# Global Medical Device Nomenclature
# GMDN
## Overview & Updates

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GMDN Agency

www.gmdnagency.org

# Overview

- Introduction and GMDN worldwide
- GMDN terminology and categorisation structure
- GMDN in UDI
- Case-study: retrieval of UDI data for clinical use
- GMDN Website
  - Membership
  - Term search and enquiries
  - Term changes
- GMDN in Hospitals
- Questions

# What does the GMDN do?

A DEVICE is described by a GMDN Term which represents a GENERIC DEVICE GROUP

**GMDN Code: 35195**
**Term Name: Electrocardiographic monitor**
**Term Definition:** A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

within a DATABASE and allows for HARMONIZED NAMING



GMDN

# Why GMDN?

The GMDN data gives the user i.e. a Regulator, Registry, Hospital, Manufacturer:

- A non-proprietary device name and definition that describes the device clearly and succinctly
- A way to categorize the device at many levels
- A global solution:
  - Only one code needed worldwide
  - Regulators can spot trends and do powerful data analysis
  - Device registries use data to do clinical research
  - Hospitals manage their inventories/device lifecycle
  - Consistent communication of data across boarders

# GMDN worldwide

- Used by 80+ national Medical Device Regulators e.g. US, UK, Germany, France, Italy, Sweden, Australia, Czech Rep.
  - 7500+ Manufacturers worldwide
- Recent adoptions: Russia, South Africa, Brazil, Colombia, Saudi Arabia
- US FDA implementation of UDI Rule
  - All medical devices sold in the US need a GMDN code
- European Commission uses the GMDN for their EUDAMED (market surveillance database)
  - European UDI to become a reality soon
- Widely supported by device Trade Associations (Advamed, MedTech Europe, GMTA, DITTA, etc)
- The WHO use GMDN in their field guide for developing countries
- Website and Database translated into several languages

GMDN

# GMDN: grouping of medical devices

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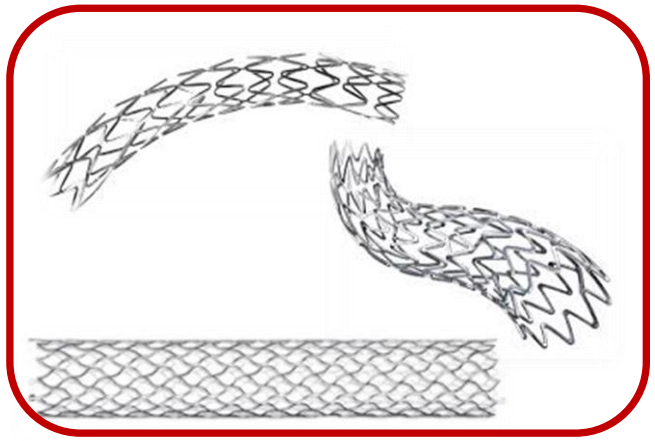

# How do we define a generic group of devices i.e. a GMDN term?

The GMDN terms are non-proprietary groups written to outline:

- **Intended use** of the device
- **Technology** on which the device functions
- The **components** that the device includes (if more than one)
- A series of **significant attributes**, e.g.:
  - Invasiveness
  - Sterility
  - Use-frequency
  - Pharmaceutical inclusion
  - Device power
  - Animal- or human-derived

# GMDN term

**GMDN Code: 35195**

**Term Name: Electrocardiographic monitor**

**Term Definition:** A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits.

# GMDN term = Device group

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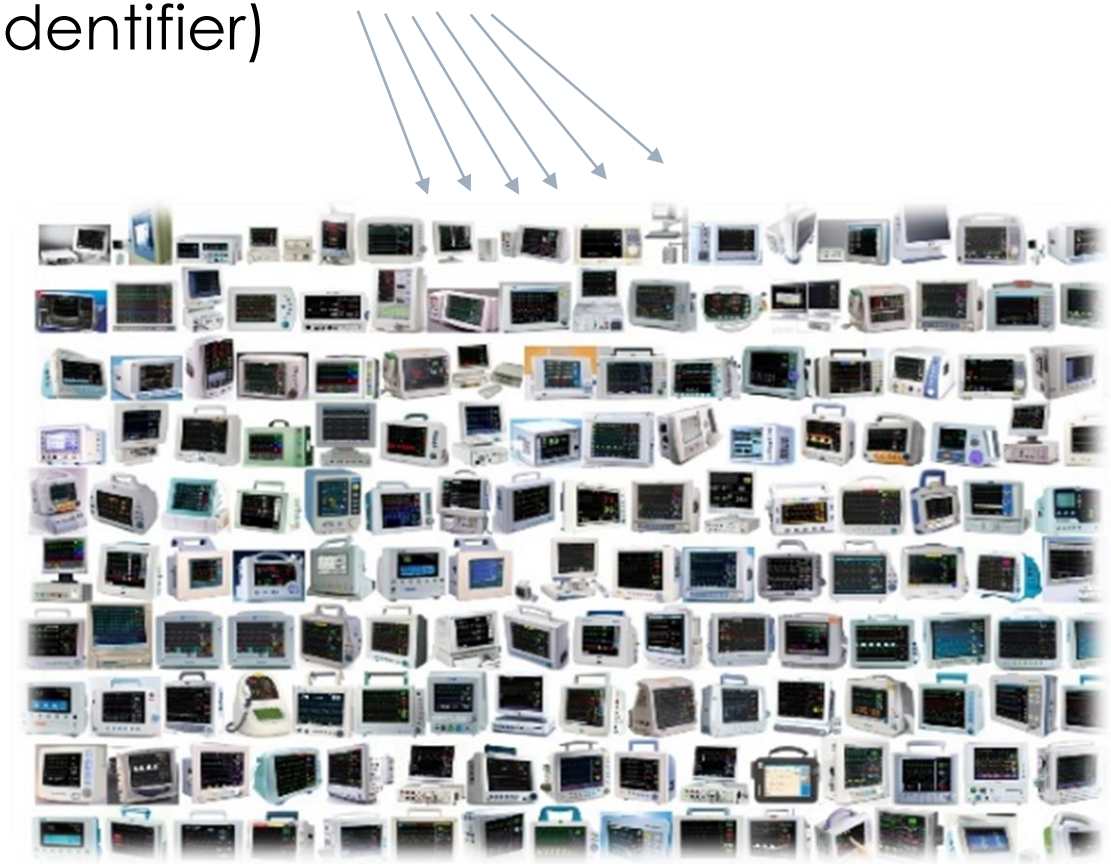
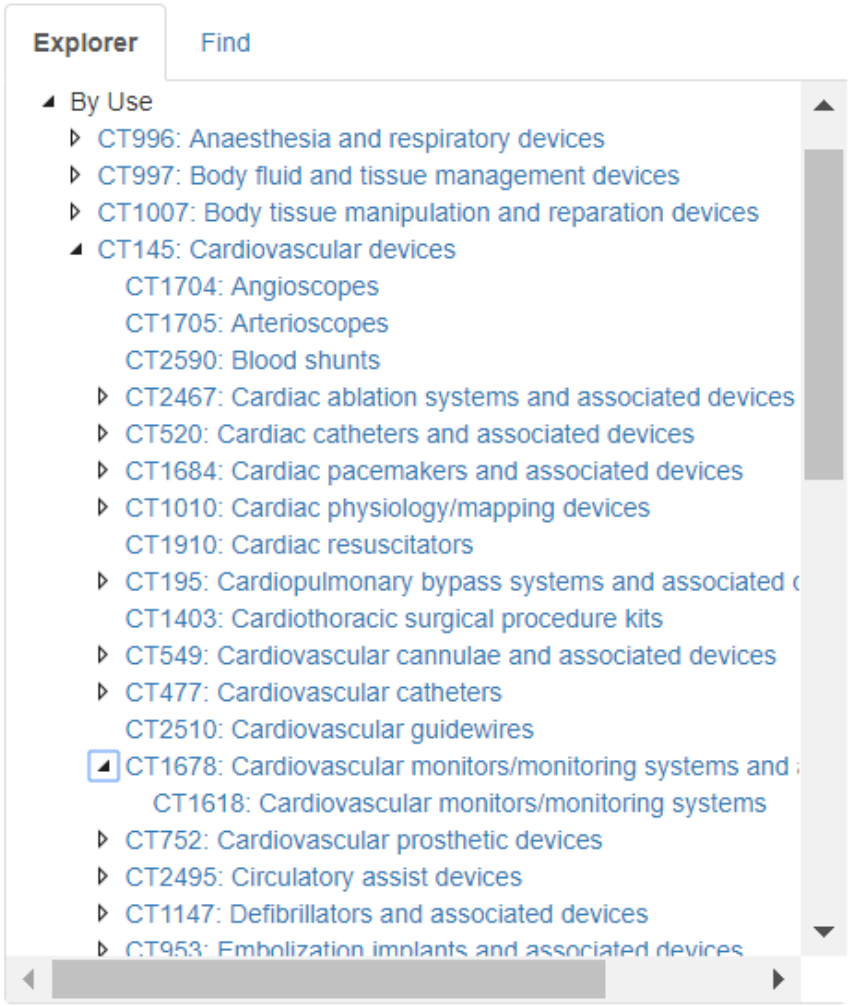
But all Electrocardiographic monitors have a different DI (Device Identifier)



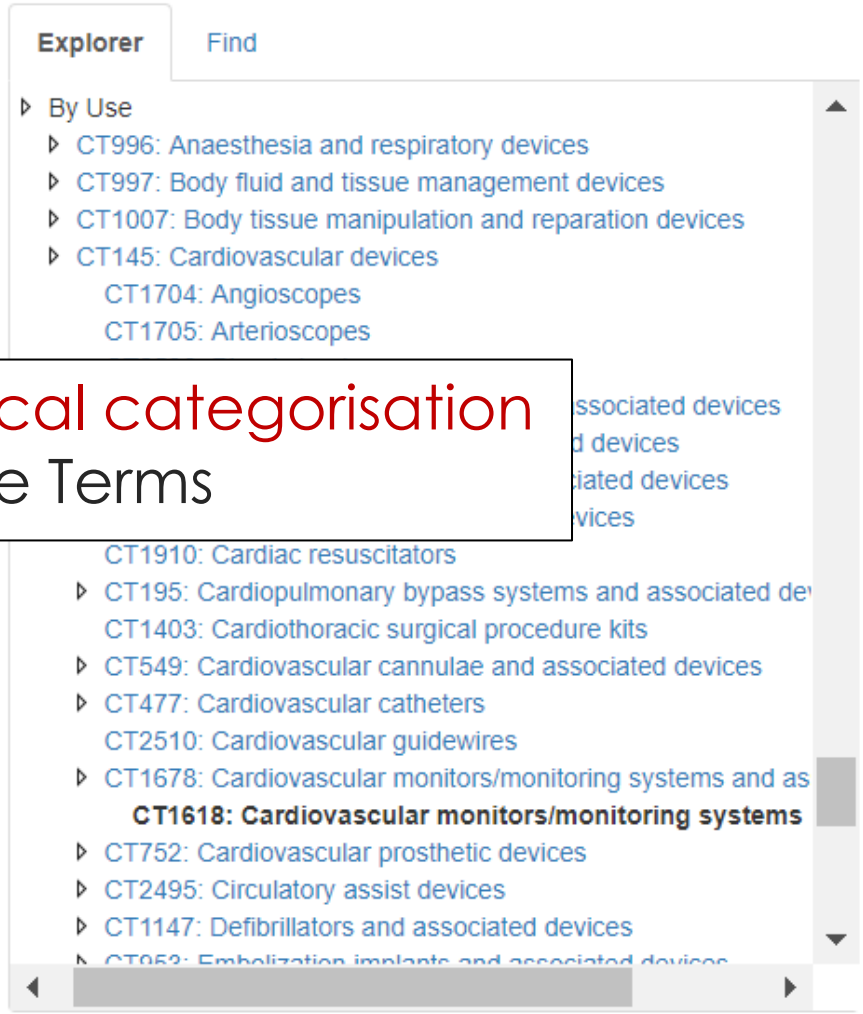
# High-level grouping and categorisation: Collective Terms

