

Global Medical Device Nomenclature (GMDN)

GMDN – A Requirement for UDI

Mark Wasmuth – CEO, GMDN Agency

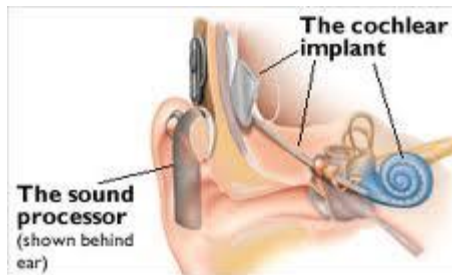
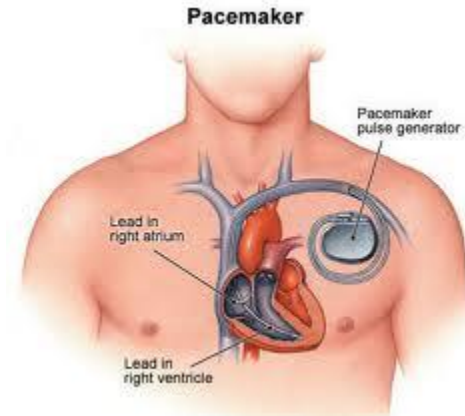
G•M•D•N

What we will be discussing

- Why is the GMDN needed
- GMDN data structure
- How to find GMDN terms
- Unique Device Identification
- UDI & GMDN Relationship
- Examples of GMDN in use
- Questions?

Why the need for Device names?

Large variety of devices!



Why is consistent naming important?

- ❑ Medical Devices are traded internationally
- ❑ **Regulators** need to approve devices efficiently by identifying the product group and the related hazards / risks
- ❑ **Regulators** need to identify 'systematic' failures of medical devices
- ❑ **Hospitals** can identify the products they need and manage their inventory

Why was the GMDN needed?

Existing nomenclatures:

- 'National' systems (not suitable for international harmonisation) & Single language
- Unstructured / un-standardised
- Too vague / poor definitions
- Too rigid – difficult to include new technology
- Can't keep up with volume of innovation
- Too many duplicates / overlaps
- Uncontrolled – no update method for users

Not meeting Regulator needs

What is the GMDN?

Global Medical Device Nomenclature (GMDN)

- The international standard (ISO 15225) for naming Medical Devices
- Used by 65 national Medical Device Regulators - Backed by IMDRF
- Over 4000 Manufacturers worldwide
- Translated into 25 languages
- 22,000 Preferred Terms with Definitions
- Controlled distribution and updating
- International acceptance

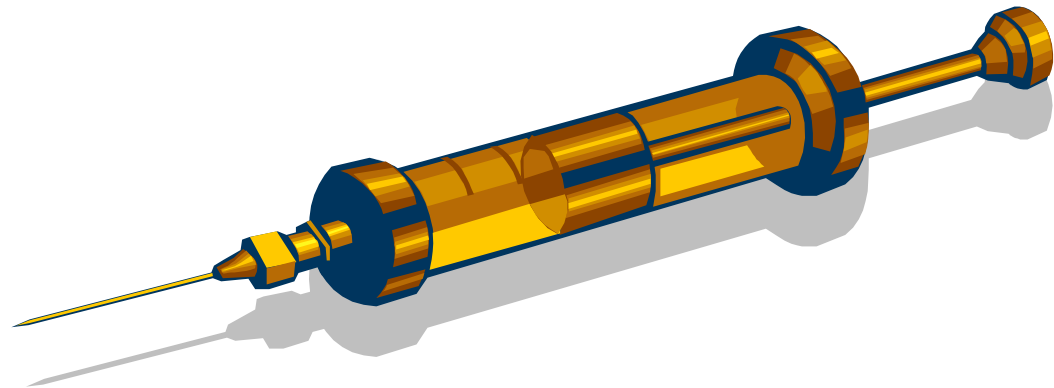
Global acceptance?

