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# Global Medical Device Nomenclature (GMDN)

## Update for UkrMedCert

Edward Glenn  
GMDN Agency  
Feb 2019



- 
- GMDN introduction
  - Using the data
  - Implementation and UDI
  - Data quality

# What does the GMDN do?

|A DEVICE|

is assigned to

|A GMDN Term|

which creates

|A GENERIC DEVICE GROUP|



**GMDN Code:** 35195

**GMDN Term Name:** Electrocardiographic monitor

**GMDN 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

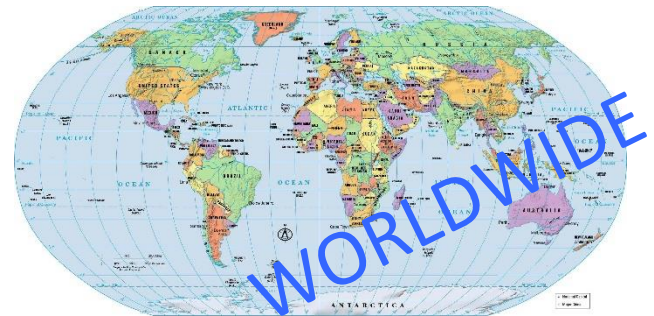
|A DATABASE|

and allows for

|HARMONIZED NAMING|



WHAT IS IT?



# What's the GMDN Process?

|THE GMDN Term|

**GMDN Code:** 35195

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is assigned to

|THE DEVICE|



by

|THE MANUFACTURER|



for

|REGULATORS|

and

|HOSPITALS|



# What's UDI?

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



0) 1 0614141 012345678



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



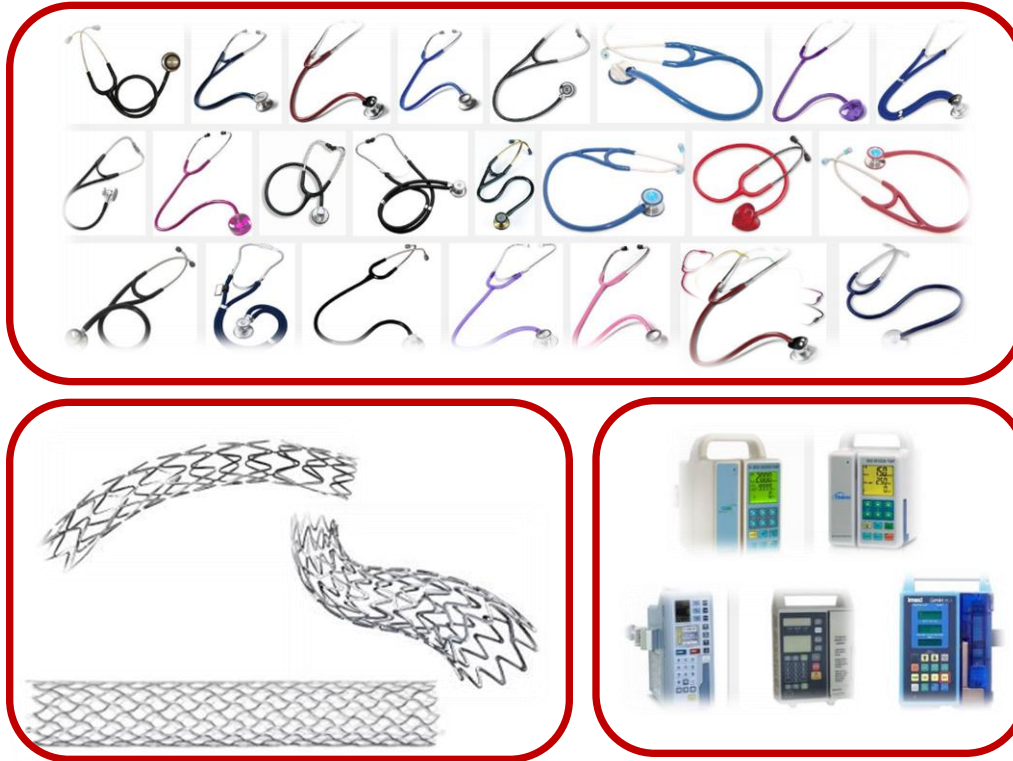
DI number  
SIZE GMDN code  
Brand name Company info



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# To this ?

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# Naming and grouping – The role of GMDN

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## Device Group





# The GMDN term

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# The GMDN term

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- Names the group
- Defines scope of the generic device group
- Many Products assigned to 1 GMDN term