- GMDN uses **Collective Terms (CTs)** to organize related GMDN terms:
  - By clinical application (e.g., cardiovascular devices)
  - By name (e.g., prostheses, scissors, catheters)
  - By attribute (e.g., material, invasiveness, sterility, use-frequency)
- CTs are a **hierarchical categorisation tool**

# Advanced grouping and categorisation: Collective Terms



# Advanced grouping and categorisation: Collective Terms




Hierarchical categorisation
Collective Terms

1-25 of 31 term(s)

Bedside heart rate monitor

Blood glucose/blood pressure monitoring system, home-use

Blood glucose/blood pressure monitoring system, point-of-care

Cardiac arrhythmia monitoring system

Cardiac catheterization monitoring system

Cardiac stress exercise monitoring system

Cardiopulmonary bypass system pressure mo

Cardiopulmonary stress exercise monitoring system

Electrocardiographic monitor

Electrocardiography telemetric monitoring system

Emergency heart rate monitor

Extracorporeal blood gas/pH monitor

Foetal cardiac monitor

Implantable cardiac monitor

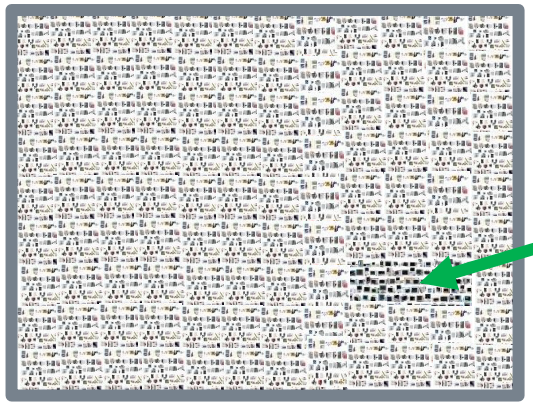
Nomenclature
GMDN Terms

GMDN

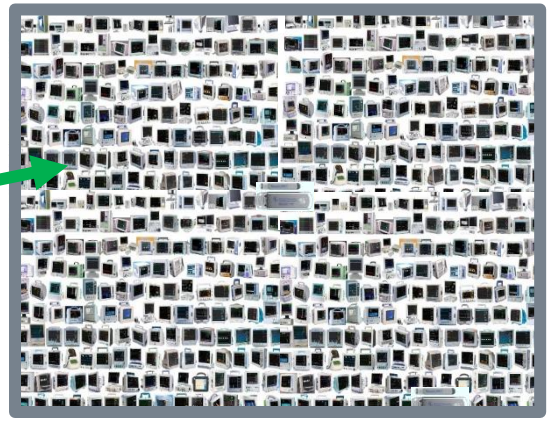
# GMDN - Advanced grouping

- Each GMDN Term is linked to a number of Collective terms
- This allows for broader grouping in many different ways

CT314 Electrically powered/operated

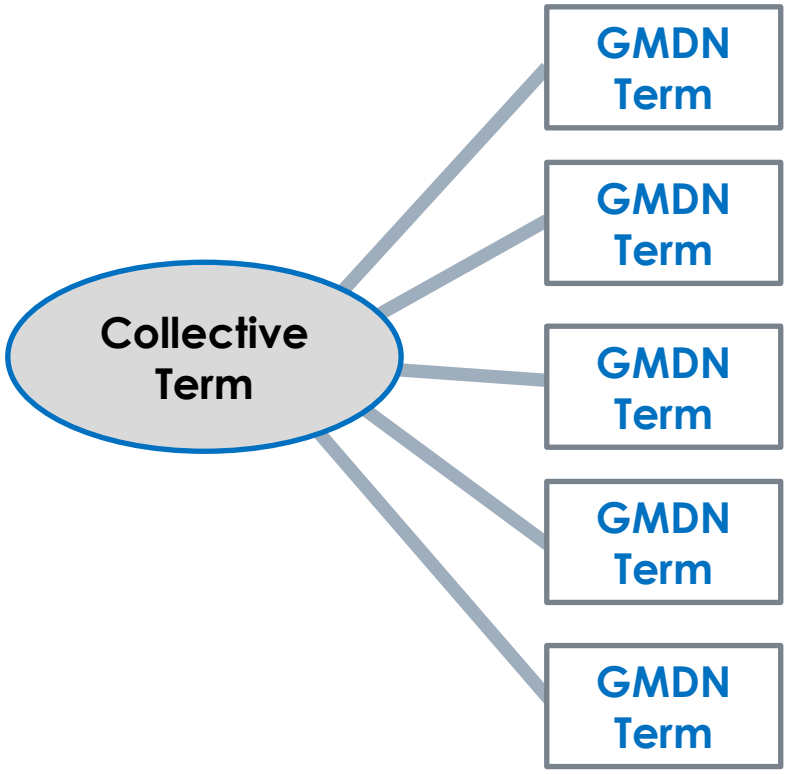


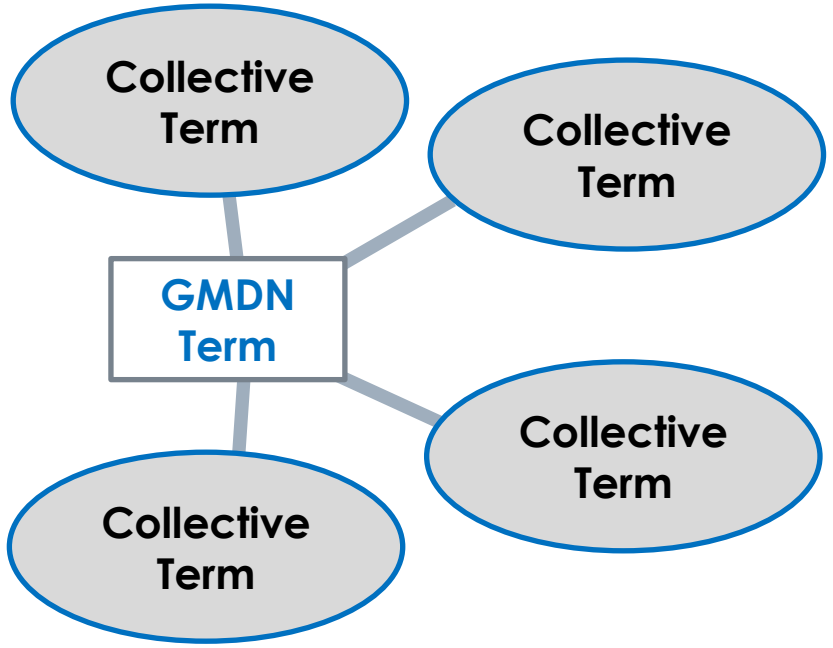
CT1618 Cardiovascular monitors/monitoring systems



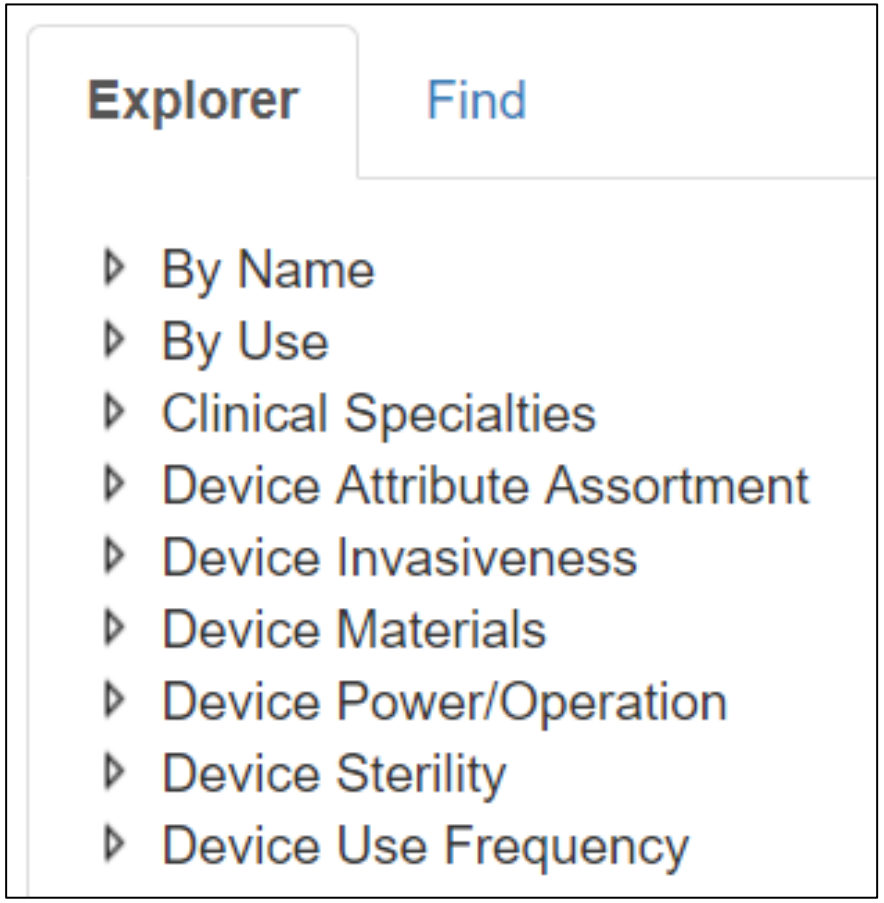
Some CTs group hundreds of terms (and subsequently may group millions of devices), some just a few terms