- ❑ GHTF (now **IMDRF**) proposes GMDN for UDI
- ❑ EC proposes GMDN for the **EUDAMED** (market surveillance database)
- ❑ **EUCOMED** supports the use of GMDN in meeting the needs of European manufacturers
- ❑ EC has translated the GMDN into **20 languages**
- ❑ **WHO & MSF** use GMDN in guidance for developing countries
- ❑ Collaboration Agreement with IHTSDO (**Snomed CT**)
- ❑ US **FDA** are using GMDN in the first national implementation of UDI

GMDN Term Structure

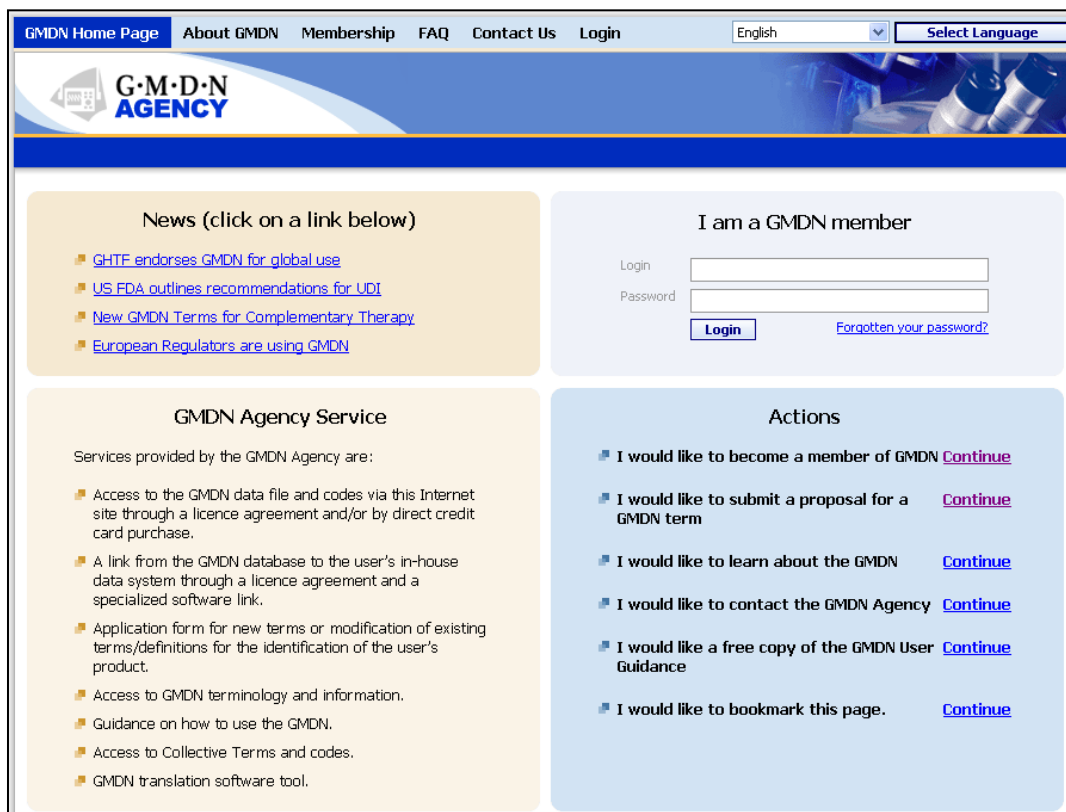
Each GMDN Term consists of 3 parts:

- **Term Name:** General-purpose syringe
- **Definition:** A sterile device that consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical
- **Code:** 47017



How can you find GMDN Codes?

www.gmdnagency.org



The screenshot shows the GMDN Agency website homepage. At the top, there is a navigation bar with links for "GMDN Home Page", "About GMDN", "Membership", "FAQ", "Contact Us", and "Login". A language dropdown menu is set to "English" with a "Select Language" button. The GMDN Agency logo is on the left, and a background image of laboratory equipment is on the right.

News (click on a link below)

- [GHTF endorses GMDN for global use](#)
- [US FDA outlines recommendations for UDI](#)
- [New GMDN Terms for Complementary Therapy](#)
- [European Regulators are using GMDN](#)

I am a GMDN member

Login:
Password:
 [Forgotten your password?](#)

GMDN Agency Service

Services provided by the GMDN Agency are:

- Access to the GMDN data file and codes via this Internet site through a licence agreement and/or by direct credit card purchase.
- A link from the GMDN database to the user's in-house data system through a licence agreement and a specialized software link.
- Application form for new terms or modification of existing terms/definitions for the identification of the user's product.
- Access to GMDN terminology and information.
- Guidance on how to use the GMDN.
- Access to Collective Terms and codes.
- GMDN translation software tool.