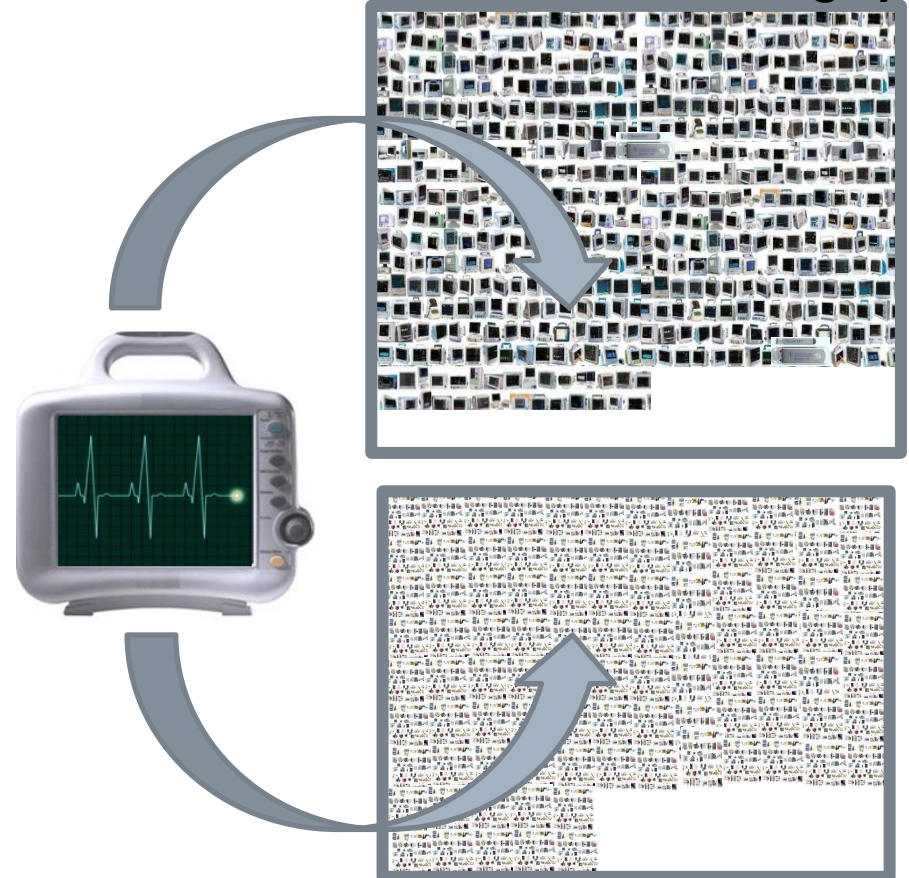


Products assigned to  
**35195**  
**Electrocardiographic**  
**monitor**

# GMDN higher level grouping (CT's)

- Each GMDN term is linked to many higher level (broader) Collective terms (CT's)
- CT's arranged in a (multi-) hierarchy
- Therefore each Collective term creates a broader group of devices

## CT1444 Patient monitors/monitoring systems



## CT314 Electrically powered/operated

# GMDN higher level grouping (CT's)

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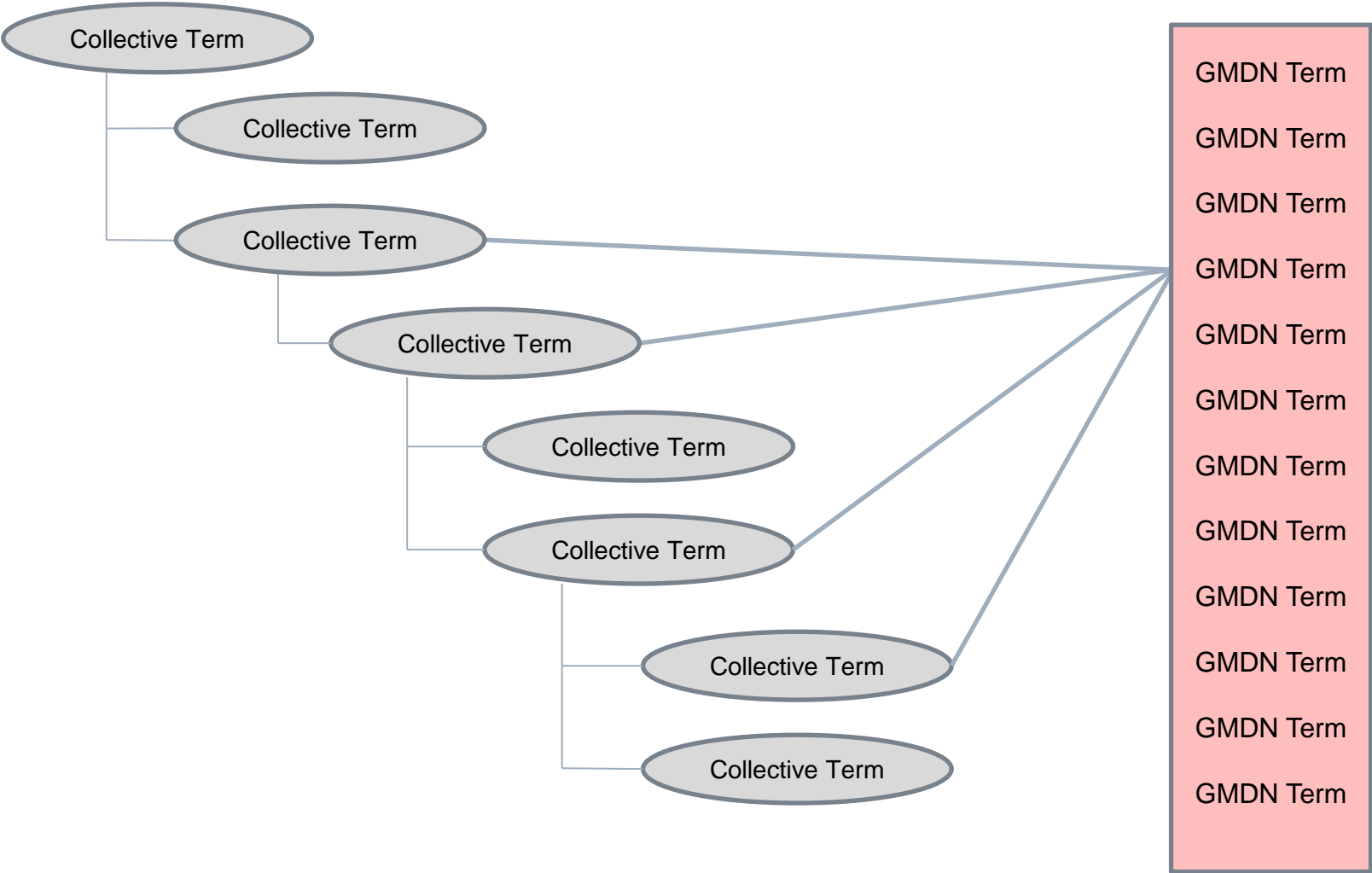
- **CT's** group/organize:
  - By clinical application (e.g., cardiovascular devices)
  - By name (e.g., prosthesis, scissors, catheter)
  - By attribute (e.g., Material, Invasiveness, sterility, Use frequency)
  
