

Publicly Accessible Databases for MDSAP Audits

| | Main page | Market Authorizations | Site Licenses/ Registrations | Adverse Events | Advisory Notices | Other topics |
|--------|------------------------|--------------------------------------|------------------------------|--|--|---|
| TGA | TGA | eBusiness | NA | Adverse Event Notifications (DAEN) | Recalls (SARA) | TGA Act & Regulations Standards Orders and Medical Devices Clinical Evidence Guidelines IVD Guidelines Other guidance |
| ANVISA | ANVISA | Product Registration | | Adverse Events and Quality Issues Adverse Events and Quality Issues* <small>*computerized system developed by ANVISA for the</small> | Recalls, Counterfeit, Suspended Products | MD IFU |

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|---------------|--|---|---|--|---|--|
| | | | | news of incidents, adverse events (AE) and technical complaints (QT) related to the use of products and services under sanitary surveillance | | |
| Health Canada | Health Canada Medical Devices | Medical Device Active License Listing (MDALL) | Medical Device Establishment Licence Listing (MDEL) | Medical Device Incidents | Recalls and Safety Alerts | NA |
| MHLW/ PMDA | PMDA | NA | Foreign Manufacturing Sites | NA | Recalls | PMD Act MHLW MO169 Standards for Medical Devices |
| FDA | 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) |

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|--|-----------|-----------------------|------------------------------|----------------|------------------|---|
| | | | | | | Total Product Life Cycle Product Code Builder Unique Device Identifier CFR Code of Federal Regulations Title 21 eCFR ICH Guidelines Warning Letters |