Actions

- [I would like to become a member of GMDN Continue](#)
- [I would like to submit a proposal for a GMDN term Continue](#)
- [I would like to learn about the GMDN Continue](#)
- [I would like to contact the GMDN Agency Continue](#)
- [I would like a free copy of the GMDN User Guidance Continue](#)
- [I would like to bookmark this page. Continue](#)

Searching for GMDN Terms



Show results with one or more options

Search text :

For :

All the words GMDN Code(s)

Any of the words Original Source Code(s)

The exact phrase Translation Code(s)

None of these words

In : ▼

Review the Results

Show results with one or more options

Search text :

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Any of the words Original Source Code(s)


The exact phrase Translation Code(s)

None of these words

In :

Search Terms

Records 1-1 from 1

Term	Type	GMDN Code	Definition
1. General-purpose syringe Categories: 10 Single-use devices			
General-purpose syringe	P	 Add To Basket	A sterile device that consists of a calibrated hollow barrel (cylinder) into, and/or withdraw fluids/gas from. At the distal end of the barrel is a male connector (typically a hub) of a hypodermic needle or an administration set. It is typically designed with anti-sticking properties (internally pre-coated with compound) to facilitate manual or by a syringe pump. This is a single-use device.

How can you find GMDN Codes?

Show results with one or more options

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For :

All the words GMDN Code(s)

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The exact phrase Translation Code(s)

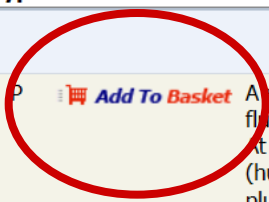
None of these words

In : ▼

Search Terms

Records 1-1 from 1

Term	Type	GMDN Code	Definition
1. General-purpose syringe Categories: 10 Single-use devices			
General-purpose syringe			

 [Add To Basket](#) A sterile device that consists of a calibrated hollow barrel (cylinder) into which fluids (e.g., medication) are introduced and/or withdrawn. At the distal end of the barrel is a male connector (typically a hub) of a hypodermic needle or an administration set. It is typically used to administer fluids (e.g., medication) and has anti-sticking properties (internally pre-coated with corn oil). This is a single-use device.

More detail

Term Details

Product Identifier

Created 21/06/2007 14:08:18

Modified 11/02/2013 22:45:31

Term General-purpose syringe

Definition A sterile device that consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical applications. At the distal end of the barrel is a male connector (typically a Luer-lock type) for the attachment of the female connector (hub) of a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have plunger anti-sticking properties (internally precoated with compatible substances) allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.

Categories

10 Single-use devices

Collective Terms

- └─ CT233 Surgical
- └─ Device Materials
 - └─ CT979 Inorganic materials
 - └─ CT201 Synthetic polymers
 - └─ CT179 Plastics
 - └─ CT212 Silicone
 - └─ CT180 Synthetic rubber
- └─ Device Power/Operation
 - └─ CT326 Manually powered/operated
- └─ Device Sterility
 - └─ CT336 Sterile
- └─ Device Use Frequency
 - └─ CT981 Single use
- └─ High-Level Device Groups
 - └─ CT309 Syringes/Injectors and associated devices
 - └─ CT1943 Syringes

Reveal the GMDN Code

Show results with one or more options

Search text :

For :

- All the words
- Any of the words
- The exact phrase
- None of these words
- GMDN Code(s)
- Original Source Code(s)
- Translation Code(s)

In :



Search Terms

Records 1-1 from 1

Term	Type	GMDN Code	Definition
1. General-purpose syringe Categories: 10 Single-use devices			
General-purpose syringe	P	47017	A sterile device that consists of a calibrated hollow barrel (cylinder) into, and/or withdraw fluids/gas from, the barrel. One end of the barrel is a male connector (typically a Luer-lock type) and the other end is a female connector (typically a needle or an administration set). It is typically made of plastic (internally precoated with compatible substances) allowing syringe to be used as a single-use device.



Collective Terms

GMDN uses **Collective Terms** to provide:

- ❑ Better navigation with variable hierarchies
- ❑ Compare common features:
 - Materials (Inert, Latex, Animal)
 - Invasiveness (Internal / External)
 - Sterility (Supplied Sterile / non-sterile)
 - Use Frequency (Single Use / Reusable)
 - Powered by (mains, battery, air, etc.)
- ❑ Flexible to meet future needs

Collective Terms

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 - └─ CT981 Single use
- └─ High-Level Device Groups
 - └─ CT309 Syringes/Injectors and associated devices
 - └─ CT1943 Syringes

Using Collective Terms to search

My GMDN Terms Search **Navigator** Information Basket Request a Code

You have selected:
[High-Level Device Groups](#) - **CT309** [Syringes/Injectors and associated devices](#) - **CT1943** [Syringes](#)