- A hierarchical categorisation ...

# Hierarchical classification

## Collective Terms

# Nomenclature

## GMDN terms

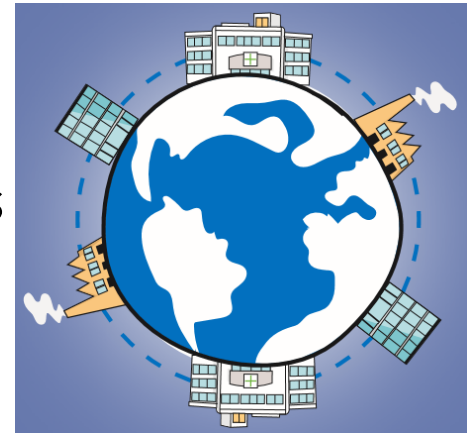


# What does GMDN give the user

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The GMDN data gives the user (Regulator, Registry, Hospital, Manufacturer):

- A name and definition that describes the device clearly and succinctly without proprietary jargon (in up to 20 languages)
- A way to group the device at many levels (e.g., for inventory management, regulatory risk trending, recall analysis)
- A global solution:
  - Only one code needed worldwide
  - Allows for global analysis of data
  - Consistent communication of data across borders



# GMDN Uses

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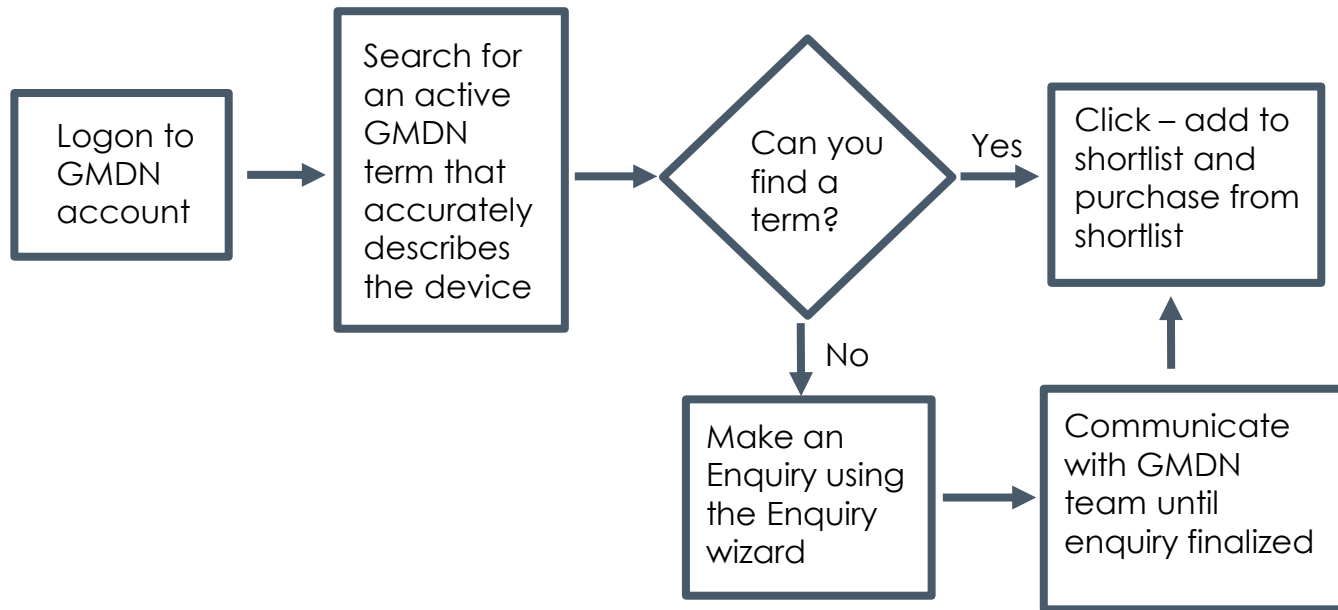
- Used by:
  - 118 national medical device Regulators members
  - 50+ using regular download options
  - 4500+ manufacturers worldwide
  - Medical engineering e.g Scandinavia (MTPReg), UK hospitals
  
