



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 - Suture, polyglactin**

<b>ARTG Identifier</b>	369710
<b>ARTG Start Date</b>	17/06/2021
<b>Product Category</b>	Medical Device Included Class III
<b>GMDN</b>	17471
<b>GMDN Term</b>	Suture, polyglactin
<b>Intended Purpose</b>	Q-close Synth suture is intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular 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-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 - Suture, polyglactin

<b>Functional Description</b>	Q-close Synth suture after implantation elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an ingrowth of fibrous connective tissue. Q-close Synth 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 attributes	Needle Type : Reverse Cutting, Spatulamicropoint
Suture, needle, physical attributes	Needle Type : Blunt Point, Conventional Cutting

Description	Range
Suture, needle, physical attributes	Needle Type : Round Bodied, Taper Cutting
Suture, gauge	Dyed (Violet), Undyed
Suture, gauge	EP Metric Size : 0.3 - 5 (9-0 - 2 USP)
Length (mm)	Needle Length : 6mm - 60mm
Suture, needle, physical attributes	Needle Shape : 1/2 Circle, 3/8 Circle, 5/8 Circle
Suture, needle, physical attributes	Needle Shape : 1/4 Circle, Straight, J Shape
Suture, needle, physical attributes	Needle Type : Trocar Point
Length (cm)	Suture Length : 15cm - 250cm

### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
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