales Office
Nihon Seimei Bldg. 2F,
2-34-13 Seijyo,
Setagaya-ku,
Tokyo
157-0066
Japan
相模ゴム工業株式会社
東京営業所
〒157-0066
東京都
世田谷区
成城2-34-13
日本生命ビル2F

Distribution of Natural Rubber Latex Condoms and Natural Rubber Latex Ultrasound Probe Covers.
天然ゴムラテックス製コンドーム及び天然ゴムラテックス製超音波診断用プローブカバーの販売

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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.bsigroup.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
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