# CT relationships

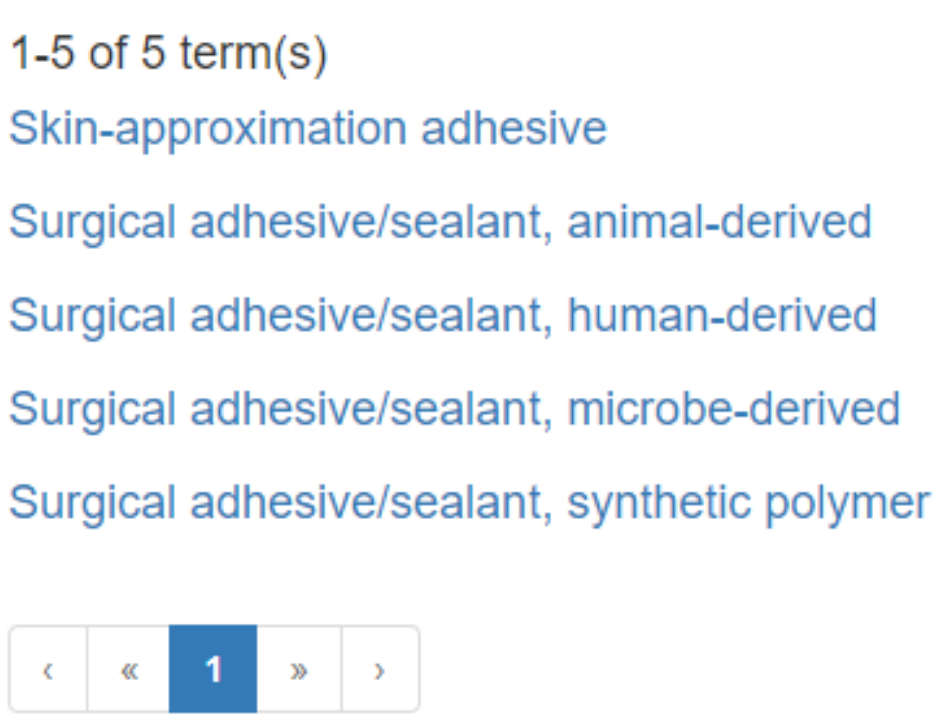


# Advanced grouping and categorisation: Collective Terms

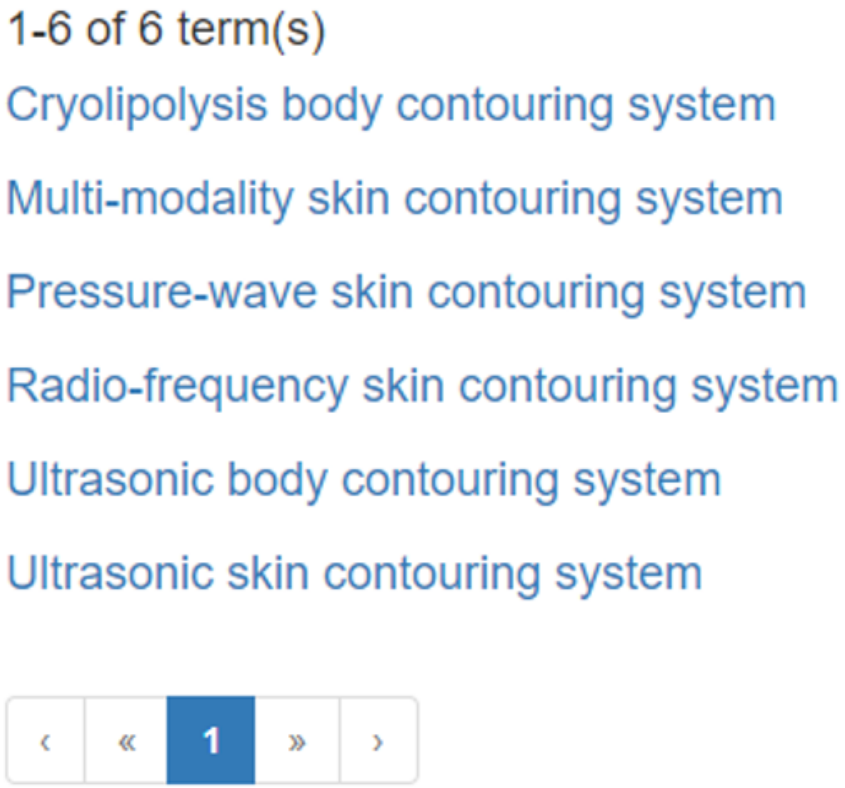


# Advanced grouping and categorisation: Collective Terms


GMDN

# Advanced grouping and categorisation: Collective Terms

# Advanced grouping and categorisation: Collective Terms

**Explorer** Find

- By Name
- By Use
- Clinical Specialties
- Device Attribute Assortment
- Device Invasiveness
  - CT984: Non-surgical invasive
    - CT322: Long-term non-surgical invasive
    - CT318: Short-term non-surgical invasive
    - CT323: Transient non-surgical invasive
  - **CT983: Surgical invasive**
    - CT321: Long-term surgical invasive
    - CT319: Short-term surgical invasive
    - CT320: Transient surgical invasive

1-25 of 2771 term(s)

Abdominal aorta endovascular stent-graft

Abdominal fluid shunt system

Abdominal hernia surgical mesh, collagen, antimicrobial

Abdominal hernia surgical mesh, composite-polymer

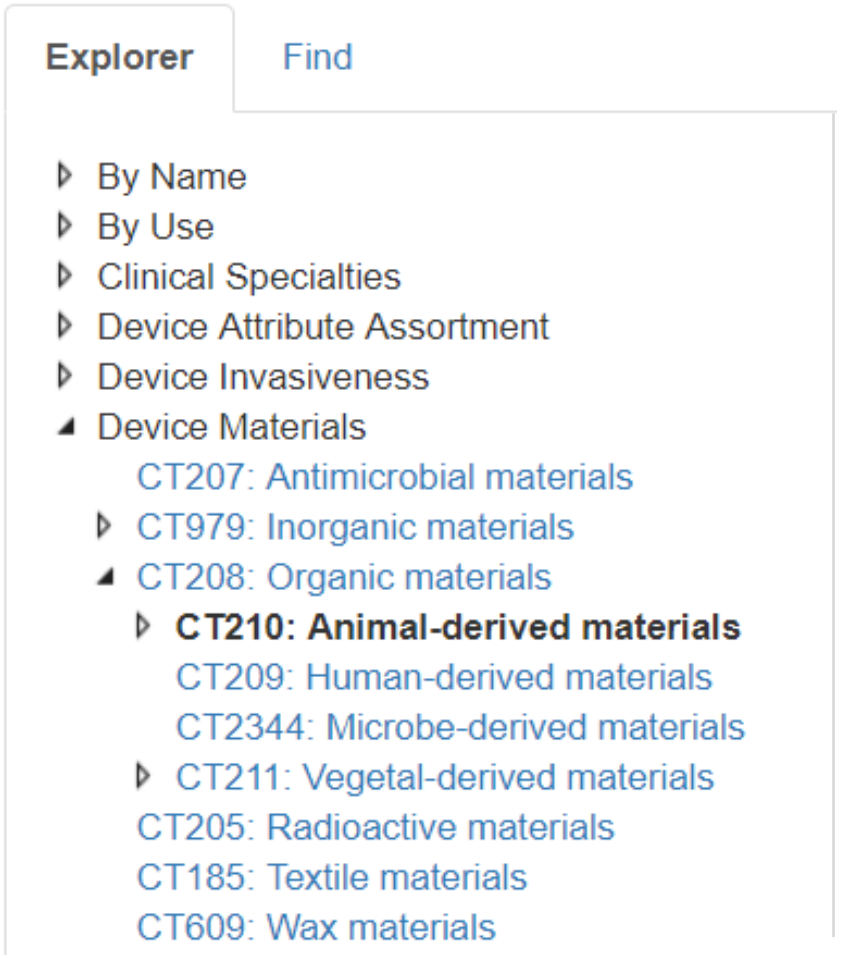
Abdominal hernia surgical mesh, synthetic polymer

Abdominal hernia surgical mesh, synthetic polymer, antimicrobial

Abdominal paracentesis needle, reprocessed

GMDN

# Advanced grouping and categorisation: Collective Terms




1-25 of 134 term(s)

Abdominal hernia surgical mesh, collagen, antimicrobial

Angiographic x-ray phantom, anthropomorphic

Animal-skin bed mattress overlay

Animal-skin chair pad

Antimicrobial glove/mitten

Antimicrobial head garment

Antimicrobial infant garment

Aortic arch branch vessel endovascular stent-graft

Aortic bi-leaflet mechanical heart valve prosthesis/biologic-polymer aorta graft

GMDN

# Advanced grouping and categorisation: Collective Terms

- Device Power/Operation
  - CT314: Electrically powered/operated
  - CT316: Hydraulically powered/operated
  - CT326: Manually powered/operated
  - CT327: Pneumatically (Gas) powered/operated
  - CT256: Vacuum powered/operated
- Device Sterility
  - CT329: Non-sterile
  - CT336: Sterile
  - CT337: Sterilizable
  - CT143: Sterilization/Disinfection
- Device Use Frequency
  - CT697: Refurbished
  - CT696: Reprocessed
  - CT982: Reusable
  - CT981: Single use

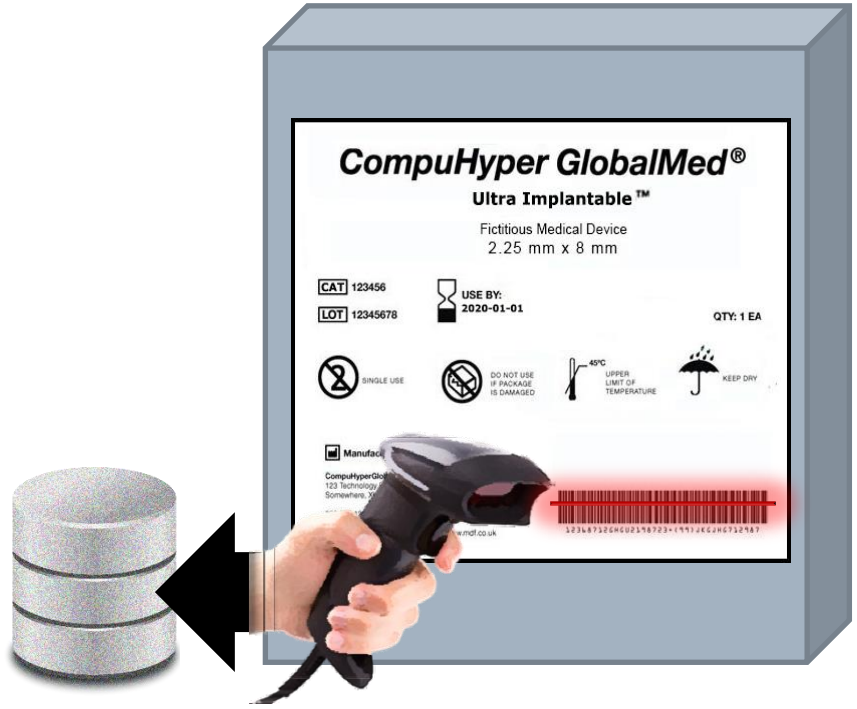
GMDN

# GMDN in Unique Device Identification (UDI) systems

# GMDN code: a mandatory element in UDI

## Unique Device Identification (UDI) – US FDA

- The Unique Device Identification (UDI) System assigns a Unique Device Identifier to each medical device from any supplier
- Uses a globally unique number, in a barcode
- When read by a machine identification errors are reduced
- Enhances electronic tracking
- Once scanned all pertinent data is retrieved from a database
- This is the same data entered to the FDA GUDID



# UDI – Unique Device Identification

A UDI ISSUING AGENCY provides THE MANUFACTURER with A UNIQUE NUMBER to be put in A BARCODE


(01) 10614141 012345678


for THE DEVICE allowing accurate RETRIEVAL of DEVICE DATA from A DATABASE


- DI number
- Brand name
- GMDN code
- SIZE
- Company info

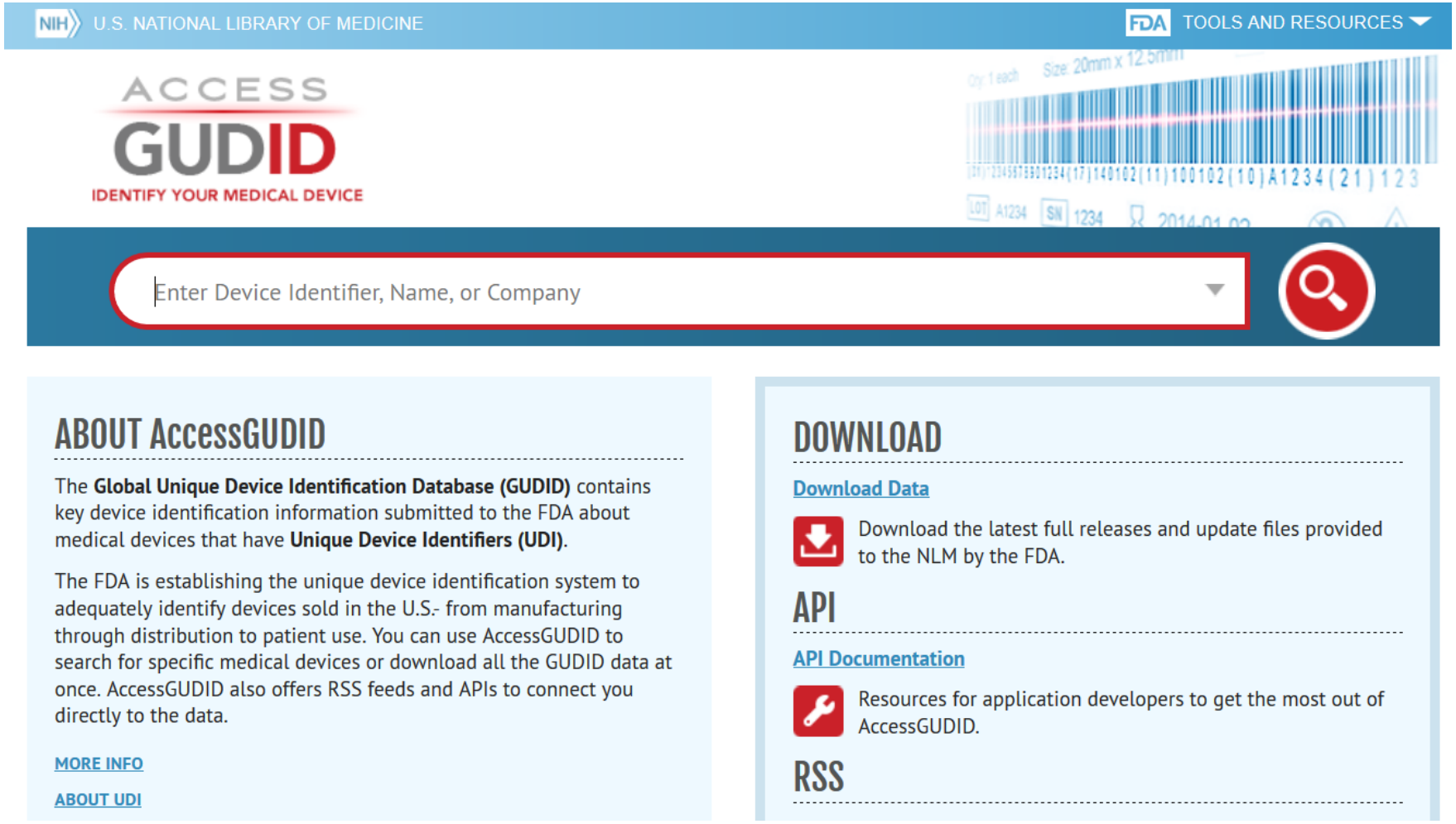
GMDN

# UDI – Unique Device Identification

- US FDA UDI
- UDI Database = GUDID
  - GMDN code is a mandatory field on device record submission
  - https://accessgudid.nlm.nih.gov/

