Certificate GB18/873806

The management system of



Andersen Caledonia Limited

Caledonian House Phoenix Crescent Strathclyde Business Park Bellshill Lanarkshire ML4 3NJ United Kingdom

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 April 2024 until 19 January 2027 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 19 January 2018

Last certificate expiry date 19 January 2024 Recertification audit date 15 June 2023

allen M. Hell

Authorised by Jonathan Hall Global Head - Certification Services

SGS United Kingdom Ltd Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK t +44 (0)151 350-6666 - www.sgs.com





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