



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

FOTEK

for approval to supply

FOTEK - ACTITON - Electrosurgical system, ultrasonic/mechanical vibration

ARTG Identifier	349872
ARTG Start Date	27/11/2020
Product Category	Medical Device Included Class IIb
GMDN	44778
GMDN Term	Electrosurgical system, ultrasonic/mechanical vibration
Intended Purpose	Ultrasonic cavitation surgical units is an assembly of devices that converts the high-frequency current into ultrasonic oscillation to mechanically fragment soft-tissue cells upon contact with a vibrating tip for cutting and/or coagulating tissue during surgery, possibly in combination with irrigation and aspiration. Ongoing vibration may create heat in cells (diathermy) to increase the cutting/coagulating capacity. It includes an energy-producing generator with monitoring functions, a handpiece(s) with tip(s) to convert and apply the energy, connecting cables, a foot-switch as an option to regulate the energy, and an irrigation/suction system.

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. ACTITON - Electrosurgical system, ultrasonic/mechanical vibration

Product Specific Conditions

No specific conditions have been recorded against this entry.