# Access GUDID

## Global Unique Device Identifier Database




GMDN

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

"aortic stent"

HOME | ABOUT | NEWS | API | DOWNLOAD | HELP

## SEARCH RESULTS FOR: "aortic stent" (176 results)

EXPORT RESULTS

FILTERS | SORT BY | 10 RESULTS PER PAGE | < PAGE 1 >

- Company Name
- Brand Name
- GMDN Term
- FDA Product Code Name
- FDA Product Code
- Device Packaged As Sterile
- Sterilization Prior To Use
- Issuing Agency
- Device Size Type
- Device Class
- Implantable

**CP Stent™ - 04046964899096**
MCP017 Mounted CP Stent 3.9 14 4 8F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614328

**CP Stent™ - 04046964899089**
MCP016 Mounted CP Stent 3.4 22 3.5 9F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614327

**CP Stent™ - 04046964899058**
MCP013 Mounted CP Stent 3.4 16 3.5 9F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614324

**CP Stent™ - 04046964899027**
MCP010 Mounted CP Stent 2.8 18 3 9F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614321

**CP Stent™ - 04046964899010**
MCP009 Mounted CP Stent 2.8 16 3 9F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614320

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

"aortic stent"

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## SEARCH RESULTS FOR: "aortic stent" (176 results)

EXPORT RESULTS

FILTERS | SORT BY | 10 RESULTS PER PAGE | < PAGE 1 >

Company Name
Brand Name
GMDN Term
General aorta endovascular stent-graft (89)
Bare-metal aortic stent (87)
FDA Product Code Name
FDA Product Code
Device Packaged As Sterile
Sterilization Prior To Use
Issuing Agency
Device Size Type
Device Class
Implantable

**CP Stent™ - 04046964899096**
MCP017 Mounted CP Stent 3.9 14 4 8F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614328

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**CP Stent™ - 04046964899010**
MCP009 Mounted CP Stent 2.8 16 3 9F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614320

**CP Stent™ - 04046964899003**
MCP008 Mounted CP Stent 2.8 14 3 8F
**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC **Version or Model:** 614319

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

"aortic stent"

HOME | ABOUT | NEWS | API | DOWNLOAD | HELP

## SEARCH RESULTS FOR: "aortic stent" (176 results)

EXPORT RESULTS

FILTERS | SORT BY | 10 RESULTS PER PAGE | < PAGE 1 >

Company Name
Brand Name
GMDN Term
General aorta endovascular stent-graft (89)
Bare-metal aortic stent (87)
FDA Product Code Name
FDA Product Code
Device Packaged As Sterile
Sterilization Prior To Use
Issuing Agency
Device Size Type
Device Class
Implantable

### CP Stent™ - 04046964899096

MCP017 Mounted CP Stent 3.9 14 4 8F

**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC

**Version or Model:** 614328

**Device IDs:**

- 04046964899096 (Primary)

**GMDN Terms:**

- Bare-metal aortic stent

**Device Sizes:**

- Diameter (mm) : 14.000 MM
- Length : 39.000 MM

### CP Stent™ - 04046964899089

MCP016 Mounted CP Stent 3.4 22 3.5 9F

**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC

**Version or Model:** 614327

### CP Stent™ - 04046964899058

MCP013 Mounted CP Stent 3.4 16 3.5 9F

**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC

**Version or Model:** 614324

### CP Stent™ - 04046964899027

MCP010 Mounted CP Stent 2.8 18 3 9F

**Company Name:** B BRAUN INTERVENTIONAL SYSTEMS, INC

**Version or Model:** 614321

# GUDID August 2017

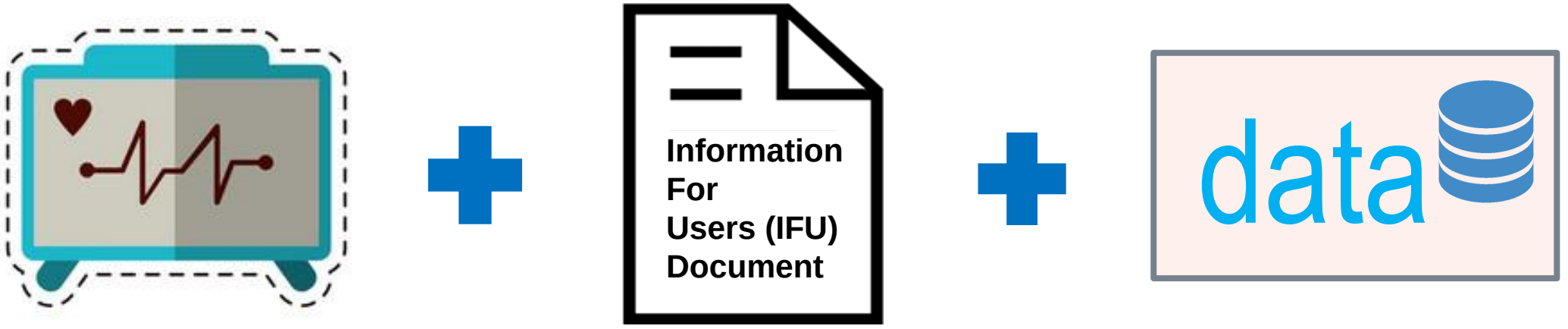
- DI records: 1,895,416
- Unique GMDN codes: 8187
- GMDN term : DI record *ratio* = 1 : 232

- Active implantable device records: 2813
- Non-active implantable device records: 524,094
- IVD device records: 24,817

→ Data retrieved using GMDN grouping

GMDN

# Shared data – an important element of your device



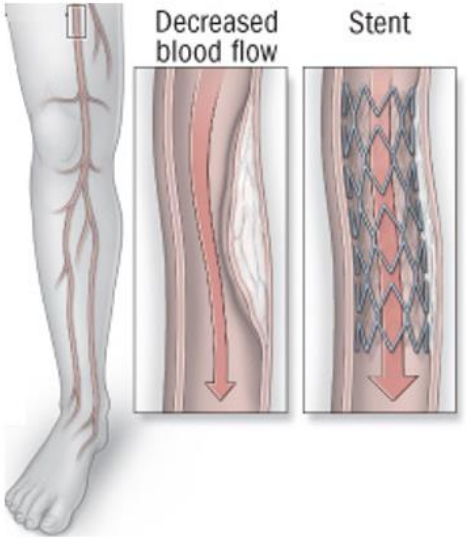

The device itself

Product documentation in the box

Publicly shared data (inc. GMDN term)

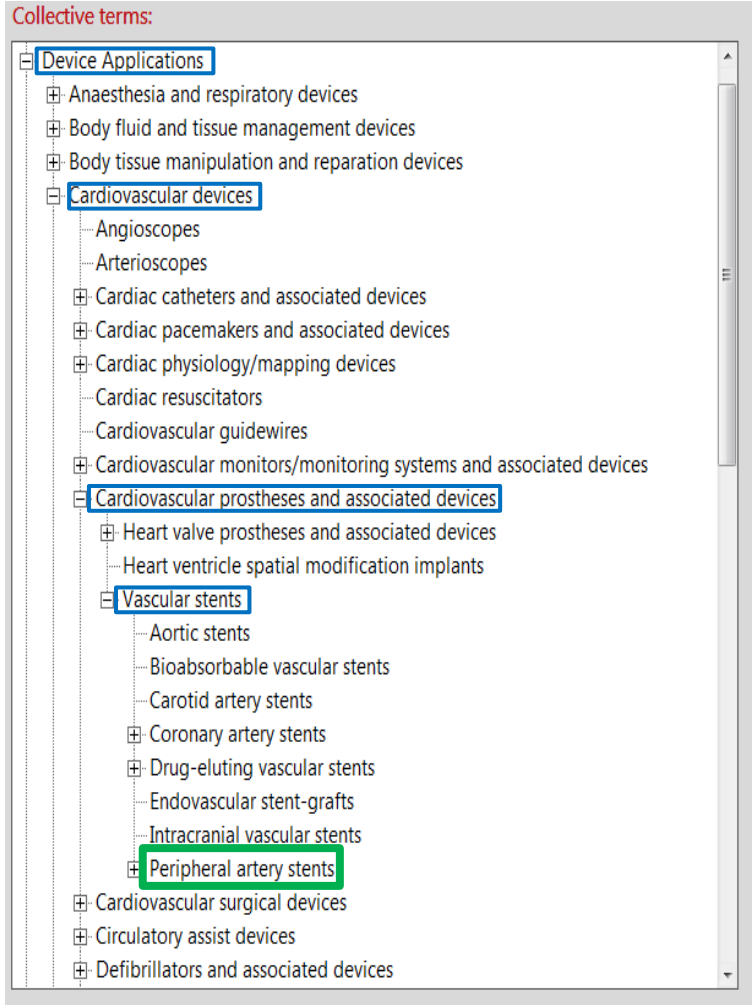
# Example of GMDN in action: GMDN Agency working with the FDA

- A clinical study was undertaken to find all **peripheral artery stents** sold in the US
- Looking for a few hundred devices in a population of ~ 2 million records
- Without the GMDN results rely heavily on manufacturer names and descriptions of their device e.g.,
  - Self-Expanding Stent System
  - Self-Expanding Peripheral Stent System
  - STENT COMPLETE SE LONG US
  - Self-Expanding Stent
  - *"Trade name"* Stent System
  - No description
- Need for a standardized name everyone can use




