

SGS

Certificate GB18/873806

The management system of

Andersen Caledonia Limited

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

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Provision of environmental monitoring and microbiological testing.

**Ethylene oxide sterilisation and validation in accordance
with BS EN ISO 11135-1 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 Single Use instruments Rampley Sponge holder (non
invasive, Sterile tubing and pressure valve kit. Single use – intended to be used
with inflation/deflation devices used with balloon and bellows type catheters,
Sterile Single Use instruments spackman cannula – (invasive in body orifice),
sterile procedure packs**

Sterile Single Use surgical instruments

i. Mosquito Halstead forceps curved ii. Mayo Scissors straight

iii. Long Mayo Scissors curved iv. Polypus forceps bonney

v. Iris non toothed forceps

This certificate is valid from 19 January 2018 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 31 March 2019

Issue 1. Certified since 19 January 2018

Authorised by



0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2003 0118

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.