

Using the ARTG to Verify TGA Approval

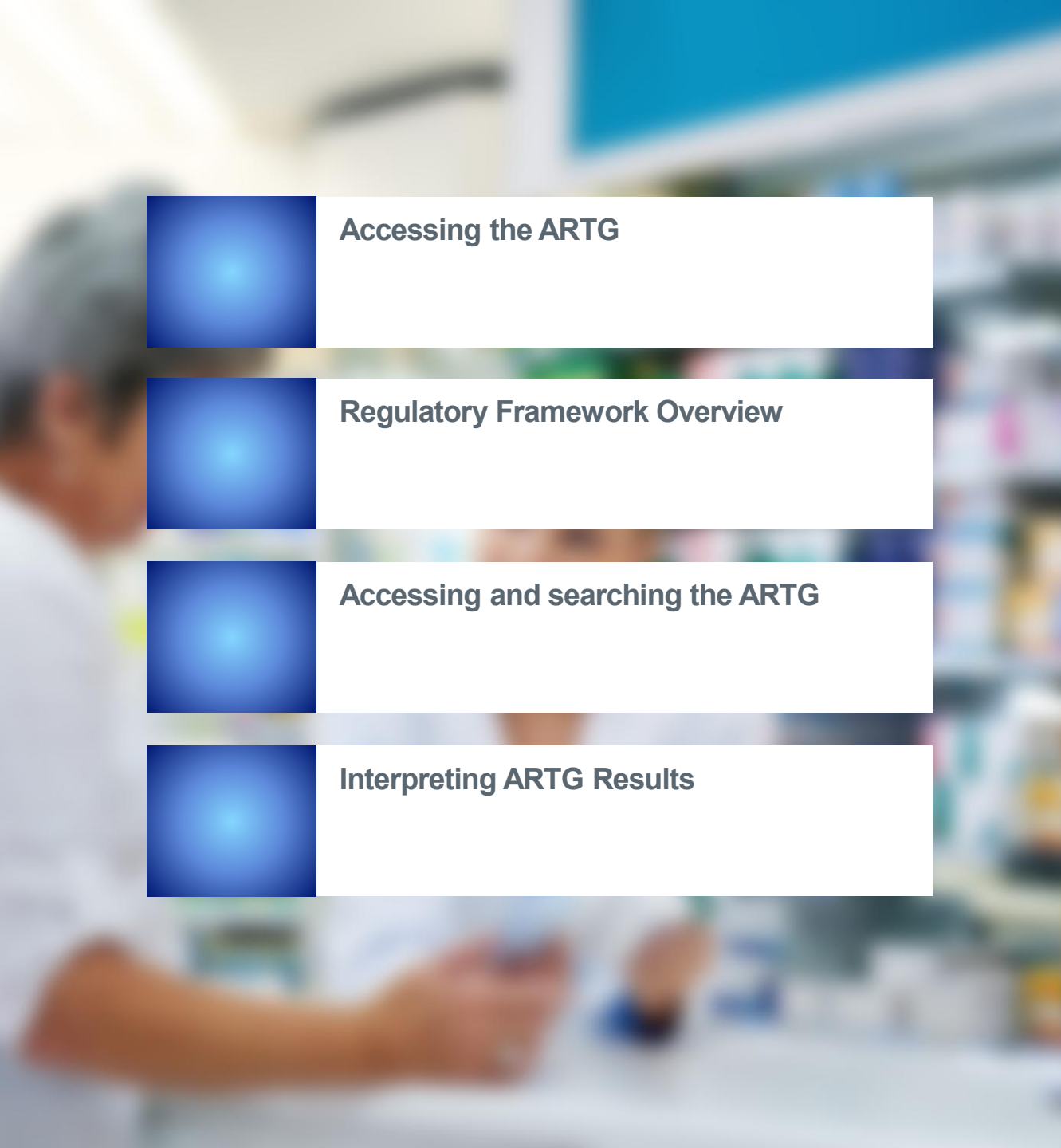
Jane Shum

Medical Devices and Product Quality Division
Health Products Regulation Group



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration



Accessing the ARTG

Regulatory Framework Overview

Accessing and searching the ARTG

Interpreting ARTG Results

Session focus and objectives

1. Learn how to efficiently access and navigate the ARTG via the TGA website using effective search methods.
2. Focus on key ARTG data fields like sponsor, manufacturer, intended purpose, and classification for verification.
3. Comprehend the 'kind of medical device' concept to avoid misinterpretation of ARTG entries and regulatory scopes.
4. Gain a brief overview of Australian legislation and risk-based classification supporting ARTG context.