GMDN

# Example of GMDN in action
## Finding peripheral artery stents



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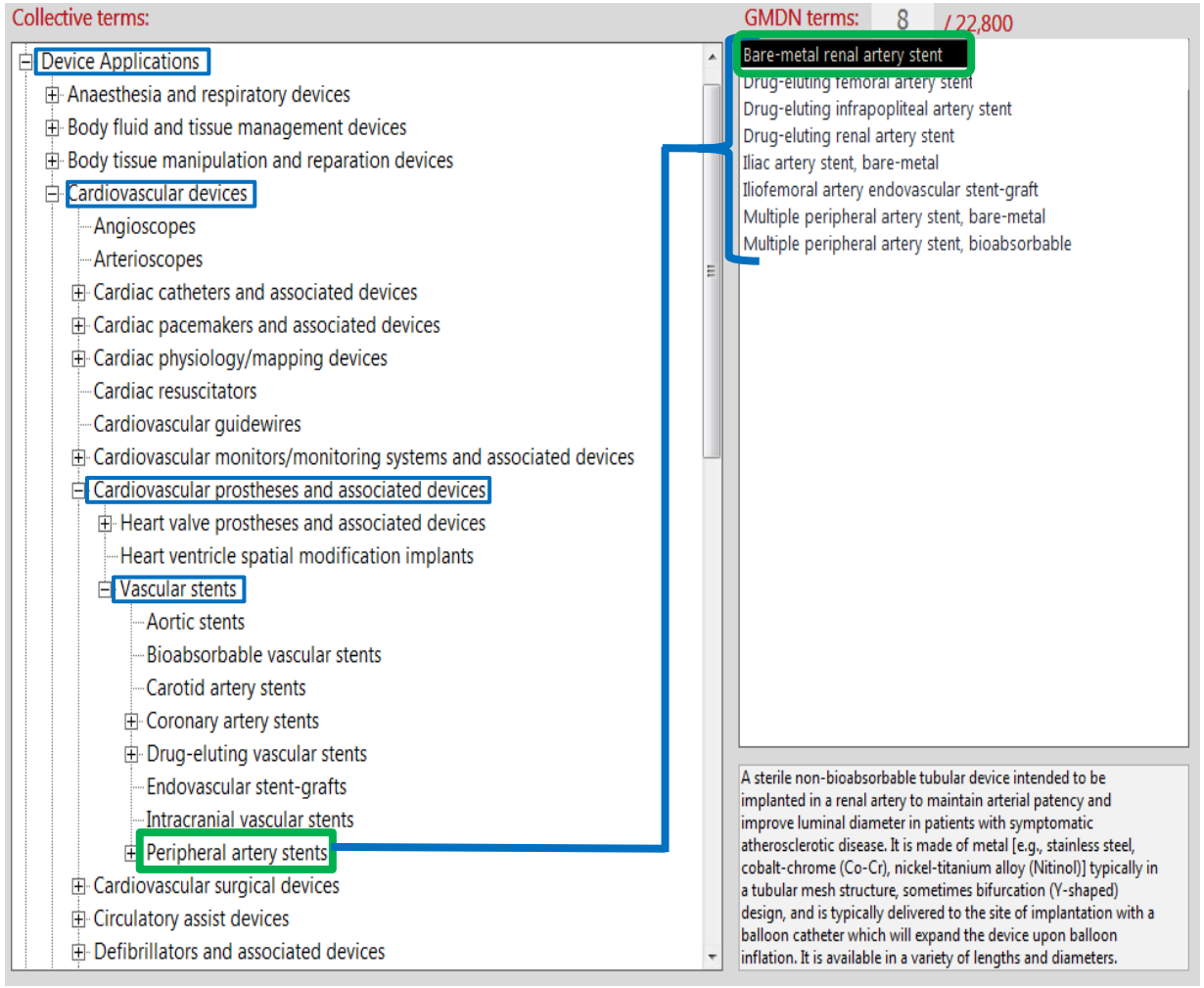

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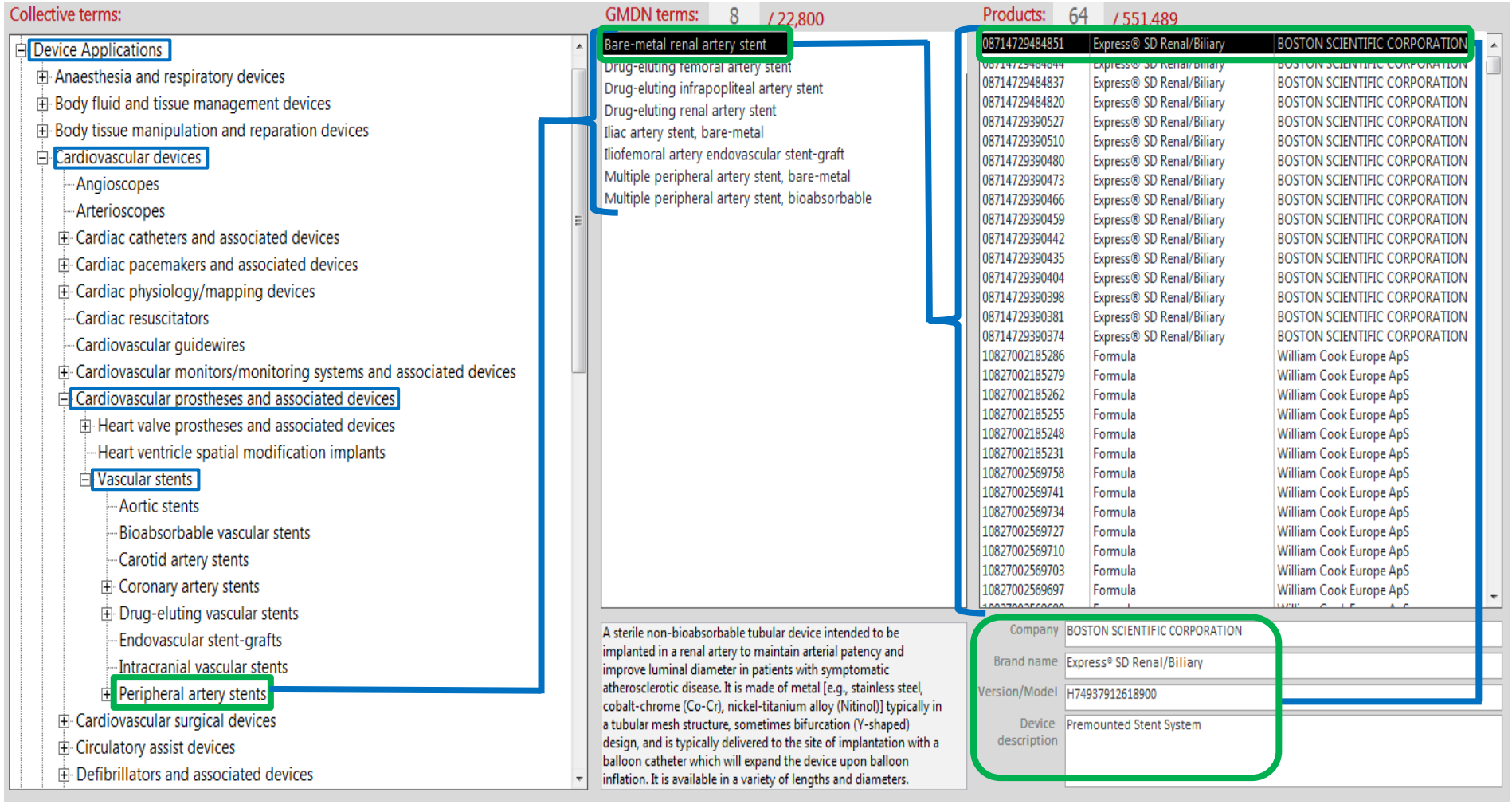
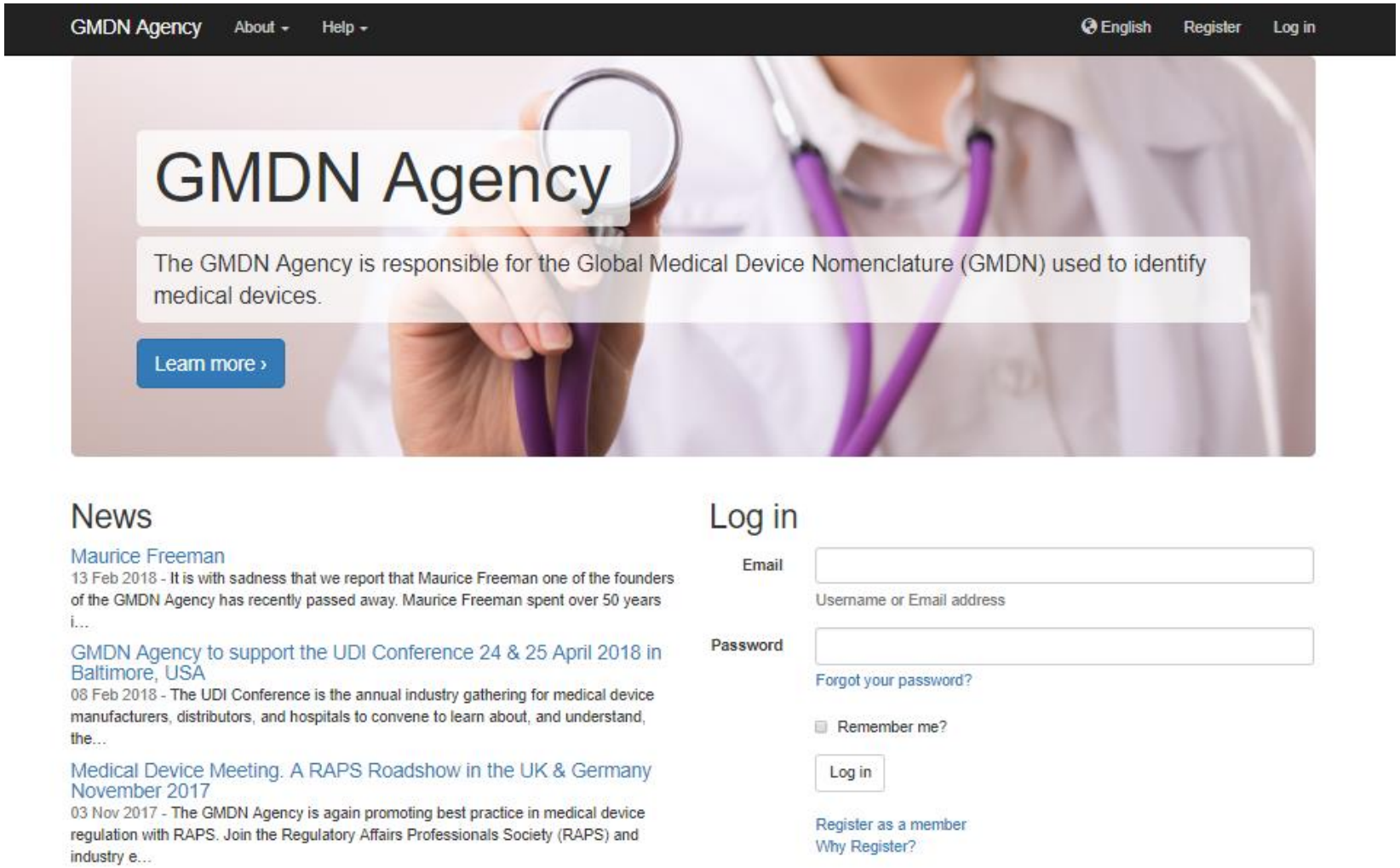
## Finding peripheral artery stents




