ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 103871 0001 Rev. 00

Manufacturer:

Beaver-Visitec International, Inc.
500 Totten Pond Road- 10 CityPoint
Waltham MA 02451
USA

EC-Representative:

VITREQ B.V.
Seggelant- Noord 2, MG 3237 Vierpolders, THE NETHERLANDS

Product Category(ies):

Sterile ophthalmic needles and cannulae, sterile ophthalmic surgical instruments, sterile fluid administration sets. Sterile surgical blades, knives and trephines, sterile cystotomes, sterile dissectors, sterile spatulas, 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.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72147780

Valid from: 2019-05-07
Valid until: 2022-01-28

Date, 2019-05-07

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

Beaver-Visitec International, Inc.
500 Totten Pond Road- 10 CityPoint, Waltham MA 02451, USA

Beaver-Visitec International
Valle del Cedro No. 1520, Parque Industrial Intermex, CP 32575
Ciudad Juarez, Chihuahua, MEXICO

-/-

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