

Certificate Number US19/81841492

The management system of

Beaver-Visitec International, Inc.

500 Totten Pond Rd - 10 CityPoint,
Waltham, MA, 02451, United States

Dun & Bradstreet D-U-N-S identification number : 00-140-6024

has been audited against the criteria stated below and found to conform to those criteria for the scope
contained in this certificate



MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) –
Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D / 21 CFR 821

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2019-04-02 until Expiry Date: 2022-04-02
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2021-05-18
Issue 1. Certified since 2019-04-02

Authorised by J Hall
Business Manager



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MDSAP M2

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Beaver-Visitec International, Inc.

MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

Design, development and manufacture of sterile ophthalmic needles and cannulae, sterile ophthalmic surgical instruments, sterile fluid distribution sets, sterile viscoelastic solutions and sterile procedure kits. Manufacture of sterile semi-permeable adhesive wound dressings and drapes for use in ophthalmic surgery. Design, development and manufacture of sterile surgical blades, knives and trephines, sterile cystotomes, sterile dissectors, sterile probes, sterile retractors, sterile rotators, sterile dilators, sterile spatulas, sterile specula, sterile filters, sterile and non-sterile eye shields, sterile corneal light shields, sterile ENT, sterile surgical spears, sponges, absorbent swabs and sticks, sterile ocular markers and surgical glides, electrosurgical coagulation systems including sterile and non-sterile cables, non-sterile bipolar forceps and sterile erasers, sterile fluid collection bags with or without wicks, sterile instrument wipes, sterile and non-sterile electro-cautery devices, ophthalmic powered hand-pieces including sterile and non-sterile burrs, sterile ophthalmic intubation sets, sterile absorbable and sterile and non-sterile non-absorbable punctal occluders, I-Rings and sterile procedure kits for use in ophthalmic surgery.