- US FDA implementation of UDI Rule
  - All medical devices sold in the US will need a GMDN code





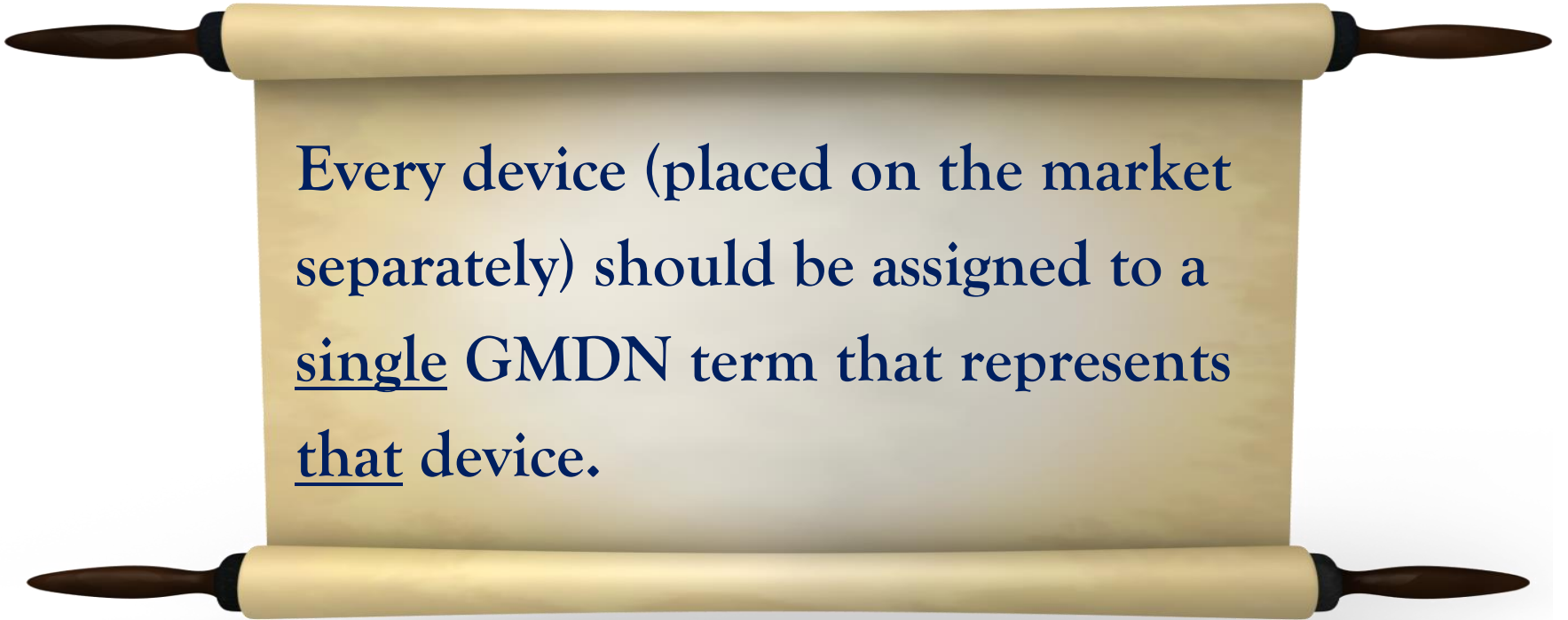
# The Process for Manufacturer members

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# Golden rule

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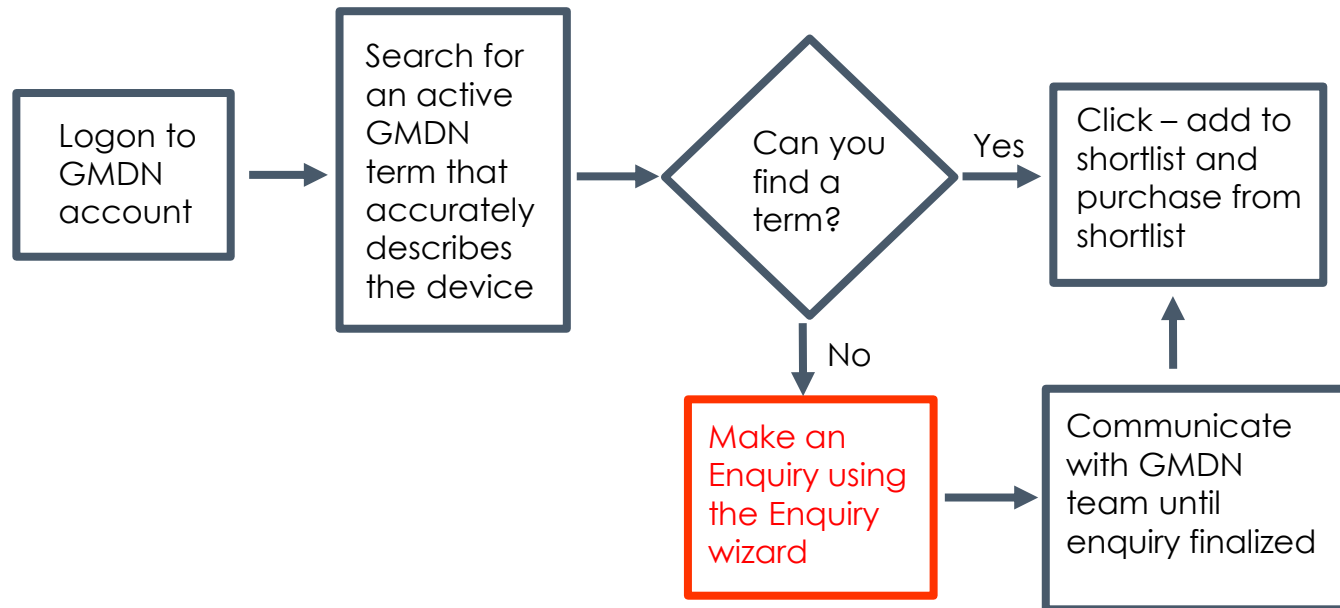
A 3D-rendered scroll with a light beige, textured surface, unrolled to reveal text. It has dark brown, tapered handles at both ends. The text is written in a dark blue, serif font.

