



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Aria Healthcare Pty Ltd

for approval to supply

Aria Healthcare Pty Ltd - Q-close Silk - Silk suture, sterile

ARTG Identifier	370568
ARTG Start Date	5/07/2021
Product Category	Medical Device Included Class III
GMDN	13910
GMDN Term	Silk suture, sterile
Intended Purpose	Q-close Silk is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological tissues.

Manufacturer Details	Address	Certificate number(s)
Healthium Medtech Private Limited	No 472 D 13th Cross 4th Phase Peenya Industrial Area Bangalore , Karnataka , 560 058 India	DV-2020-MC-28147-1

ARTG Standard Conditions

The above Medical Device Included Class III 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. Q-close Silk - Silk suture, sterile

Functional Description	Q-close Silk elicits an initial inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Q-close Silk is not absorbed, progressive degradation of the proteinaceous silk fibres in vivo may result in gradual loss of the suture's tensile strength over a period of time.
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Variant Information

Description	Range
Suture, gauge	EP Metric Size : 0.2 - 6 (10-0 - 3&4 USP)
Suture, needle, physical attributes	Needle Shape: Straight
Suture, needle, physical	Needle Shape : 1/2 Circle, 3/8 Circle, 1/4 Circle

Description	Range
attributes	
Suture, needle, physical attributes	Needle Type : Taper Cutting, Reverse Cutting
Suture, needle, physical attributes	Needle Type : Taper Point, Conventional Cutting
Suture, colour	Dyed (Black)
Length (mm)	Needle Length : 10mm - 90mm
Length (cm)	Suture Length : 35cm - 180cm

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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