



Australian Register of Therapeutic Goods Certificate

Issued to

FOTEK

for approval to supply

FOTEK - Electrosurgical system, general-purpose

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|-------------------------|---|
| ARTG Identifier | 348110 |
| ARTG Start Date | 12/11/2020 |
| Product Category | Medical Device Included Class IIb |
| GMDN | 44776 |
| GMDN Term | Electrosurgical system, general-purpose |
| Intended Purpose | Electrosurgical systems "FOTEK" is an assembly of devices intended to generate, and apply radio-frequency (RF) alternating current to soft tissues for cutting and coagulation during an endoscopic or open surgical procedure. The assembly includes a mains electricity-powered (AC-powered) RF generator with monitoring functions/controls, connection cables, a handpiece, and electrodes to apply the energy to the surgical site. Tissue resistance to the electrical current creates the heat as the current travels through the body between electrodes. "FOTEK" generators and accessories are compatible with electrosurgical accessories and generators of all modern manufactures. |

| Manufacturer Details | Address | Certificate number(s) |
|----------------------|---|-----------------------|
| Fotek OOO | Malisheva Street 145 A liter A , Ekaterinburg , 620049 Russian Federation | DV-2020-MC-30153-1 |

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Electrosurgical system, general-purpose

Product Specific Conditions

No specific conditions have been recorded against this entry.