

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

WESTLAB PTY LTD

for approval to supply

WESTLAB PTY LTD - Anaesthesia kit, epidural

ARTG Identifier 397208

ARTG Start Date 7/10/2022

Product Category Medical Device Included Class IIa

GMDN 34842

GMDN Term Anaesthesia kit, epidural

Intended Purpose Intended to be used to provide, via percutaneous administration,

continuous and/or intermittent infusion of local anaesthetics and

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analgesics in the epidural space prior to spinal cord.

Manufacturer Details	Address	Certificate number(s)
Suru International Pvt Ltd	Plot 5 Poonamia Compound Saravali Jawhar Road Dahana District Palghar , Maharashta , 401602 India	DV-2022-MC-20131-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Anaesthesia kit, epidural

Product Specific Conditions

No specific conditions have been recorded against this entry.

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