

Certificate of Registration

QUALITY 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

Latest Revision Date: 2022-09-21

Effective Date: 2022-09-29

Expiry Date: 2025-09-28

Page: 1 of 1



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