MDSAP
Medical Device Single Audit Program

Version 005

MDSAP Databases Identifier in Preparation for Audits and Assessment

AUTHORING GROUP

MDSAP Regulatory Authorities

20 May 2025

	Main Page	Market Authorizations	Site Licenses /Registrations	Adverse Events	Advisory Notices	Other Topics
TGA **Australia**	TGA	eBusiness	NA	Adverse Event Notifications (DAEN)	Recalls (SARA)	TGA Act & Regulations Standard Orders and Medical Devices Clinical Evidence Guidelines IVD Guidelines Other Guidelines
ANVISA **Brazil**	ANVISA	Product Regulation	International Regulators ID	Adverse Events and Quality Issues* *computerized system developed by ANVISA for the news of incidents, adverse events (AE) and technical complaints (QT) related to the use of products and services under sanitary surveillance	Recalls, Counterfeit, Suspended Products	ANVISA Website Guidance
Health Canada	Health Canada Medical Devices	Medical Device Active Licence Listing (MDALL)	Medical Device Establishment Licence Listing (MDEL)	Medical Device Incidents	Recalls and Safety Alerts	NA
MHLW/PMDA **Japan**	PMDA	NA	Foreign Manufacturing Sites	NA	Recalls	PMD Act MHLW MO169 Standards for Medical Devices in Japan

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FDA **USA**	FDA	Device Registration and Listing (online search) Establishment, Registration & Device Listing	Device Registration and Listing (online search) Establishment, Registration & Device Listing	MDR (online search) MAUDE	List of Device Recalls Medical Device Safety (online search) Recalls	Inspection Classification 510(K) Premarket Notification Premarket Approval (PMA) Total Product Life Cycle Product Code Builder Unique Device Identifier CFR Code of Federal Registrations Title 21 eCFR ICH Guidelines Warning Letters

Please visit our website for more details.

www.mdsap.global