

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 9001:2008

For the following activities

**Provision of environmental monitoring and microbiological testing to
healthcare and other industries including bioburden determination and
monitoring of controlled environments.**

**Ethylene oxide processing of medical devices to customer specified
requirements including, where appropriate, the applicable
requirements of ISO 11135.**

Cleanroom packing of medical devices.

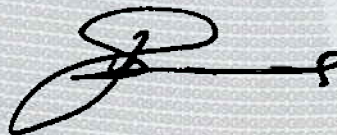
Further clarifications regarding the scope of this certificate and the applicability of
ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 09 December 2011 until 09 December 2014 and
remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 December 2014

Issue 16. Certified since 09 February 1998

Authorised by



SGS United Kingdom Ltd Systems & Services Certification
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SGS 9001-8 01 0311

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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 13485:2003 / AC:2009

For the following activities

Provision of environmental monitoring and microbiological testing to healthcare and other industries including bioburden determination and monitoring of controlled environments.

Ethylene oxide processing of medical devices to customer specified requirements including, where appropriate, the applicable requirements of ISO 11135.

Cleanroom packing of instrument kits and procedure packs.

This certificate is valid from 09 December 2011 until 09 December 2014 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 December 2014

Issue 15. Certified since 18 January 1999

Authorised by



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EC Certificate Production Quality Assurance System: Certificate
GB99/15368

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Lanarkshire, ML4 3NJ, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex V

For the following products

Procedure packs and single-use surgical instruments.

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 09 December 2011 until 09 December 2016 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 December 2014
Issue 18. Certified since 18 January 1999

Certification is based on reports numbered GB/PC 08642

Authorised by



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