GMDN CTs → GMDN Terms → Devices

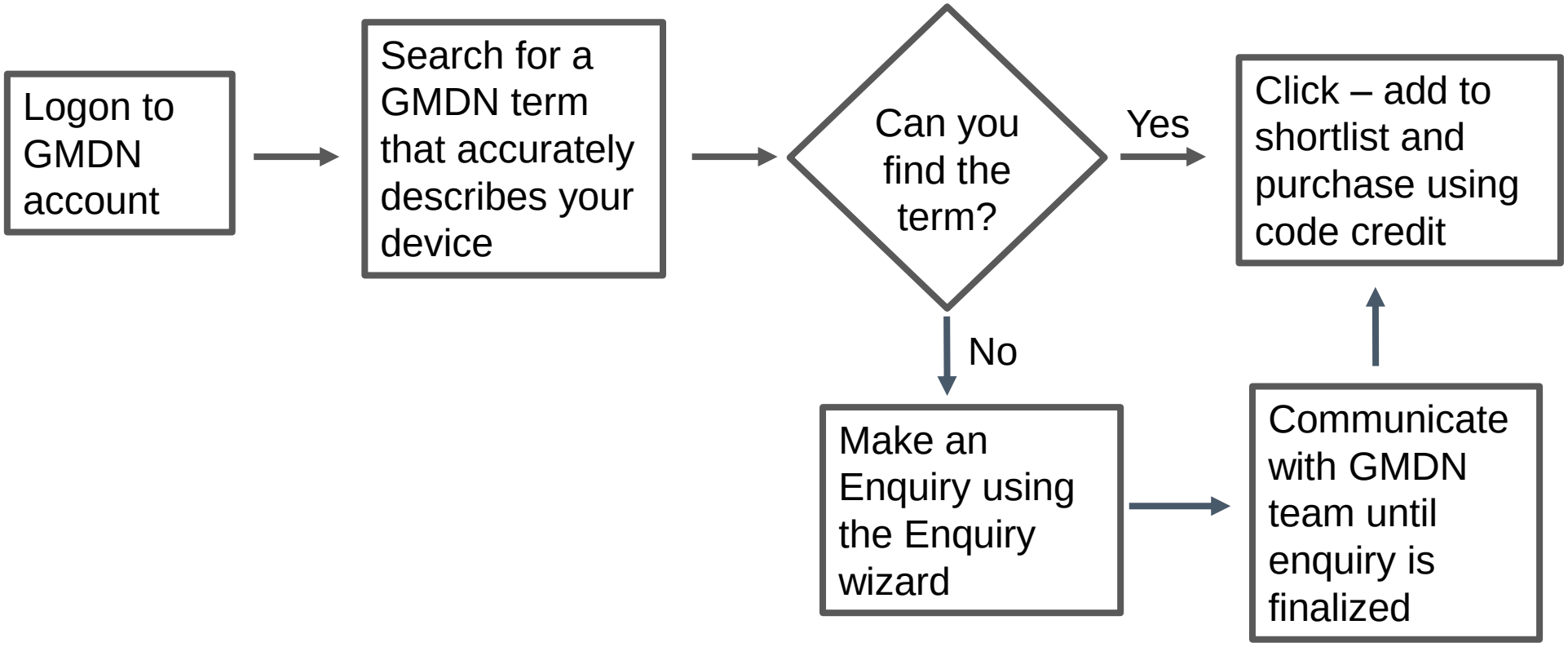
# GMDN website



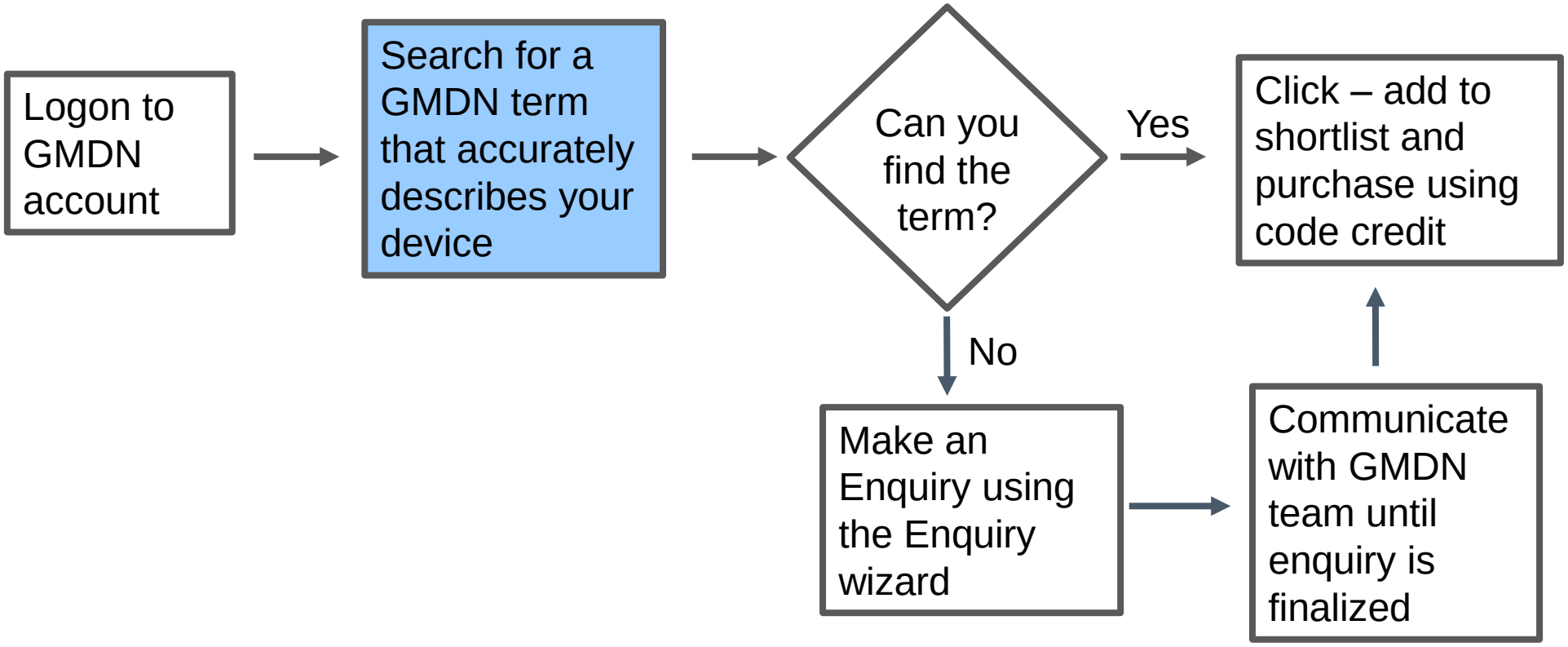
# Membership for Manufacturers

- Use the website www.gmdnagency.org
- Password protected
- Multi-user accounts (users can be setup with different permissions)
- Multi-language
- Advanced search tools
- We monitor and inform on relevant GMDN changes
- Free enquiry service – if we don't have it we will make it
- Annual fee – proportional to organisation size

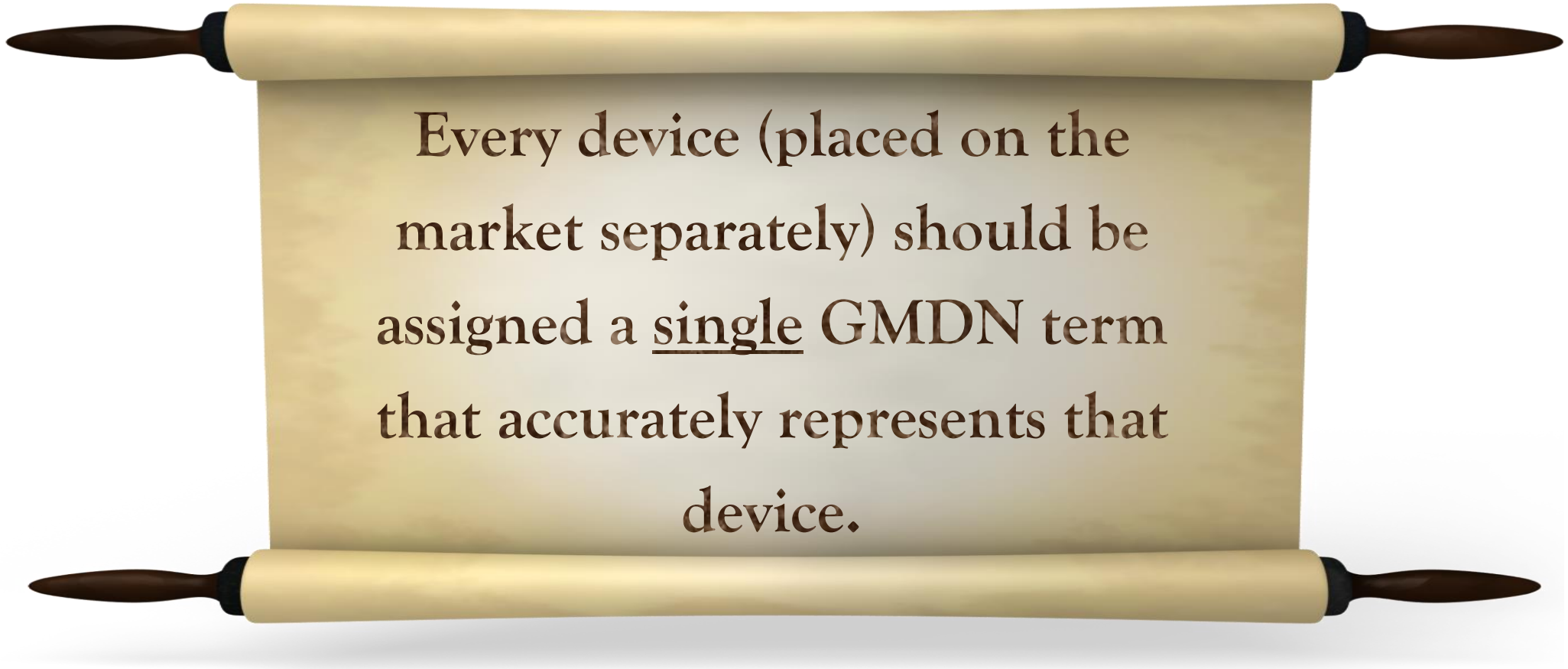
# The Process for Manufacturer members



# GMDN Term Searching and Enquiry Procedure



# GMDN Term assignment – The Golden Rule



# GMDN Term Search – keyword search

Search

- You can do a simple word or part-word search
- The results appear in order of relevance


GMDN

# GMDN Term Search

Search

## Term Details

| | |
|---|---|
| **Name** | Electrocardiographic monitor |
| **Definition** | A mains electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits. |
| **Code** | |
| **Status** | **Active** |
| **Created Date** | 26 Jan 2007 |
| **Modified Date** | 13 Mar 2010 |

Add To Enquiry | Add to My Shortlist | Move to My Archive | Return to My Terms

Note: Terms in "My Archive" do not generate Alerts.

GMDN

# GMDN Term Search

Search

## Term Details

### Translations

| | |
|---|---|
| **Language** | Russian ▼ View |
| **Name** | Монитор электрокардиограммы |
| **Definition** | Устройство, которое обрабатывает и отображает электрокардиограмму (ЭКГ) пациента. Отдельные ЭКГ мониторы также отображают частоту сердца. Оно может продуцировать визуальные и/или звуковых сигналы/тревожные, когда регистрируются неблагоприятные условия. |
| **Translated Date** | 01 Mar 2016 |

### Explorer Groups

By Name / Electrodes/Leads and associated devices

By Name / Patient monitors/monitoring systems and associated devices / Patient monitors/monitoring systems / Cardiovascular monitors/monitoring systems

By Use / Cardiovascular devices / Cardiac physiology/mapping devices / Cardiographs and associated devices

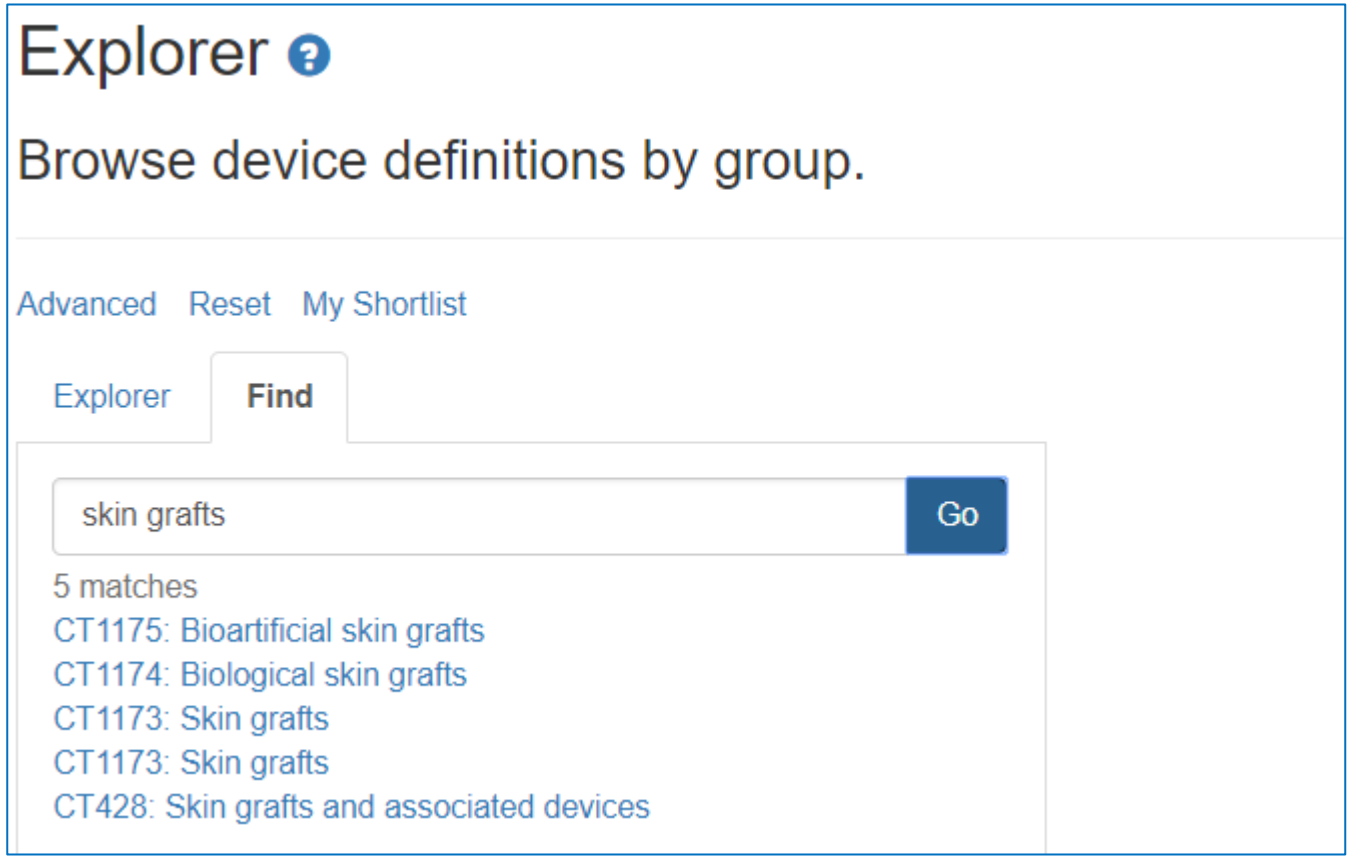
By Use / Cardiovascular devices / Cardiovascular monitors/monitoring systems and associated devices / Cardiovascular monitors/monitoring systems