Australian Regulatory Context

Framework basics

Devices regulated under legislation

Risk-based classification system (medical devices and IVDs)

ARTG inclusion required for supply

How devices are included

Included as a **“kind of medical device”**

One ARTG entry may include **more than one device**

Must have same:

- sponsor
- manufacturer
- classification
- GMDN code



What is the ARTG?

ARTG Overview

ARTG is Australia's central public database listing approved therapeutic goods like medicines and devices.

Regulatory Purpose

ARTG confirms products meet safety, quality, and performance standards under the Therapeutic Goods Act 1989.

Information Provided

ARTG offers summary product info including identifiers, sponsor details, and classification, not detailed assessments.

Usage Limitations

ARTG is not a source for clinical advice or comprehensive technical data and should not be solely relied upon.

Step-by-Step ARTG Search Process

Step 1: Access the TGA website

Navigate to Official Website

Users must access the official TGA website to ensure accurate and up-to-date regulatory information.



Locate ARTG Search Function

The ARTG search tool can be found prominently or within product regulation sections for easy access.

Use Basic and Advanced Search

TGA website offers both basic and advanced search options to suit different user needs.

Access Additional Resources

Guidance documents and contact links on the website provide extra support beyond search results.

Step-by-Step ARTG Search Process

Step 2: Open ARTG search

Access ARTG Search Interface

Users open the ARTG search page on the TGA website to begin querying the register.

Multiple Search Parameters

The search supports inputs like product name, sponsor name, and ARTG identifier number for flexible querying.

Advanced Filters and Usage

Advanced search filters help refine results; users learn to input, clear, and filter search terms efficiently.

Step-by-Step ARTG Search Process

Step 3: Enter search parameter (ARTG number, name)

Unique Identifier Importance

ARTG numbers provide a unique code for precise and direct product retrieval in the register.

Primary Search Method

Using the ARTG number minimizes ambiguity and avoids multiple search results. But you can search using other details

Retrieval

View the product list and identify product of interest

Product type

☐ Medical devices (219)

Sponsor

☐ Boston Scientific Pty Ltd (85)

☐ Medtronic Australasia Pty Ltd (52)

☐ Abbott Medical Australia Pty Ltd (40)

☐ Biotronik Australia Pty Ltd (24)

☐ Microport Crm Pty Ltd (12)

[Show more](#)

Published date

☐ 2026 (3)

☐ 2025 (4)

☐ 2024 (34)

☐ 2023 (15)

☐ 2022 (74)

[Show more](#)

219 result(s)

[Abbott M](#)
[Model M](#)
[system \(5](#)

29 May 2026

Australian Reg
Device Engine

[Micropo](#)
[implanta](#)

1 May 2026 |

Australian Reg
- Lead, pacem

[Abbott M](#)
[Pacemak](#)

12 February 20

Australian Reg
Atrial Leadless

Search for health products on our register

Search the Australian Register of Therapeutic Goods (ARTG) by name, ID or sponsor. Search results from the ARTG include Consumer Medicine Information (CMI) and Product Information (PI). Not all CMI and PI documents are available on this website.



Australian Register of Therapeutic Goods (ARTG)

Search medicines, medical devices and biologicals that can be supplied within Australia.

You can search the ARTG by name, ID or sponsor. Search results include product name and formulation details, sponsor (company) and manufacturer details, Consumer Medicine Information (CMI) and Product Information (PI). Not all CMI and PI documents are available.

 [Listen](#)  [Print](#)  [Share](#)

Use the filters below to narrow your search.

