Certificate GB99/50311

The management system of

Altomed Limited

Unit 2 Witney Way, Boldon Business Park, Tyne and Wear, NE35 9PE, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture, Service and Sales of Surgical Instruments and Devices.

This certificate is valid from 25 October 2018 until 25 October 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 25 October 2021
Issue 15. Certified since 23 March 1999

Authorised by

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 2016 0118

UKAS MANAGEMENT SYSTEMS
0005

EC Certificate Full Quality Assurance System: Certificate GB12/86445

The management system of

Altomed Limited

Unit 2 Witney Way, Boldon Business Park, Tyne and Wear, NE35 9PE, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile and non-sterile:
Implantable tubes,
Symblepharon rings,
Ophthalmic conformers,
Ocular tumour markers

Sterile:
Orbital Implants
Platinum segment eyelid weights
Lacrimal intubation systems.

Non-sterile:
Bipolar forceps

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 25 October 2018 until 25 October 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 25 October 2021
Issue 10. Certified since 23 March 1999

Certification is based on reports numbered GB/PC 09704

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215

EC Certificate Production Quality Assurance System: Certificate GB99/50312

The management system of

Altomed Limited

Unit 2 Witney Way, Boldon Business Park, Tyne and Wear, NE35 9PE, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

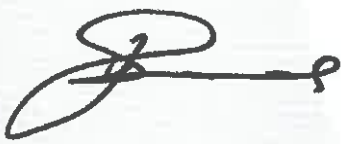
For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 07 March 2019 until 25 October 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 25 October 2021
Issue 38. Certified since 23 March 1999

Certification is based on reports numbered GB/PC 09704

Authorised by



SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 13 0311 M2

Altomed Limited

Directive 93/42/EEC

on medical devices, Annex V

Issue 38

Detailed scope

Sterile single use:
Iris retractor;
Ophthalmic cannulae & tubing;
Backflush handpieces and inserts;
Algerbrush burrs;
Damato illuminator,
Damato ruthenium plaque templates:
Damato Marker Depressor.

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile eye shields,
suction cups for use with corneal eye shields;
Sterile Ophthalmic Cellulose Sponges

Annex V Metrological aspects only - Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements:
Opthalmic measuring gauges and rod,
Opthalmic callipers and rules

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.