The International Medical Devices Database (IMDD) Variable Descriptions

Device ID (device_id): ID of medical device

Device Name (device_name): Name of medical device

Country of Device (device_country): Country of origin for medical device

Event ID (event_id): ID of event reported

Event Risk Class (action_classification): A numerical designation assigned by local authorities to a particular event that indicates the relative degree of health hazard. Not all countries classify events by degree of hazard. There may be differences between the class systems, if they exist.

The most commonly used one includes a numerical designation (I, II, or III):

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Country of Event (event_country): Country the event took place in

Reason of Reported Event (reason): Text describing why event was reported and put under investigation

Event Type (type): Reports about the type of event taken place. The type of events reported are Recall, Safety Alert, and Field Safety Notice.

Recall: A correction or removal action taken by a manufacturer to address a problem with a medical device. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

A medical device recall does not always mean that a patient must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed.

Safety Alert: Alerts provide important information and recommendations about products. Even though an alert has been issued, it does not necessarily mean a product is considered to be unsafe. Safety Alerts, addressed to health workers and users, may include recalls. They can be written by manufacturers, but also by health officials.

Field Safety Notice: Field safety notices are communications sent out by medical device manufacturers or their representatives in relation to actions that they may be taking in relation to their product that is on the market. These are mainly for health workers, but also for users. They can include recalls and alerts.

Cleaned Reason Text (clean_reason): Text from the reason column that were lowercased and stemmed with the non-alphabetical text, whitespaces, and stop words removed