



**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 - Guayule-latex surgical glove, non-powdered

<b>ARTG Identifier</b>	341210
<b>ARTG Start Date</b>	10/08/2020
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	61217
<b>GMDN Term</b>	Guayule-latex surgical glove, non-powdered
<b>Intended Purpose</b>	The device in question is natural latex, in polymer coated form. Used as a Single Use device by a health care professional during invasive surgery in order to prevent the cross contamination between the user and the patients.

Manufacturer Details	Address	Certificate number(s)
Healthium Medtech Private Limited	Plot No 13-16 Kiadb Industrial Area Kalanayakanahalli Kunigal (T) Tumkur D , Karnataka , 5721 26 India	DV-2020-MC-22923-1

### 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. Guayule-latex surgical glove, non-powdered

### 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](mailto:info@tga.gov.au)

ARTG Identifier: 341210  
ARTG Start Date: 10/08/2020