Every device (placed on the market separately) should be assigned to a single GMDN term that represents that device.

- **A thought:** If you have the device in front of you and someone asked “What is that?” – would the GMDN term be a reasonable answer? Hopefully yes.

# The Process for Manufacturer members

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# GMDN Website - Enquiry

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- Search first – if cant find suitable term use Enquiry.
- Enquiry is the only way to get help from the GMDN Agency for assigning Terms to products. The outcome will be:
  - An appropriate existing Term.
  - Modification of an existing Term to include the new product's characteristics.
  - A new GMDN Term is created.

# Changes to GMDN data

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- Develop new terms (average 2-3 day)
- We only modify existing Terms (average 3-4 day)
  - To increase the scope / improve the definitions
- We obsolete Terms (average 10/m or 0.5% per year)
  - To remove ambiguity / term overlap
- GMDN is dynamic and current to keep up with innovation
- Members are notified about changes...

# Notifications to manufacturers

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- Manufacturers will receive alerts relating to any changes
  - All changes will be seen at the alerts page on their account
  - Notification e-mails will be sent out
  - Manufacturers will receive a monthly newsletter by e-mail detailing these changes

# GMDN dataset availability:

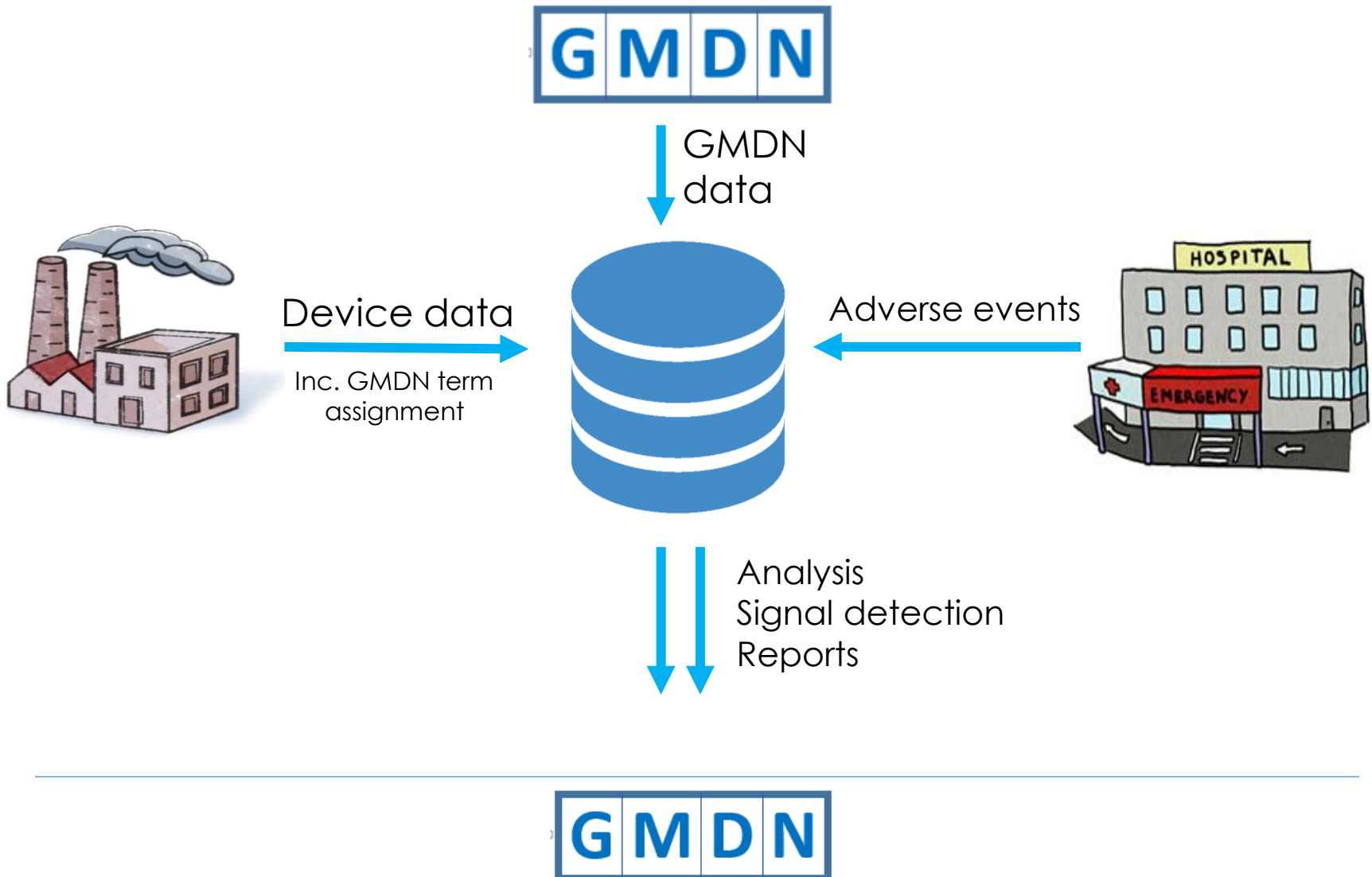
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- Website download
  - Monthly full and delta
- FTP
  - Daily full and delta
  - Monthly full and delta
  - Monthly CTs
- All in English, French and Spanish
- API in development



