



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Product Category	Medical Device Included - IVD Class 1
GMDN	CT943
GMDN Term	Instrument/analyser IVDs
Intended Purpose	This product is an analytical instrument designed to be used with a compatible specific dry reagent based on fluorescence immunochromatography, for the quantitative or semi-quantitative detection of specific analytes in biological samples.

ARTG Standard Conditions

The above Medical Device Included - IVD Class 1 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. Instrument/analyser IVDs

This entry: does not contain System(s)/Procedure Pack(s)

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

ARTG Start Date: 16/06/2026