[Open all](#)

Product type

☐ Medical devices (219)

Sponsor

Published date

Access our [ARTG search visualisation tool](#) for advanced search functionality.

pacemaker



219 result(s) found, displaying 1 to 25

[Abbott Medical Australia Pty Ltd - Merlin.net Virtual Device Engine \(VDE\) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system \(527301\)](#)

29 May 2026 | ARTG

Australian Register of Therapeutic Goods (ARTG) information for Abbott Medical Australia Pty Ltd - Merlin.net Virtual Device Engine (VDE) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system.

Step-by-Step ARTG Search Process

Step 4: Select results

Results Display Overview

Search results show matching entries with key details like product and sponsor names for easy review.

Single vs Multiple Results

ARTG number searches return single entries; sponsor or product name searches may yield multiple results.

Careful Selection Importance

Selecting the correct entry is vital to avoid misinterpretation or verification errors during review.

Contextual Details Check

Consider product naming variations and manufacturer details to ensure accurate identification.

219 result(s) found, displaying 1 to 25

[Abbott Medical Australia Pty Ltd - Merlin.net Virtual Device Engine \(VDE\) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system \(527301\)](#)

29 May 2026 | ARTG

Australian Register of Therapeutic Goods (ARTG) information for Abbott Medical Australia Pty Ltd - Merlin.net Virtual Device Engine (VDE) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system.

[Microport Crm Pty Ltd - XFINE Endocardial Pacing Lead - Lead, pacemaker, implantable, endocardial \(526316\)](#)

1 May 2026 | ARTG

Australian Register of Therapeutic Goods (ARTG) information for Microport Crm Pty Ltd - XFINE Endocardial Pacing Lead - Lead, pacemaker, implantable, endocardial.

[Abbott Medical Australia Pty Ltd - AVEIR AR 2 Right Atrial Leadless Pacemaker Model LSP203A - Intracardiac pacemaker \(523385\)](#)

12 February 2026 | ARTG

Australian Register of Therapeutic Goods (ARTG) information for Abbott Medical Australia Pty Ltd - AVEIR AR 2 Right

ARTG Name	Abbott Medical Australia Pty Ltd - Merlin.net Virtual Device Engine (VDE) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system
------------------	--

Product name	Merlin.net Virtual Device Engine (VDE) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system
---------------------	---

ARTG Date	29 May 2026
------------------	-------------

Registration Type	Device
--------------------------	--------

Therapeutic good type	Medical devices
------------------------------	-----------------

Sponsor	Abbott Medical Australia Pty Ltd
----------------	--

Manufacturers	Abbott Medical
----------------------	----------------

Licence category	INC
-------------------------	-----

Licence status	A
-----------------------	---

Licence class	Class III
----------------------	-----------

Summary	Download PDF
----------------	------------------------------

Step-by-Step ARTG Search Process

www.tga.gov.au

Step 5: Open ARTG entry

Accessing ARTG Entry

Users open the ARTG entry after selecting the product to view detailed regulatory information and confirmation of inclusion.

Regulatory Information Details

ARTG entries display key data fields such as sponsor, manufacturer, classification, and intended purpose of the product.

Interpreting ARTG Entries

The ARTG entry is a summary confirming regulatory status, not a comprehensive dossier of all supporting evidence

Public summary and certificates

www.tga.gov.au

Purpose of Public Summaries

Public summaries provide key sponsor, manufacturer, and product details for additional verification.

Nature of Summaries vs Certificates

These summaries are not full regulatory certificates but represent selected ARTG data publicly.

Usage in Regulatory Processes

Summaries can support regulatory decisions when used alongside other information sources.

Access and Availability

Not all products have downloadable summaries; availability varies by product type and classification.

Sponsor Identification

The sponsor field identifies the Australian entity responsible for the medical device, ensuring accountability.

Manufacturer Details

The manufacturer field reveals the organization producing the device, clarifying its origin and supply chain.

Intended Purpose and Classification

Intended purpose explains device usage, while classification indicates associated risk and regulatory controls.

Important Dates

Key dates like ARTG start and effective dates track product registration and updates in the register.

