

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 PolyP - Suture, polypropylene monofilament

 ARTG Identifier
 370600

 ARTG Start Date
 5/07/2021

Product Category Medical Device Included Class III

GMDN 13909

GMDN Term Suture, polypropylene monofilament

Intended Purpose Q-close PolyP 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 PolyP - Suture, polypropylene monofilament

Functional Description

Q-close PolyP being a monofilament suture is remarkably smooth and easy to handle. It does not have interstices in its structure and being a monofilament suture, has been successfully employed in surgical wounds which could subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion. It elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue.

Variant Information

Description	Range
Suture, needle, physical attributes	Needle Shape : Straight, J Type

Description	Range
Suture, needle, physical attributes	Needle Shape : 1/2 Circle, 3/8 Circle, 1/4 Circle
Suture, needle, physical attributes	Needle Type : Square Body Needle
Suture, needle, physical attributes	Needle Type : Rectangular Body Needle
Suture, needle, physical attributes	Needle Type : Antiglare Needle
Suture, needle, physical attributes	Needle Type : Micropoint spatula, Taper Cutting
Suture, needle, physical attributes	Needle Type: Conventional Cutting, Taper Point
Suture, needle, physical attributes	Needle Type : Reverse Cutting, Trocar Point
Suture, colour	Dyed (Blue)
Suture, gauge	EP Metric Size : 0.2 - 6 (10-0 - 3&4 USP)
Length (cm)	Suture Length: 35cm - 150cm
Length (mm)	Needle Length : 6mm - 90mm

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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