Australian Government

Department of Health

Therapeutic Goods Administration

RETRACTION OF SAFETY ALERT NOTIFICATION

Dear State or Territory Recall Co-Ordinator,

Please be advised of a retraction of a Safety Alert notification.

The Safety Alert notification was originally distributed on **17th October 2019.**

Please forward this retraction letter on to any party who may have received the original Safety Alert notification.

Original Safety Alert Information

CLASS:	Class II
DATE AGREED:	14/10/2019
REFERENCE:	RC-2019-RN-01553-1
PRODUCT:	Cyclomedica Technegas Generator
	ARTG 128867 (Cyclomedica Australia Pty Ltd - Gamma camera, gas generator)
SPONSOR:	Cyclomedica Australia Pty Ltd

Description of the Products Involved

The 'Gamma camera, gas generator' sponsored by Cyclomedica Australia Pty Ltd (ARTG 128867) (hereafter the Cyclomedica Technegas Generator) is a Class IIb medical device used to manufacture a lung imaging agent, Technegas, for use in the diagnosis of lung disease.

The Cyclomedica Technegas Generator must be used in combination with a single patient 'radioaerosol administration set' comprising of the tubing and filter system that delivers the Technegas to the patient.

Cyclomedica Australia Pty Ltd sponsors a radioaerosol administration set for this purpose, being ARTG 128868 (Cyclomedica Vent-Medic-Kit).

Charter Main also sponsors a radioareosol administration set for this purpose, being ARTG 319260 (Charter Main Vent-Medic-Kit).

Reason for Retraction of Safety Alert

Cyclomedica Australia Pty Ltd provided to the TGA a safety alert titled 'Safety Alert Regarding Counterfeit Technegas Consumables' dated 15 October 2019. (Cyclomedica Safety Alert). The TGA circulated the Cyclomedica Safety Alert on 17 October 2019 under reference number RC-2019-RN-01553-1.

The Cyclomedica Safety Alert Statement stated that:

- An Urgent Field Safety Notice was issued on the German Federal Institute for Drugs and Medical Devices website in relation to two 'patient safety misadministration occurrences' in Germany;
- Cyclomedica Australia Pty Ltd undertook a 'root cause investigation' into the relevant patient safety misadministration occurrences
- The Cyclomedica Australia Pty Ltd investigation found that the patient safety misadministration occurrences arose where the Cyclomedica Technegas Generator was used with the Charter Main Vent-Medic-Kit because:
    - the Charter Main Vent-Medic Kit contains counterfeit accessories, being 'contacts'(Charter Main Contacts); and
    - as a result of the functioning of the Contacts, use of the Charter Main Vent-Medic Kit with the Technegas Generator results in unauthorised variations to the operating parameters of the Technegas Generator.
- Both using the Charter Main Contacts and subsequently changing the operating parameters of any Technegas Generator violates numerous international medical device regulations and increases risk to patients.

Following internal investigation into the content of the Cyclomedica Safety Alert by the Therapeutic Goods Administration, the TGA considers that:

- there is no evidence of the Charter Main Vent-Medic-Kit or any component thereof (including the Charter Main Contacts) being counterfeit for the purposes of the *Therapeutic Goods Act 1989* (Cth); and
- Charter Main has submitted sufficient evidence to demonstrate the equivalency of the Charter Main Contacts to the contacts included in the Cyclomedica Vent-Medic-Kit. The Charter Main Vent-Medic-Kit (including the Charter Main Contacts) can therefore safely be used with the Cyclomedica Technegas Generator.

The TGA Recall section is therefore retracting the original Safety Alert notification. RC-2019-RN-01553-1.