Public Summary

Summary for ARTG Entry:	527301	Abbott Medical Australia Pty Ltd - Merlin.net Virtual Device Engine (VDE) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system
ARTG entry for	Medical Device Included Class III	
Sponsor	Abbott Medical Australia Pty Ltd	
Postal Address	299 Lane Cove Rd, Macquarie Park, NSW, 2113 Australia	
ARTG Start Date	29/05/2026	
Product Category	Medical Device Class III	
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		
Name	Address	Location Id
Abbott Medical	15900 Valley View Court Sylmar, CA, 91342 United States Of America	134255

Products
1 . Merlin.net Virtual Device Engine (VDE) Model MN7000 with AI - Transtelephonic implantable pacemaker analysis system

Product Type	Single Device Product	Effective Date	29/05/2026
GMDN	47269 Transtelephonic implantable pacemaker analysis system		
Functional Description	The Merlin.net VDE Model MN7000 is a component that is part of Abbott's Merlin.net Patient Care Network (PCN) that enables authorised clinicians to remotely program certain compatible Abbott Medical cardiac implantable devices, allowing individualised device programming. The Device incorporates CARE AI models designed to omit false episodes from the Merlin.net PCN, reducing clinician review burden.		
Intended Purpose	The Merlin.net™ Patient Care Network (PCN) is intended to allow clinicians to view and remotely monitor a patient's implanted heart device data and condition via the web portal by receiving the data from a compatible Abbott transmitter, programmer or mobile application and displaying it for review on Merlin.net™ PCN by authorised clinic personnel. The Merlin.net VDE Model MN7000 enables physicians and clinicians to remotely program certain compatible Abbott Medical cardiac implantable devices, allowing individualised device programming. For compatible Implantable Cardiac Montor (ICM) devices, the Classification using AI for Rhythm Evaluation (CARE) module integrated in the Merlin.net VDE MN 7000 is intended to identify false positive stored electrogram (SEGM) recordings of Atrial Fibrillation (AF) and Pause episodes and omit them from the Merlin.net™ PCN.		
Variant information	Nil variant (as 1 device) N/A		

Specific Conditions
No Specific Conditions included on Record



ARTG Search Visualisation Tool

[Back to tga.gov.au](#)



Medical Devices

[Glossary](#)



[User Manual](#)

[Clear Selections](#)

[Filters](#)

Filters on this page

ARTG ID
is (All)

Sponsor Name
is (All)

Manufacturer N...
is (All)

GMDN Code
is (All)

GMDN term
is (All)

Class
is (All)

ARTG Category
is (All)

Good Name
is (All)

[ARTG Home](#)

[Advanced Search](#)

[Medical Devices](#)

[Medicines](#)

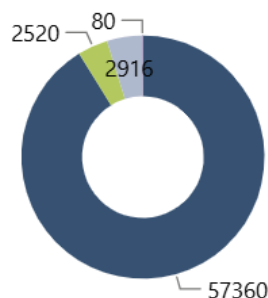
[Other Therapeut...](#)

[Biologicals](#)

[Advanced Query](#)

[TGA Home](#)

Medical Devices by Category



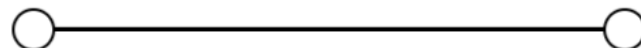
Selected: 62879

- General
- General-Export
- IVD
- IVD-Export
- IVD-In-house

Medical Devices Started by Date Range

2 Days	7 Days	14 Days	31 Days	All Dates
0	67	174	449	62879

Select Date Range:



Focussed Search

Medical Devices by Class

AIMD	17
Class 1	894
Class 2	1134
Class 3	757
Class 4	214
Class I	29195
Class IIa	14336
Class IIb	7358
Class III	5874
Class Im	504
Class Is	2596

Search ARTG Medical Devices

Medical Devices Started By Calendar Year



Search Results (62879 ARTG entries)

Hover here to see more options (export data, full-page table, etc.) ->

ARTG ID	Sponsor Name	Manufacturer Name	GMDN (Code-Text)	Class	ARTG Category	Start Date	Good Name	Therapeutic Type	Product Name
---------	--------------	-------------------	------------------	-------	---------------	------------	-----------	------------------	--------------

ARTG Search

Get in touch

Contact us by phone, email or post for help, enquiries and information.

[Contact us | Therapeutic Goods Administration \(TGA\)](#)

www.tga.gov.au/contact-us

Medical devices devices@tga.gov.au
[1800 141 144](tel:1800141144)



Questions?

www.tga.gov.au



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration