Medical Device Labelling

History and Overview

Anton Coetzee - Medical Device Innovation - Consultant

Medicinal manufacturing has been around for centuries. Herbal remedies raw, boiled, crushed or mixed with other herbs have been used to treat a variety of injuries and ailments.

In 1938, due to rising concern over contaminated pharmaceuticals and poor production standards, legislative action resulted in the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. § 360) and created the FDA as a regulatory body for drug manufacturing.

In January 1965 the European Union adopted Council Directive 65/65 on the approximation of the law relating to medicinal products.

South Africa followed with the Drug Control Act (101 of 1965)

By the 1970's Medical Devices had dramatically evolved and the need for advanced patient safety measures become apparent.

In July 1978 the USA - FDA issued 21 CFR part 820 prescribing GMP requirements for medical device manufacturing which traceability labeling requirements.

Europe did not follow, they recognized that a different approach was needed and looked to include harmonized standards.

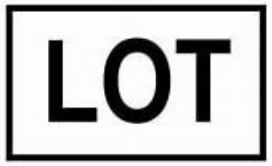
In 1994 the European Union introduced the Medical Device Directive (MDD 93/42/EEC), a risk based approached using Standards as the prescribed method for designing, testing and manufacturing medical devices for user, patient and environmental safety. The System was designed with 3 pillars, a Quality management system, Risk assessment and Traceability

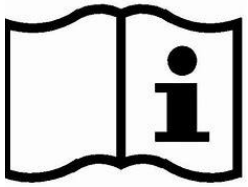
This new Directive saw the implementation of the CE mark, placed on a product which was independently audited and certified to have met the requirements of the Medical Devices Directive.

CE CE 0086 CE 0123

Special Labelling requirements

- Symbols according to EN 980 – EU has 24 official languages
- Label must be readable from 30cm
- Label must not fade or be affected by solvents or plasticizers
- Name & Address of European Authorised Representative

In **2013** the FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use.

When fully implemented, the label of most devices will include a **unique device identifier** (UDI) in human- and machine-readable form, which will ultimately improve patient safety, modernize device postmarket surveillance, and facilitate medical device innovation.

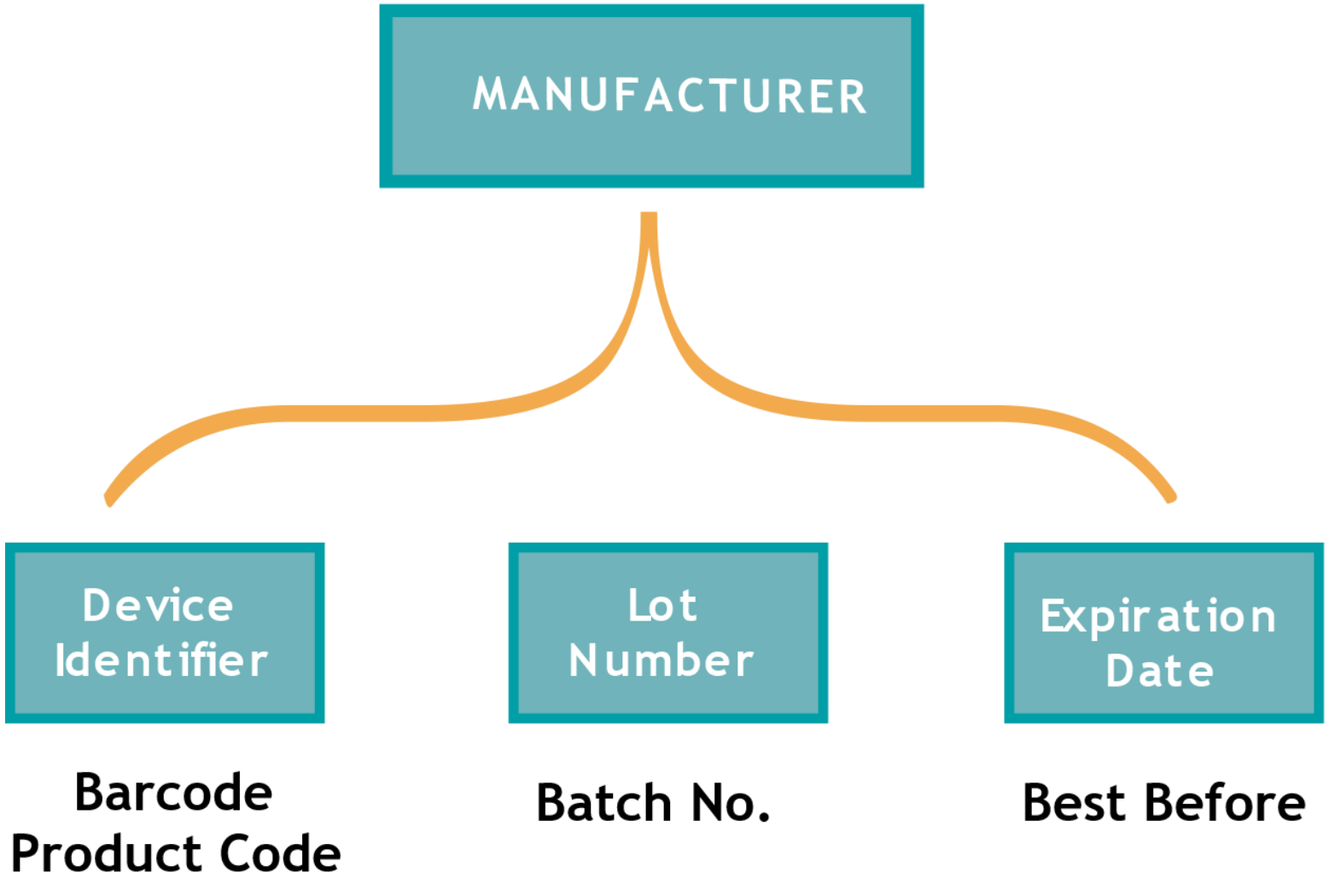
FDA also introduces a Third Party Review System and adopts many of the ISO Standards to improve patient safety.

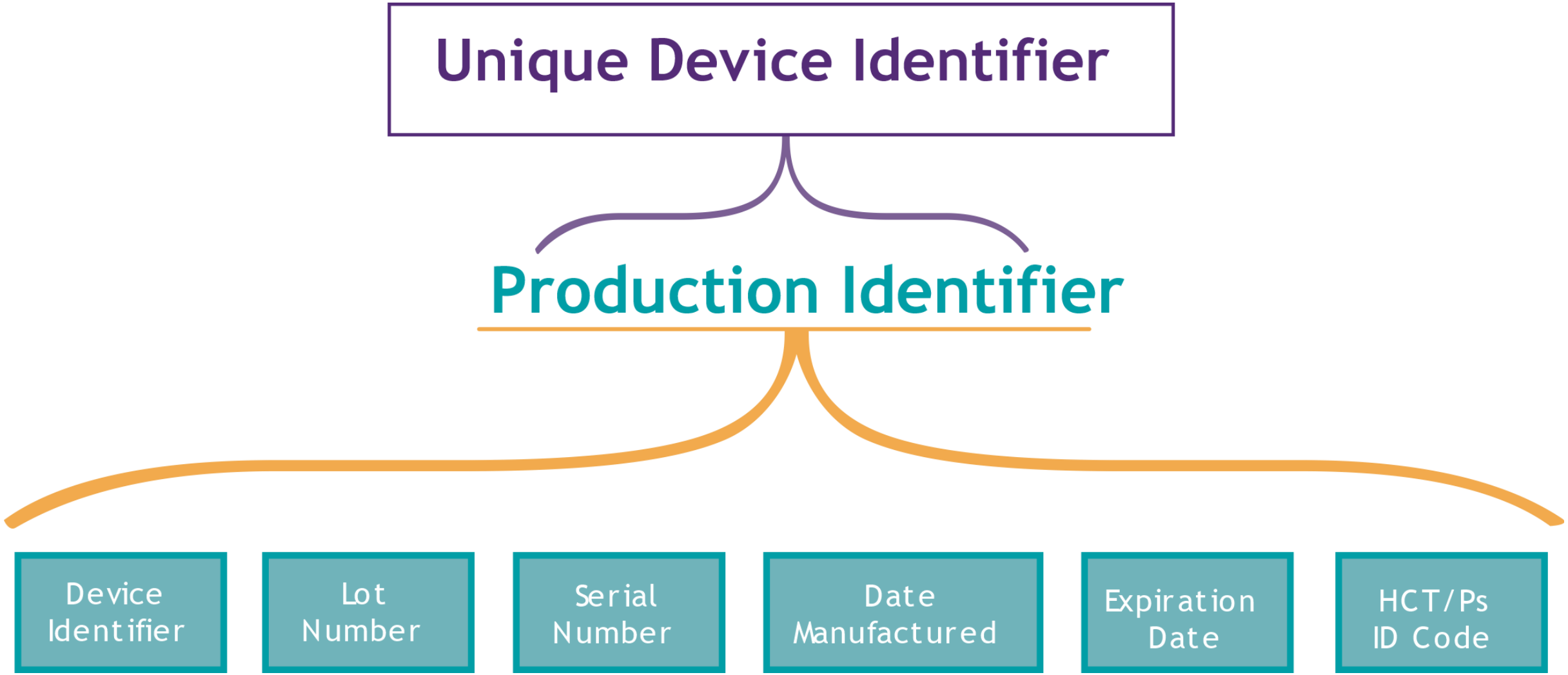
The Food and Drug Administration (FDA) regulates over **190,000** different devices, which are manufactured by more than **18,000** firms in more than **21,000** medical device facilities worldwide.

FDA creates Global Unique Device Identification Database (GUDID), a database of device identifiers and information for medical devices in the U.S.

Europe introduces MDR 2017/745 and EUDAMED

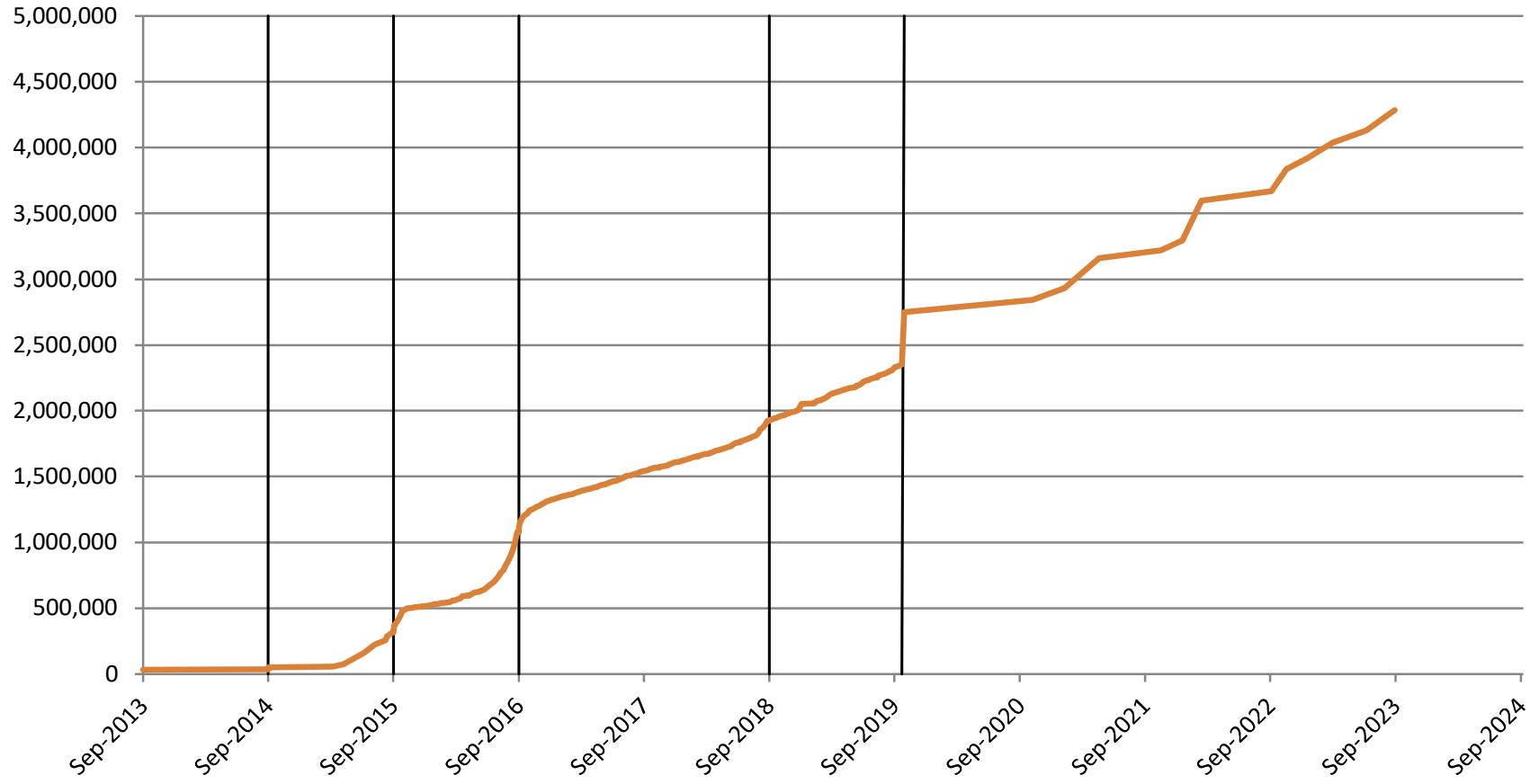
Production Identifier




Unique Device Identifier
Production Identifier
Device Identifier
Lot Number
Serial Number
Date Manufactured
Expiration Date
HCT/Ps ID Code

GUDID Records and Submission Compliance Dates

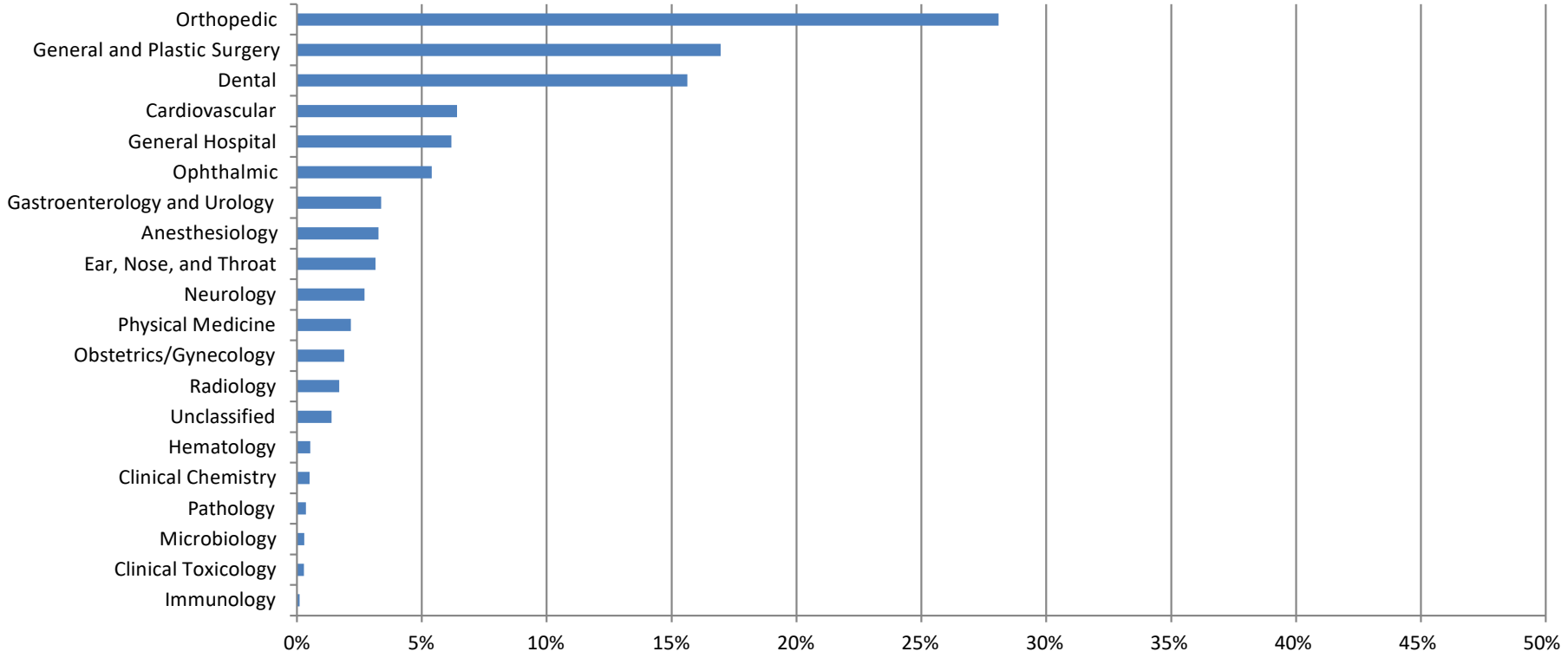
Data Current as of Feb 1, 2024



Medical Specialties in GUDID

Data Based on FDA Product Codes

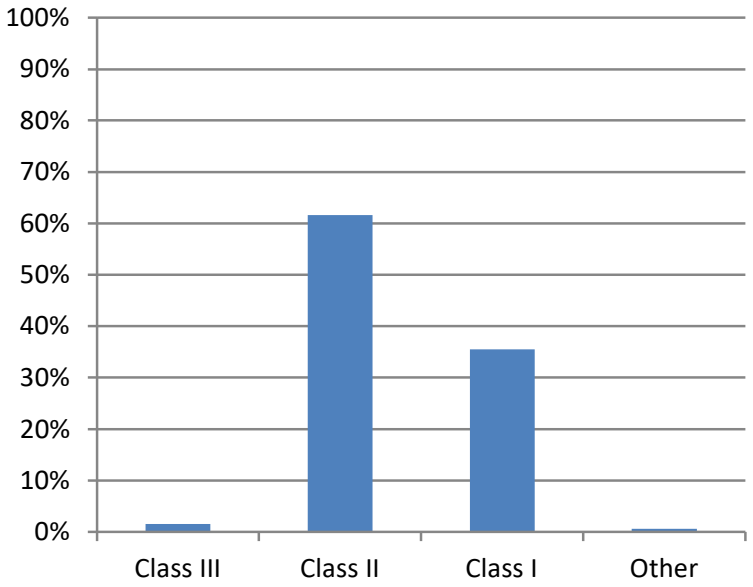
Data Current as of Feb 1, 2024

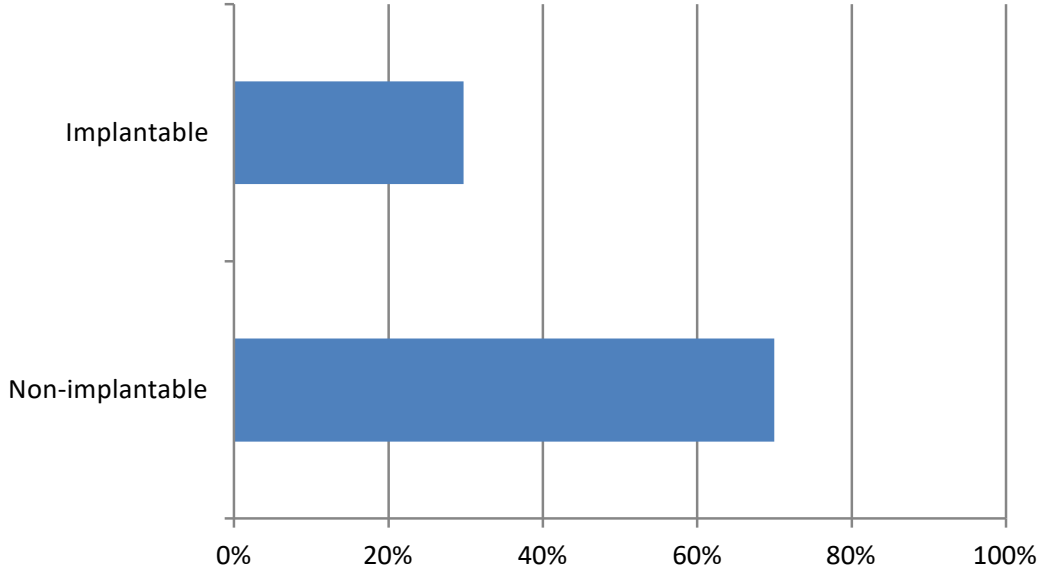


Most GUDID Records are Class II; About 31% are Associated with Implantables

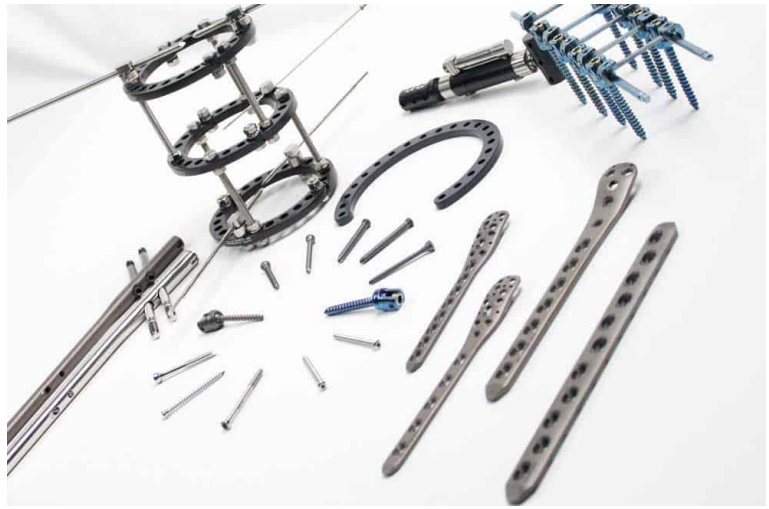
"Implantable" Devices are those Assigned FDA Product Codes Associated with Implantable Devices, Systems and Accessories

