



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 Synth Fast - Suture, polyglactin

ARTG Identifier	369711
ARTG Start Date	17/06/2021
Product Category	Medical Device Included Class III
GMDN	17471
GMDN Term	Suture, polyglactin
Intended Purpose	Q-close Synth Fast suture is intended for use in general soft tissue approximation where only short term wound support is required and where rapid absorption of the suture would be beneficial. Due to the rapid absorption profile, Q-close Synth Fast suture is useful for skin closure, particularly in paediatric surgery, episiotomies, circumcision and closure of oral mucosa. Q-close Synth Fast suture is also useful for conjunctival suturing in ophthalmic surgery.

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-28221-1

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 Synth Fast - Suture, polyglactin

Functional Description	Q-close Synth Fast suture after implantation elicits a mild to moderate initial inflammatory reaction in tissues and is eventually replaced with an ingrowth of fibrous connective tissue. Q-close Synth Fast suture being absorbable in nature gets absorbed in the tissues by means of hydrolysis, during which the Polyglactin 910 co-polymer is degraded into Glycolic acid and Lactic acid which is eventually absorbed and metabolized in the body.
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Variant Information

Description	Range
Suture, needle, physical	Needle Shape : 1/2 Circle, 3/8 Circle, 5/8 Circle

Description	Range
attributes	
Suture, needle, physical attributes	Needle Type : Reverse Cutting, Taper Cutting
Suture, needle, physical attributes	Needle Type : Round Bodied, Coventional Cutting
Suture, colour	Undyed
Length (cm)	Suture Length : 35cm - 150cm
Length (mm)	Needle Length : 10mm - 60mm
Suture, gauge	EP Metric Size : 0.4 - 5 (8-0 - 2 USP)
Suture, needle, physical attributes	Needle Shape : Straight, J Shape

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
 PO Box 100, Woden ACT 2606 Australia
 Phone: 1800 020 653
 Email: info@tga.gov.au

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