

Certificate of Registration

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

This is to certify that:

Bergamot Sdn Bhd
No. 7 & 8, Jalan Sinaran 6,
Kawasan Perindustrian Sinaran,
Kajang
Selangor
43000
Malaysia

Holds Certificate No:

MD 725441

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

Manufacture, labelling and distribution of non-sterile and sterile powdered and powder free latex surgical gloves, natural latex, synthetic latex and nitrile powdered and powder free examination gloves, face masks, sterile hypodermic disposable syringes, sterile hypodermic needles, and non-sterile dental dam

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-09-19

Latest Revision Date: 2022-05-31

Effective Date: 2020-09-19

Expiry Date: 2023-09-18



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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](https://www.bsi-global.com/ClientDirectory).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +603 9212 9638.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.