# Integrating GMDN

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# GUDID

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- US FDA UDI
- Database = GUDID
  - GMDN code is mandatory field on record submission

# FDA GUDID April 2018

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- DI records: 1,623,452
- Unique GMDN codes: 8,450  
(Active GMDN = 8,239)
- Therefore ratio = 1:192
- Unique companies: 4705
- DIs using GMDN (rather than FDA PT) = 83 %
- Active implantable device records: 3,515
- Non-active implantable device records: 638,623
- IVD device records: 32,218  
(2864 GMDN IVD terms used, therefore ratio = 1:11)



# GMDN Agency working with the FDA

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- 'Learning UDI Community (LUC)'
  - FDA initiated and participant
  - Managed by AHRMM – trade association for supply chain
  - Objectives
    - Help stakeholders understand UDI
    - Identify and explore non-regulatory uses for UDI
- GMDN involved in:
  - Device Categorisation
  - High Risk Implants
- Helping to improve GMDN definitions and user assignment of terms.

# Learning UDI Community – Use cases/projects

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- ❑ RAPID (vascular implant clinical evaluation project)/VQI (vascular implant registry)
- ❑ Augmented UDI Data (AUDI)
- ❑ Breast Implant registry

# RAPID/VQI use case

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- RAPID project (Pilot study MDEpiNet – academic group)
- Phase 2 completed
- Use GMDN to get data from GUDID for:
  - Peripheral vascular stents
  - Atherectomy/Angioplasty – 15 terms
  - Vascular grafts
  - Vascular guidewires
- Clinicians analysed results - GMDN grouping achieved and level of granularity required

# Device Identification

**Collective terms:** 13 / 26,351

**GMDN terms:** 13 / 26,351

**Products:** 1150 / 1,463,816

**By Name**

**By Use**

- Anaesthesia and respiratory devices
- Body fluid and tissue management devices
- Body tissue manipulation and reparation devices
  - Dressings and associated devices
  - Extracorporeal shock wave therapy systems and associated devices
  - Grafts and associated devices
  - Skin surface treatment systems and associated devices
  - Skin/Body contouring systems and associated devices
  - Staples and associated devices
  - Stents and associated devices
    - Extraluminal mesh-sleeves
    - Haemodynamic-modulation vessel repair implants
  - Stents
    - Bioabsorbable stents
    - Non-vascular stents
    - Vascular stents
      - Aortic stents
      - Bioabsorbable vascular stents
      - Coronary artery stents
      - Drug-eluting vascular stents
      - Endovascular stent-grafts
      - Intracranial vascular stents
      - Peripheral artery stents**
  - Surgical instruments/systems and associated devices
  - Surgical mesh and associated devices
  - Sutures and associated devices

**GMDN terms:**

- Aortic arch branch vessel endovascular stent-graft
- Bare-metal carotid artery stent
- Bare-metal renal artery stent
- Drug-eluting carotid artery stent
- Drug-eluting femoral artery stent
- Drug-eluting infrapopliteal artery stent, bioabsorbable
- Drug-eluting infrapopliteal artery stent, non-bioabsorbable
- Drug-eluting renal artery stent
- Iliac artery stent, bare-metal
- Iliofemoral artery endovascular stent-graft
- Mesh-sleeve carotid artery stent
- Multiple peripheral artery stent, bare-metal**
- Multiple peripheral artery stent, bioabsorbable

A sterile non-bioabsorbable tubular device intended to be alternatively implanted in more than one peripheral artery (e.g., iliac, carotid, renal) to indefinitely maintain patency and improve luminal diameter in patients with atherosclerotic disease or following the recanalization of a total occlusion. It is typically implanted by a dedicated instrument where it self-expands upon release or is balloon expanded. It is made of metal [e.g., nickel-titanium alloy (Nitinol)] and may be a continuous tube of a certain length, a mesh structure, or other design for supporting constant

**Products:**

00613994726513	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726476	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726445	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726438	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726353	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726773	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726643	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726629	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726575	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726568	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726544	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726384	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726377	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726360	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726346	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00643169150829	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00643169150799	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00643169150775	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994729699	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726803	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726780	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726742	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726735	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726728	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726667	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726650	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726551	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726520	COMPLETE® SE VASCULAR	MEDTRONIC, INC.
00613994726506	COMPLETE® SE VASCULAR	MEDTRONIC, INC.

