



Australian Register of Therapeutic Goods Certificate

Issued to

Australian Sales and Trade Services (ASTS)

for approval to supply

Australian Sales and Trade Services (ASTS) - Injector kit, non-medicated

ARTG Identifier	257996
ARTG Start Date	28/08/2015
Product Category	Medical Device Included Class IIb
GMDN	45451
GMDN Term	Injector kit, non-medicated
Intended Purpose	Needle free injection system for delivery of liquid medication and vaccines

Manufacturer Details	Address	Certificate number(s)
Mika Medical Co	93 Noksansaneopjung-ro Gangseo , Busan , Korea - Republic of	DV-2015-MC-07914-1

ARTG Standard Conditions

The above Medical Device Included Class IIb 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. Injector kit, non-medicated

Product Specific Conditions

- No specific conditions have been recorded against this entry.