



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 Nylon - Nylon suture, monofilament

<b>ARTG Identifier</b>	370569
<b>ARTG Start Date</b>	5/07/2021
<b>Product Category</b>	Medical Device Included Class III
<b>GMDN</b>	38000
<b>GMDN Term</b>	Nylon suture, monofilament
<b>Intended Purpose</b>	Q-close Nylon 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 Nylon - Nylon suture, monofilament

<b>Functional Description</b>	Q-close Nylon elicits a minimal initial inflammatory reaction in tissue which is followed by gradual encapsulation of suture by fibrous connective tissue. While Q-close Nylon is not absorbed, progressive hydrolysis of suture in vivo may result in gradual loss of 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)
Length (cm)	Suture Length : 20cm - 150cm
Length (mm)	Needle Length : 6mm - 90mm
Suture, colour	Dyed (Blue & Black)
Suture, needle,	Needle Type : Taper Point, Conventional Cutting

Description	Range
physical attributes	
Suture, needle, physical attributes	Needle Type : Reverse Cutting, Taper Cutting
Suture, needle, physical attributes	Needle Type : Micropoint Spatula, Blunt Point
Suture, needle, physical attributes	Needle Shape: 1/2 Circle, 3/8 Circle, 1/4 Circle,
Suture, needle, physical attributes	Needle Shape : Straight

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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