The management system of

Andersen Caledonia Limited

Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, Bellshill, ML4 3NJ, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Provision of environmental monitoring and microbiological testing.

Ethylene oxide sterilisation and validation in accordance with BS EN ISO 11135:2014

Moist heat sterilisation and validation of medical devices in accordance with BS EN ISO 17665-1:2006.

Clean room packing of medical devices.

Manufacture of sterile procedure packs.

Manufacture of Sterile Single Use Non Active Surgical & Medical
Instruments and Supplementary Devices.

This certificate is valid from 01 March 2021 until 19 January 2024 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 December 2023 Issue 5. Certified since 19 January 2018

Expiry date of last certificate: 19 January 2021 End date of last recertification audit: 19 January 2021

Authorised by



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