



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

**Public Summary**

**Summary for ARTG Entry:** 123845 0.9%w/v Sodium Chloride Solution BP

**ARTG entry for** Medicine Listed (Export Only)  
**Sponsor** Global Medical Solutions Australia Pty Limited T/A Radpharm Scientific  
**Postal Address** PO Box 3334 BMDC, BELCONNEN, ACT, 2617  
 Australia  
**ARTG Start Date** 28/11/2005  
**Product category** Medicine  
**Status** Active  
**Approval area** Export only Medicines

**Conditions**

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

**Products**

**1. 0.9%w/v Sodium Chloride Solution BP**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	28/11/2005
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

The solution is used for the elution of Technetium Generators.

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Not recorded	0 Unknown	Not recorded	Not recorded	Not recorded

**Pack Size/Poison information**

**Pack Size**

15 ml sterile Solution in 20mL glass vial.

**Poison Schedule**

Not scheduled. Not considered by committee

**Components**

1. Medicine Component

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<b>Dosage Form</b>	Injection
<b>Route of Administration</b>	Intravenous
<b>Visual Identification</b>	Clear Solution
<b>Active Ingredients</b>	
sodium chloride	9 mg/mL

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