

EC Certificate Production Quality Assurance System: Certificate US01/53983

**SGS**

The management system of

**Batrik Medical Manufacturing Inc.**  
**also doing business as**  
**7343591 Canada Inc.**

850 Halpern Avenue, Dorval, Québec, H9P 1G6, Canada

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 22 May 2019 until 22 May 2024  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04 May 2021

Issue 20. Certified since 13 December 2001

Certification is based on reports numbered WW/MC 207301

Authorised by

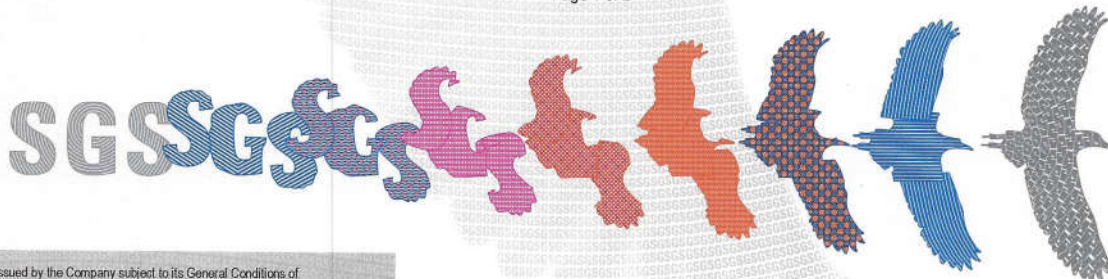


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SGS CE 13 0311 M2

Page 1 of 2



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

Issue 20

Detailed scope

**Annex V:**

**Sterile Clamp Jaw Covers used to reduce trauma to vessels requiring occlusion by rigid instruments; Sterile Vascular Silicone Ties used for occluding vessels during surgery; Sterile Anti-Fog Solution used on endoscopic and laparoscopic camera lenses to prevent fogging**

**Class I Sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:**

**Sterile Suture Clamp Tags used to protect, hold and identify sutures outside of the body; Sterile Pin Kaps used to safely cover the sharp ends of K- wire and Steinmann Pins; Sterile SKINS (surgical markers) used to mark an incision site, on the patient's skin prior to or during a surgical procedure; Sterile Infant Tourniquet used by hospital staff to wrap around the patient's arm/bicep to control venous and arterial circulation to an extremity; Sterile Hysterosalpingography and Sonohysterography catheters used to inject contrast media or saline into the uterus and/or the fallopian tubes.**

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.