GMDN

# GMDN Term Search – using the CT Explorer

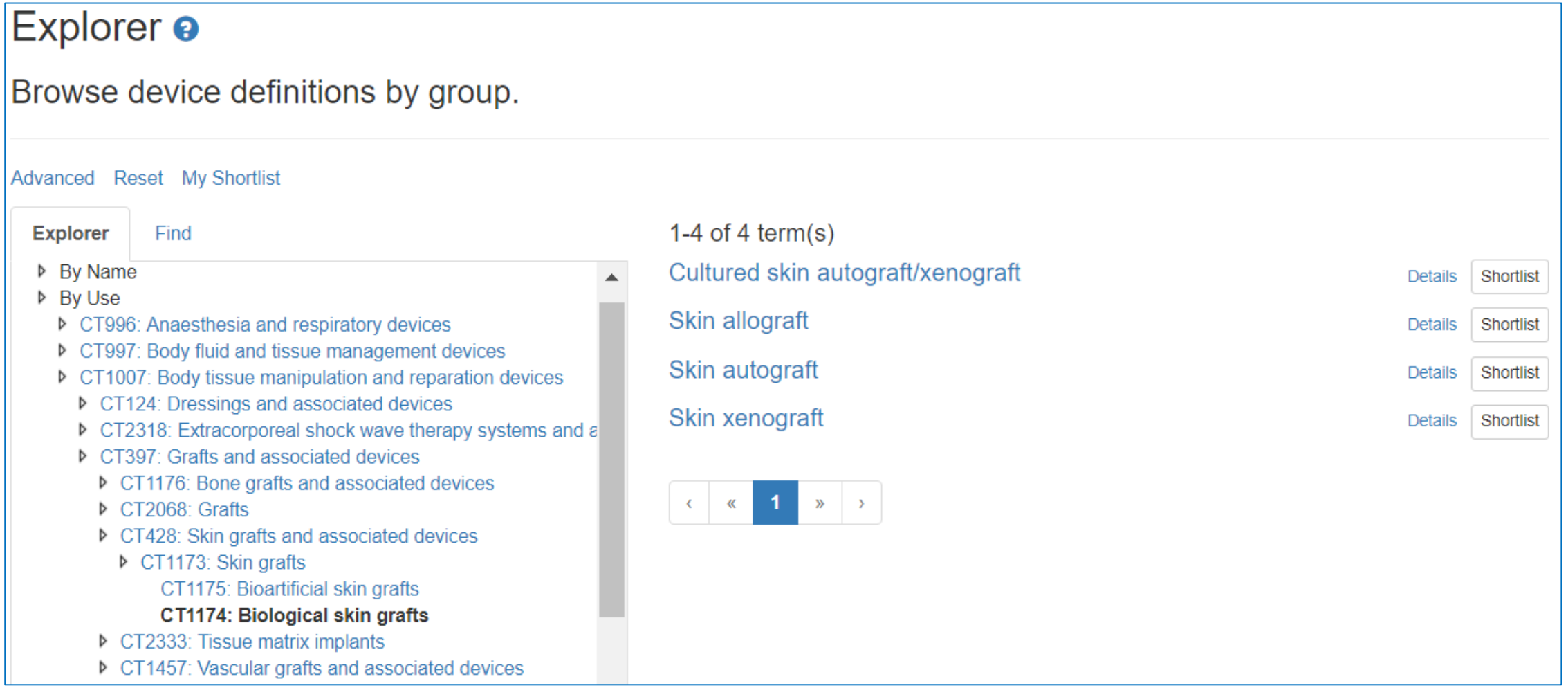
Search

- Use the CT hierarchical tree to find related GMDN terms



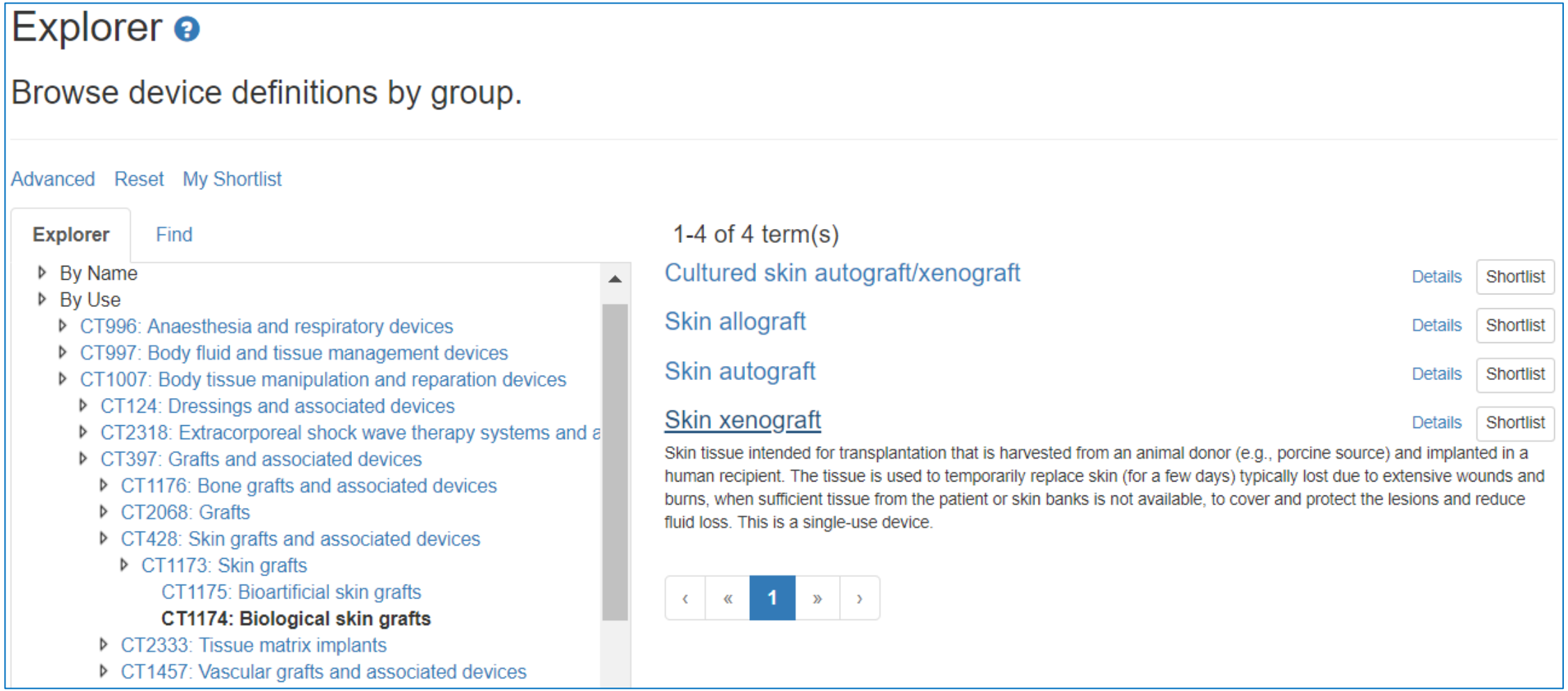
# GMDN Term Search – using the CT Explorer

