MEDSAFE

New Zealand Medicines and Medical Devices Safety Authority

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Revised: 24 April 2026

Medical Devices

This section describes how Medsafe regulates medical devices in New Zealand.

WAND

- Login to WAND
- Medical Device Glossary
- Explanation of the WAND Database
- Definition of a Sponsor
- Regulatory Requirements for Sponsors
- Risk Classification of Medical Devices
- Exempt Medical Devices

Regulatory Guidance

- Policy Statements on Medical Devices
- Importing Medical Devices into New Zealand
- Contraceptive Devices
- In-Vitro Diagnostic (IVD) Devices
- Labelling and Instructions for Use
- Advertising of Medical Devices
- Conducting Medical Device Clinical Trials in New Zealand
- Clinical Trial Safety Monitoring and Reporting *(PDF 345 KB, 14 pages*)

Surgical Mesh Implants

- Surgical Mesh Adverse Event Reporting
- Medsafe Actions
- Information for Healthcare Professionals
- Response Implementation
- Overseas Actions

Safety Information

- Recalls and Non-Recall Actions
- Safety Monitoring of Medical Devices
- Medical Device Adverse Event Reporting
- Medsafe Safety Communications
- Archive of Safety Communications

Product Recalls

- Medsafe Online Recall Database (MORD)
- Recall Actions Archive
- Recall Action Definitions
- Information for Medical Device Suppliers
- Medicines and Medical Devices Recall Code

Device Information

- New Zealand Definitions
- Medical Device Legislation
- Overseas Medical Device Regulators

If you have a query that is not answered by the information in this section please contact us at devices@health.govt.nz

For information on recalls or corrective actions please contact us at recalls@health.govt.nz

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Related Information

- Glossary
- Medical Device Definitions
- Accessing the WAND Database
- WAND Quick Reference Guide
- WAND User Manual
- Categorisation of Products
- Medical Device Adverse Event Reporting
- Medsafe Online Recalls Database

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Ministry of Health

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