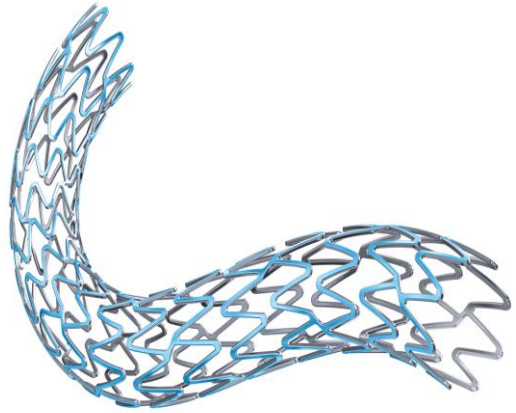
Data Current as of Feb 1, 2024

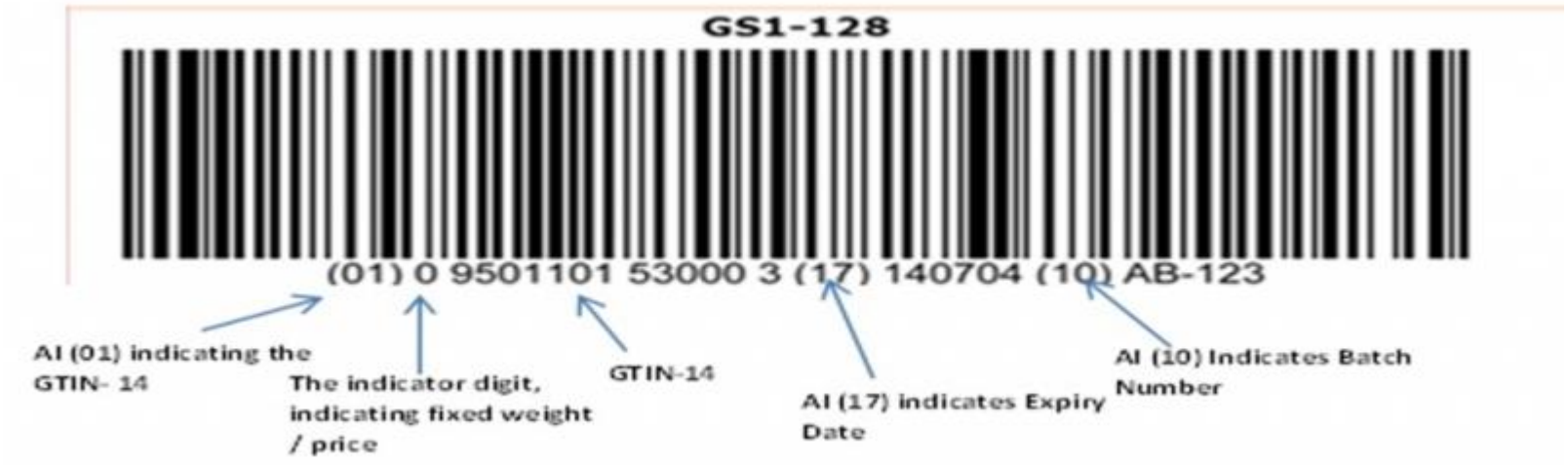


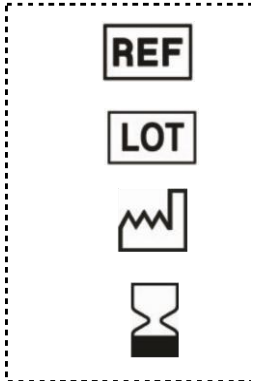


Where do I put the Barcode





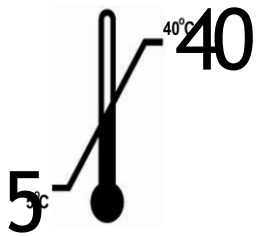

GS1-128
(01) 0 9501101 53000 3 (17) 140704 (10) AB-123
AI (01) indicating the GTIN- 14
The indicator digit, indicating fixed weight / price
GTIN-14
AI (17) indicates Expiry Date
AI (10) Indicates Batch Number

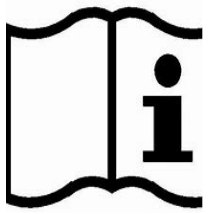

REF
LOT


MD


NON STERILE


1


40°C
40
5
5°C



Advantages of Barcoding

- **Traceability and re-calls**

  All manufacturing processes starts with a BOM (Bill of Material) Each material has Identifiable information which needs to be captured when issued by stores.

  After the manufacturing process the finished item is inspected by QC and received by stores who generates a GRV, generates a barcode and captures the stock on the accounting system.

  The expiry date of the finished item will be determined by the expiration date of the raw material or component used.

  When sold the LOT no. is captured on the invoice which completes the traceability process. Records must be kept for 5 years AFTER the expiry date.

  The Distributor or Reseller is required to do the same when invoicing.

  BUT does the Healthcare facility do the same.

- **Facilitates Process Automation**
- **Allows the use of AI**
- **Reduces human error**
- **Improves User / Patient Safety**
- **Improves Stock Control**