



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 PD Synth - Suture, polydioxanone

ARTG Identifier	369753
ARTG Start Date	17/06/2021
Product Category	Medical Device Included Class III
GMDN	16584
GMDN Term	Suture, polydioxanone
Intended Purpose	Q-close PD Synth suture is intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable. The safety and effectiveness of Q-close PD Synth suture has not been established in neurological tissue, adult cardiovascular tissue and microsurgery.

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 PD Synth - Suture, polydioxanone

Functional Description	After implantation, Q-close PD Synth suture elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an ingrowth of fibrous connective tissue. This suture being absorbable in nature gets absorbed in the tissues by means of hydrolysis, during which the Polydioxanone polymer is degraded into monomers of 2-hydroxyethoxyacetic acid which is eventually absorbed and metabolized in the body.
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Variant Information

Description	Range
Suture, gauge	EP Metric Size : 0.4 - 5 (8-0 - 2 USP)
Length (mm)	Needle Length : 8mm-60mm

Description	Range
Length (cm)	Suture Length : 35cm - 150cm
Suture, colour	Dyed (Violet), Undyed
Suture, needle, physical attributes	Needle Type : Round Bodied, Taper Cutting
Suture, needle, physical attributes	Needle Type : Blunt Point, Conventional Cutting
Suture, needle, physical attributes	Needle Type : Reverse Cutting
Suture, needle, physical attributes	Needle Shape: 1/2 Circle, 3/8 Circle, J Shape

Product Specific Conditions

No specific conditions have been recorded against this entry.

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