

EC Certificate Full Quality Assurance System: Certificate GB14/91309

The management system of

Beaver-Visitec International Ltd.

Waterloo Industrial Estate, Bidford-on-Avon, Warwickshire, B50 4JH, 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 ophthalmic needles, cannulae and cystotomes

Sterile ophthalmic surgical instruments:
Sterile ophthalmic forceps, clamps and scissors,
ophthalmic disposable instrument kits

Lacrimal Intubation Sets,
Dacryocystorhinostomy (DCR) Sets, and Ptosis Sets
Intraocular Lens Hook and Iris Retractor

Ophthalmic Spatulas
Ophthalmic Knives

Sterile ophthalmic viscosurgical devices for protection lubrication and
support of cells or tissues during ophthalmic intraocular surgery

Sterile procedure kits for use in ophthalmic surgery

Sterile Liquid Ocular Bandage for use in ophthalmic surgery

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 22 January 2016 until 28 April 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 19 February 2017

Issue 2. Certified since 28 April 2014

Certification is based on reports numbered GB/PC 232569

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 02 0215

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Certificate US10/81385

The management system of

Beaver-Visitec International, Inc.

411 Waverley Oaks Road,
Waltham, MA, 02452-8405, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2012

For the following activities

Design, development and manufacture of surgical blades and knives, eye cannulae, cystotomes, dissectors, ophthalmic procedure needles, eye probes, eye retractors, rotators, dilators, eye spatula, eye specula, lacrimal trephines, filters, tubing, eye shields, ophthalmic, ENT, and surgical sponges, absorbent swabs, ocular markers, surgical glides, electrosurgical coagulation systems including cables, bipolar forceps and erasers, electro-cautery devices, ophthalmic powered hand-pieces and burrs, sterile surgical blades, sterile intubation sets ophthalmic and surgical, absorbable and non absorbable punctal occluders and sterile I-rings. Distribution of ophthalmic aspirating syringes.

This certificate is valid from 24 March 2017 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 11. Certified since 23 August 2010

Authorised by

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