



Certificate of Registration

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

This is to certify that:

Ansell N.P. Sdn Bhd

Also trading as

Ansell Malaysia Sdn Bhd Ansell Medical Sdn Bhd

Lot 80 & 92

Air Keroh Industrial Estate

Melaka 75450 Malaysia

Holds Certificate Number: MD 85963

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

The manufacture of powdered and powder-free surgeons and examination gloves to declared manufacturer or agreed customer specifications. The manufacture of medical glove with Antimicrobial agents.

The provision of contract gamma irradiation sterilization services in accordance with EN ISO 11137-1:2015.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2004-07-29 Effective Date: 2022-09-29 Latest Revision Date: 2022-09-21 Expiry Date: 2025-09-28

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...making excellence a habit."





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 <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory