

# NSW Medical Device Governance Program

## Glossary

Abbreviation	Meaning
ACI	Agency for Clinical Innovation (NSW)
ACSQHC	Australian Commission on Safety and Quality in Health Care
AE	Adverse Event
AFM Online	Asset and Facilities Management Online system (NSW)
AIMD	Active Implantable Medical Device
ARGMD	Australian Regulatory Guidelines for Medical Devices
ARTG	Australian Register of Therapeutic Goods
AusUDID	Australian Unique Device Identification Database
BME	Biomedical Engineer
CE / CEO	Chief Executive / Chief Executive Officer
CEC	Clinical Excellence Commission (NSW)
CGU	Clinical Governance Unit (NSW)
CMMD	Custom-made medical device
CPM	Clinical Product Manager
DCG	Director Clinical Governance
eHealth NSW	NSW Health's digital and Information and Communications Technology branch
eMR	Electronic Medical Record
EU	European Union
EU MDR	European Union Medical Device Regulations
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice (TGA)
GMDN	Global Medical Device Nomenclature
GMP	Good Manufacturing Practice (TGA)
GTIN	Global Trade Identification Number
HI	Health Infrastructure
HIMF	Health Item Master File number (NSW)
HS NSW	HealthShare NSW
IMD	Implantable Medical Device
IMDRF	International Medical Device Regulators Forum
ims+	Incident Management System (NSW Health)
IRIS	Incident Report Investigation Scheme (TGA)

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IVD	In Vitro Diagnostic device
LHD	Local Health District (NSW)
MDGP	Medical Device Governance Program (NSW CEC)
MDPS	Medical Device Production Systems (TGA)
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MoH	Ministry of Health (NSW)
MRA	Mutual Recognition Agreement
NSWA	New South Wales Ambulance
OCHO	Office of the Chief Health Officer
PHCB	Private Healthcare Branch (NSW)
PICs	Patient Implant Cards
PILs	Patient Information Leaflets
PMD	Personalised Medical Device
PMMD	Patient-Matched Medical Device
PoC	Point of Care
QMS	Quality Management System
SaMD	Software as a Medical Device
SARA	System for Australian Recall Actions (TGA)
SAS	Special Access Scheme (TGA)
SCHN	Sydney Childrens Hospital Network
SCIS	Supply Chain Information Services (NSW)
SHS	State-wide health services, such as NSW Ambulance, HealthShare NSW and NSW Health Pathology
SME	Subject Matter Expert
SHN	Speciality Health Network (NSW)
TGA	Therapeutic Goods Administration
UDI	Unique Device Identifier
UDI-DI	Unique Device Identifier - Device Identifier
UDI-PI	Unique Device Identifier - Production Identifier
UMDNS	Universal Medical Device Nomenclature System
UNSPSC	United Nations Standard Products and Services Code
URPTG	Uniform Recall Procedure for Therapeutic Goods (TGA)