Company: MEDTRONIC, INC.

Brand name: COMPLETE® SE VASCULAR

Version/Model: SC820LV

Device description: STENT SC820LV COMPLETE SE LONG US V G

GMDN CTs → GMDN Terms → Devices





# Issues

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- Poor assignment
  - Multiple GMDN
  - Systems/components
  - Not using definition
  - PT code finder
  - Lazy?
- Initial assessment (cardiovascular implants) ~ 20% assigned poorly

# Common mistakes



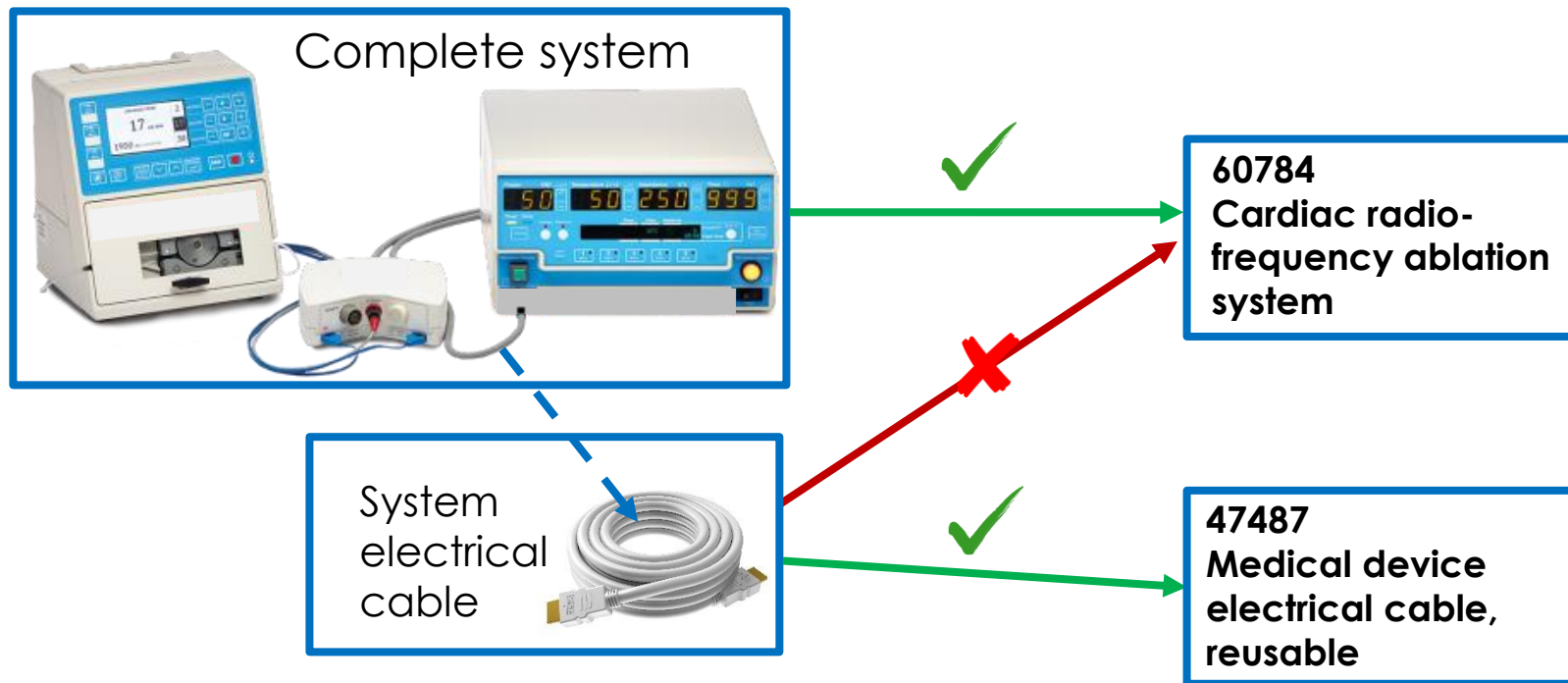
- ❑ Poorly assigned GMDN terms leads to poor data
- ❑ Data quality is key



# Systems/components

A GMDN term for a system term applied to a component of the system

Example:





# Not using definition

Judging the term by the name without review of the definition

*Ophthalmic use*

752SS11170071

CUSTOM SURGICAL KIT EYE PACK

Company Name: [REDACTED]

Version or Model: 001-117-007

Device IDs:

- [REDACTED] (Primary)

**GMDN Terms:**

- General surgical procedure kit, non-medicated, single-use

33961

**General surgical procedure kit, non-medicated, single-use**

A general-purpose collection of various sterile surgical instruments, dressings, and materials **intended to be used to assist a range of surgical procedures across multiple clinical specialities**. It does not contain pharmaceuticals. This is a single-use device.