Search

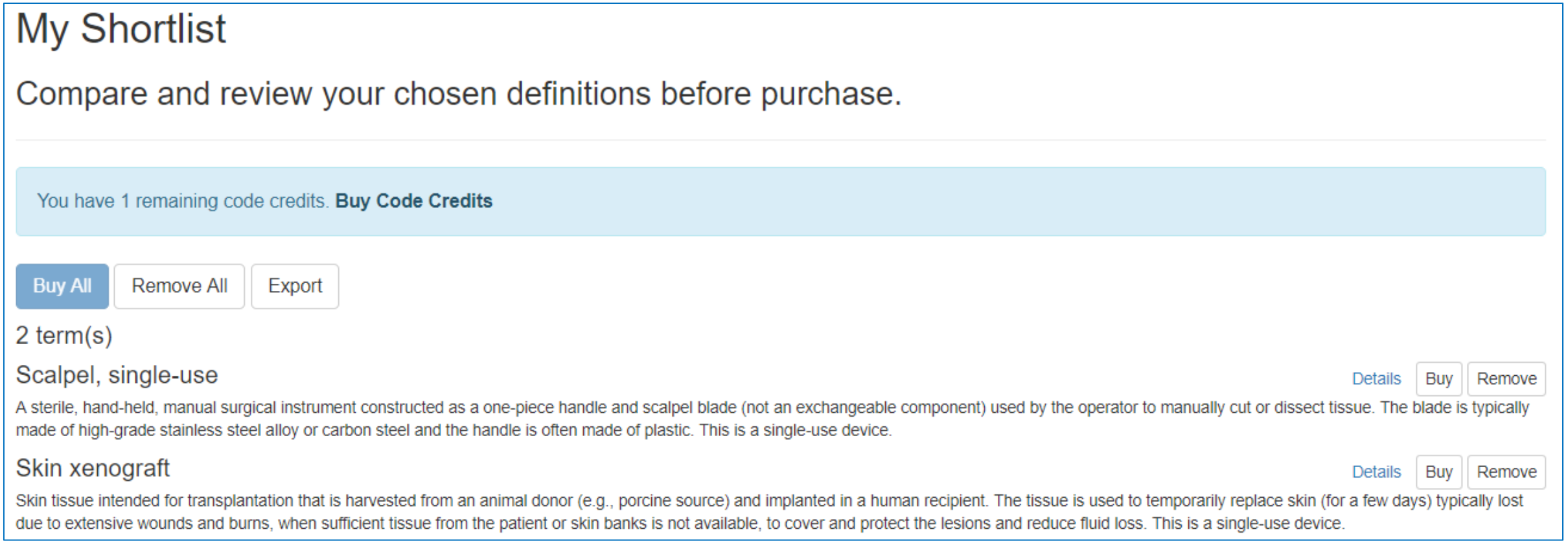


# GMDN Term Search – using the CT Explorer

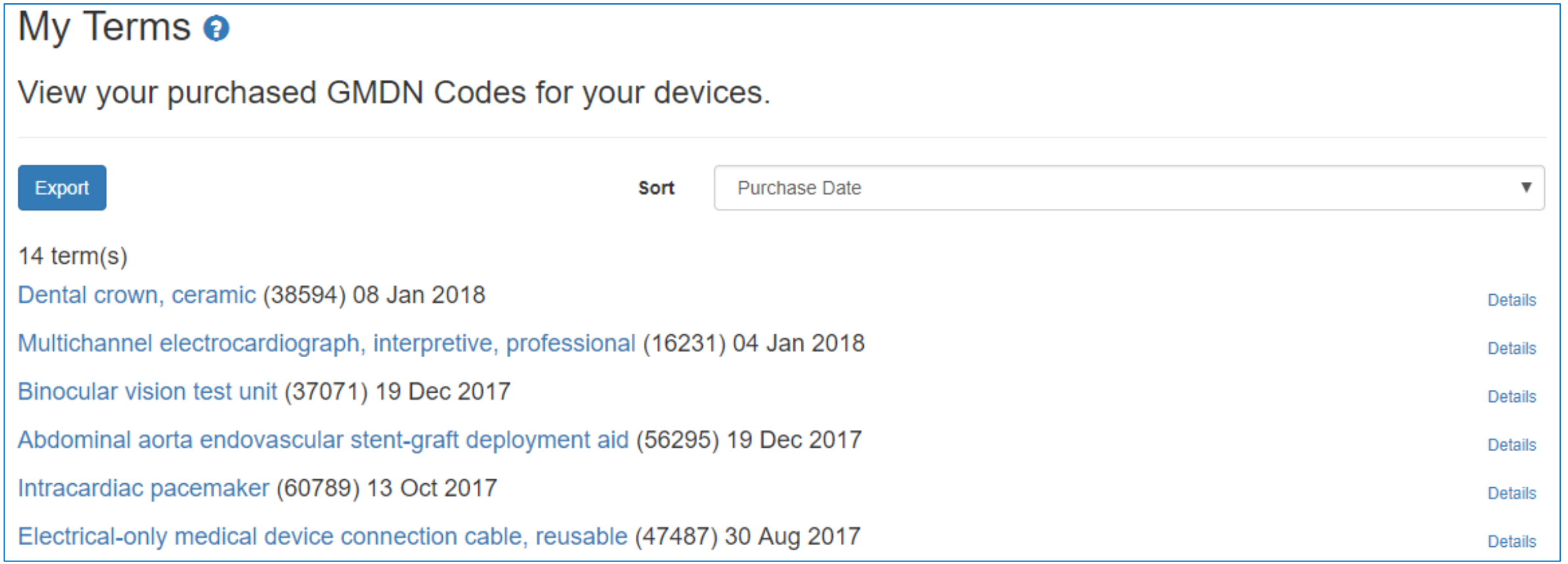
Search



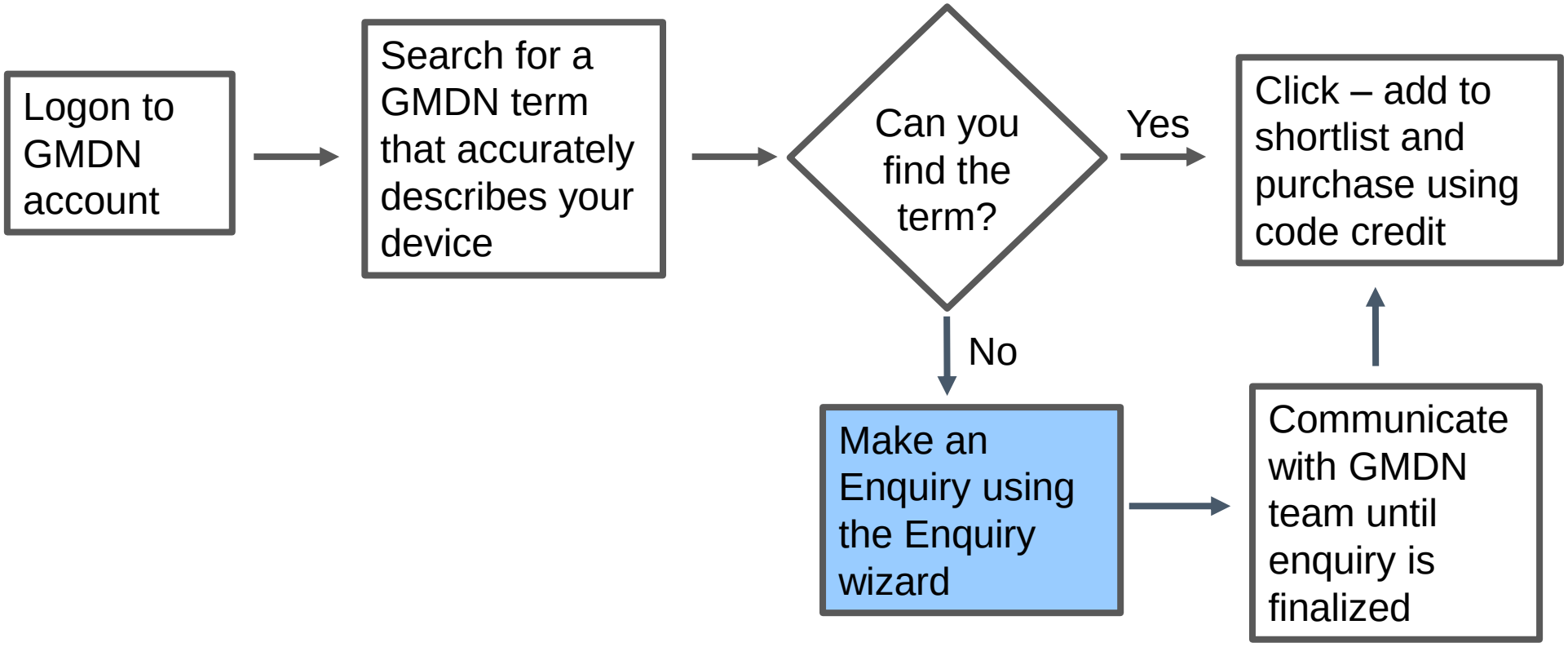
# Summary of terms in Shortlist



# My Terms


My Terms
View your purchased GMDN Codes for your devices.
Export
Sort
Purchase Date
14 term(s)
Dental crown, ceramic (38594) 08 Jan 2018
Details
Multichannel electrocardiograph, interpretive, professional (16231) 04 Jan 2018
Details
Binocular vision test unit (37071) 19 Dec 2017
Details
Abdominal aorta endovascular stent-graft deployment aid (56295) 19 Dec 2017
Details
Intracardiac pacemaker (60789) 13 Oct 2017
Details
Electrical-only medical device connection cable, reusable (47487) 30 Aug 2017
Details

# GMDN Term Searching and Enquiry Procedure



# Making an Enquiry

- Making an Enquiry is the only way to get help from the GMDN Agency Experts for assigning GMDN terms to products
- Free online application form
  - Select type of product: device, software or IVD
  - Fill in form to describe your device(s)
  - Attach product documentation (will be kept confidential)
- We communicate with you during the process to provide:
  - An appropriate existing GMDN term
  - Modification of an existing GMDN term to include the device characteristics
  - A new GMDN term

# Modifications to GMDN terms

- We only modify existing GMDN terms (approx. 2-3 per day) to increase the scope and improve the definitions
- We sometimes obsolete Terms to remove ambiguity / Term overlap
- GMDN is dynamic and current to keep up with device innovation
- Members are notified about changes in real time
  - Email notification
  - Alert on your account

# Database updates

- Dataset for regulators:
  - Monthly updates:
    - Full dataset
    - Delta
- FTP
- API in development

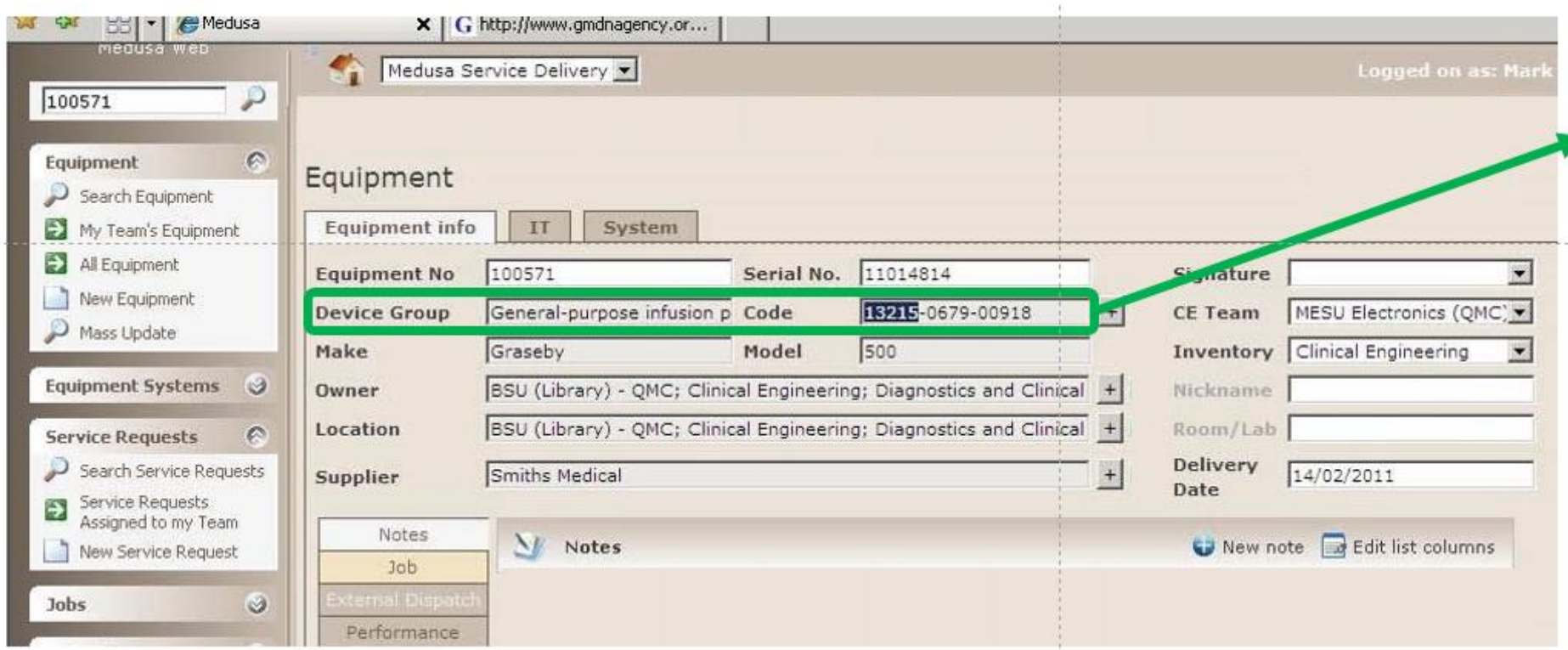
# GMDN in Hospitals

- **Asset Management**
  - Support equipment commissioning
  - Help identify equipment location
  - Support maintenance programmes
- **Inventory Control**
  - Reduce wastage
  - Translate product labels with poor descriptions
  - Improve stock control
- Replaces existing inventory classification with an externally managed globally recognized nomenclature

GMDN

# GMDN in Hospitals: UK

- UK: Nottingham NUH Trust




## 13215 General-purpose infusion pump, line-powered

A mains electricity (AC-powered) device designed to facilitate the accurate and consistent administration of drugs and solutions which can be delivered via intravenous, subcutaneous, arterial, epidural, and intracavital routes using a dedicated infusion set. It is used to supply higher pressures than those provided by manually clamped gravity infusion sets or infusion controllers. The device has a typical flow range of 1 to 999 ml/hour and delivers solutions from a standard infusion bag or bottle of fluid. It typically has internal batteries that enable operation for a short period when no mains electricity is available (e.g., during transportation or a power outage).

# GMDN in Hospitals: Sweden

- Central database of medical devices linked to GMDN Terms
- Updated and fed into local Hospital databases across Sweden

## MTPReg

### Background

At LfMT Annual Meeting 2007 decided to draw up a national register for MTP are in use at Swedish hospitals. Register shall replace SPRI registry, which once managed by SPRI - Healthcare Planning and rationalization Institute. Since spring 2008, a working group under the leadership LfMTs worked to bring the hospitals' databases to create a unified term structure. Since GMDN-Names (Global Device Nomenclature) is being translated into all EU countries, we expect that these will soon be made available. MTPReg is prepared to be synchronized with the GMDN and its future updates.

### Purpose and Mission

The purpose of a common code registry is to obtain a unified code system of medical equipment to facilitate communication between users, suppliers and authorities when exchanging information regarding medical devices.

The mission of the Management Group is to manage, develop and operate a national registry of medical devices (MTPReg) and also provide MTPReg to stakeholders outside Sweden. The registry based on the name of the Global Medical Device Nomenclature (GMDN) in combination with the make and model.

# GMDN is improving communication: a global language

GMDN

# Thank you for listening

Any questions now?

or *contact us* at
www.gmdnagency.org