



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 304305 Eudem Pty Ltd - Contrast medium injection system syringe

**ARTG entry for** Medical Device Included Class IIa

**Sponsor** Eudem Pty Ltd

**Postal Address** Po Box 5166, Kew North, VIC, 3101  
Australia

**ARTG Start Date** 14/06/2018

**Product Category** Medical Device Class IIa

**Status** Active

**Approval Area** Medical Devices

**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.

**Manufacturers**

<b>Name</b>	<b>Address</b>
Wuxi Yushou Medical Appliances Co Ltd	215 Xigang Road Dongbeitang, Wuxi/Jiangsu, 214191 China

**Products**

**1 . Contrast medium injection system syringe**

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	14/06/2018
<b>GMDN</b>	47259 Contrast medium injection system syringe		
<b>Intended Purpose</b>	The Syringe pack is a component of a contrast medium injection system for administration of contrast media during imaging. It is an exchangeable piston-in-barrel chamber for the contrast medium or saline;the movement of the piston is controlled by the contrast medium injector. The device includes check valves, spikes and tubing.		

**Specific Conditions**

No Specific Conditions included on Record

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Public Summary