Is this term more appropriate?

**Ophthalmic surgical procedure kit, non-medicated, single-use**

Size 22mm x 12.5mm

17 144 182 11 100 102 10 A1234 21 123

AG234 BN 17M 2016.04.02

## IDENTIFY YOUR MEDICAL DEVICE

basic **coronary angioplasty** balloon catheter  
catheter, percutaneous transluminal **coronary angioplasty** (ptca), cutting/scoring  
cutting/scoring **coronary angioplasty** balloon catheter  
atherectomy **coronary angioplasty** system  
device, angioplasty, laser, coronary  
atherectomy laser system beam guide-catheter, **coronary angioplasty**  
imaging **coronary angioplasty** balloon catheter  
atherectomy **coronary angioplasty** system, line-powered

[ABOUT GUIDD](#)

## AccessGUID Release Files Notification

Resources for application developers to get the most out of AccessGUDID.

[Help using AccessGUIDID](#)

### Downloading Release Files

[NLM Web Guidelines](#)

[Still Need Help?](#)

[FDA UDI Home](#)[FDA Medical Devices Home](#)

Report a Design Problem (Feedback)

drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated



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SEARCH RESULTS FOR: **drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated** (722 results)

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10 RESULTS PER PAGE



PAGE

1



Company Name



[XIENCE ALPINE - 08717648200380](#)



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 38 mm / Over-The-Wire

Brand Name



**Company Name:** ABBOTT VASCULAR INC.

**Version or Model:** 1145400-38

GMDN Term



[XIENCE ALPINE - 08717648200373](#)



FDA Product Code Name



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 33 mm / Over-The-Wire

FDA Product Code



**Company Name:** ABBOTT VASCULAR INC.

**Version or Model:** 1145400-33

Device Packaged as Sterile



[XIENCE ALPINE - 08717648200366](#)



Sterilization Prior To Use



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 28 mm / Over-The-Wire

Issuing Agency



**Company Name:** ABBOTT VASCULAR INC.

**Version or Model:** 1145400-28

[XIENCE ALPINE - 08717648200359](#)



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 23 mm / Over-The-Wire

**Company Name:** ABBOTT VASCULAR INC.

**Version or Model:** 1145400-23

[XIENCE ALPINE - 08717648200342](#)



XIENCE Alpine Everolimus Eluting **Coronary Stent** System 4.00 mm x 18 mm / Over-The-Wire

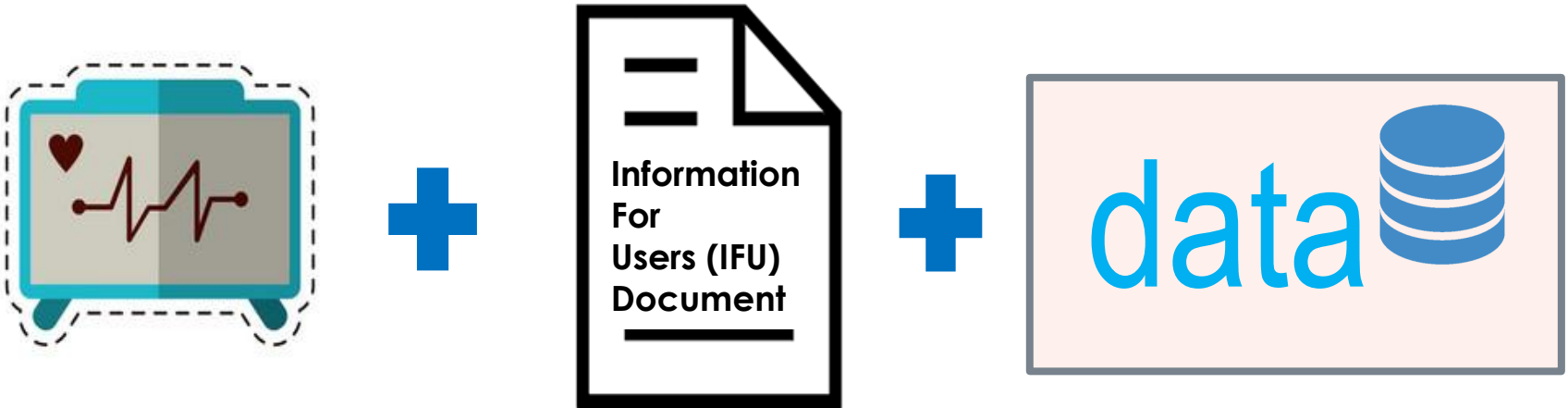
**Company Name:** ABBOTT VASCULAR INC.

**Version or Model:** 1145400-18



# A device has a new component – Shared Data

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Publically shared data  
(inc. GMDN term  
assignment) sent to  
Regulators and Customers  
(e.g., via GDSN)



# GMDN in Hospitals

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## ☐ **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

- ☐ Replace existing inventory classification with an externally managed globally recognized nomenclature

# GMDN is improving communication

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- GMDN is now the global language



# Thank you for listening

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Questions?