Apply filter immediately
 Apply Filter Reset

CT Wizard CT Finder

CT Quick Finder Name/Code:

Records 1-6 from 6

Code	Name
1. CT1586	Dental syringes
2. CT1587	Dental syringes and associated devices
3. CT2281	Needleless valve-connectors
4. CT111	Syringe pumps
5. CT1943	Syringes
6. CT309	Syringes/Injectors and associated devices

Records 1-6 from 6

Search Results PT Search

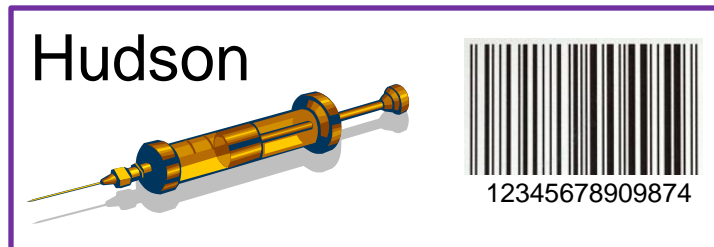
15. Dental irrigation/aspiration syringe	P	<input type="button" value="Add To Basket"/>
16. Ear syringe	P	<input type="button" value="Add To Basket"/>
17. Embolization implant syringe	P	<input type="button" value="Add To Basket"/>
18. Gas/liquid chromatography syringe	P	<input type="button" value="Add To Basket"/>
19. General-purpose syringe	P	47017
20. Hazardous fluid syringe	P	<input type="button" value="Add To Basket"/>
21. Heparin lock flush syringe, reprocessed	P	<input type="button" value="Add To Basket"/>
22. Heparin lock flush syringe, single-use	P	<input type="button" value="Add To Basket"/>
23. High performance liquid	P	<input type="button" value="Add To Basket"/>

What's the process?

- ❑ Identify the GMDN Code for all of your products, from the GMDN database
- ❑ Provide the GMDN Code to your Customers / Distributors / Data Pools
- ❑ Use the GMDN Code to register your products with your MD Regulator
- ❑ Use with **Unique Device Identification (UDI)**

Unique Device Identification

- ❑ Pack / product marking of 'unique' identifier
- ❑ Marking also includes production identifiers (e.g. Batch No., Expiry Date, Serial No...)
- ❑ **Machine** readable (e.g. bar code) and human readable
- ❑ Linked to other product data in a database (e.g. make, model, etc.)



UDI Database

- The GMDN code is one of the 25 mandatory core data elements identified in the **IMDRF ‘UDI System for Medical Devices’** *draft* Guidance Document.
- Data for each device is provided by the manufacturer to the **UDI Database (UDID)**.
- The UDID data could be distributed by:
 - Public access website
 - Bulk data download (e.g. Hospitals)

UDI requires a Carrier & Hardware

□ Product Label (Carrier)

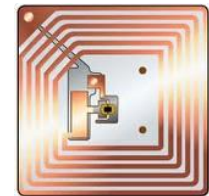
- Linear Bar Code
- 2D Bar Code (more data)
- RFID - Radio Frequency Identification (non-contact)



12345678909874



12345678909874



12345678909874

□ Hardware to read labels

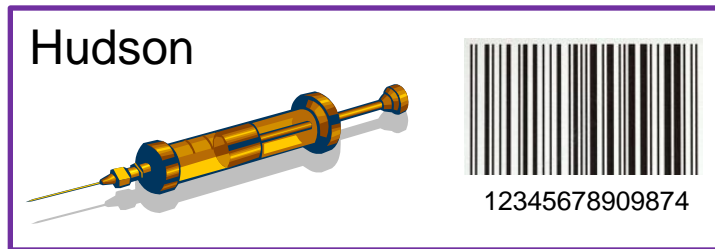
- Bar code Reader
- Image Scanner
- RFID Scanner



GMDN and UDI Relationship

Pack / Device – Unique Device Identifier

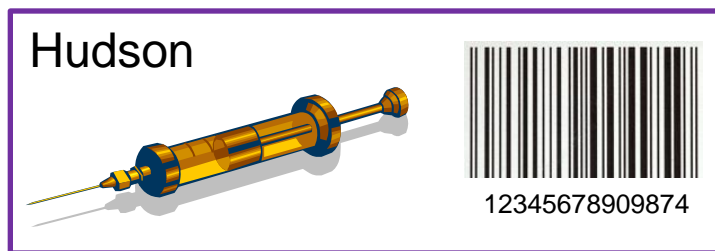
(e.g. 12345678909874)



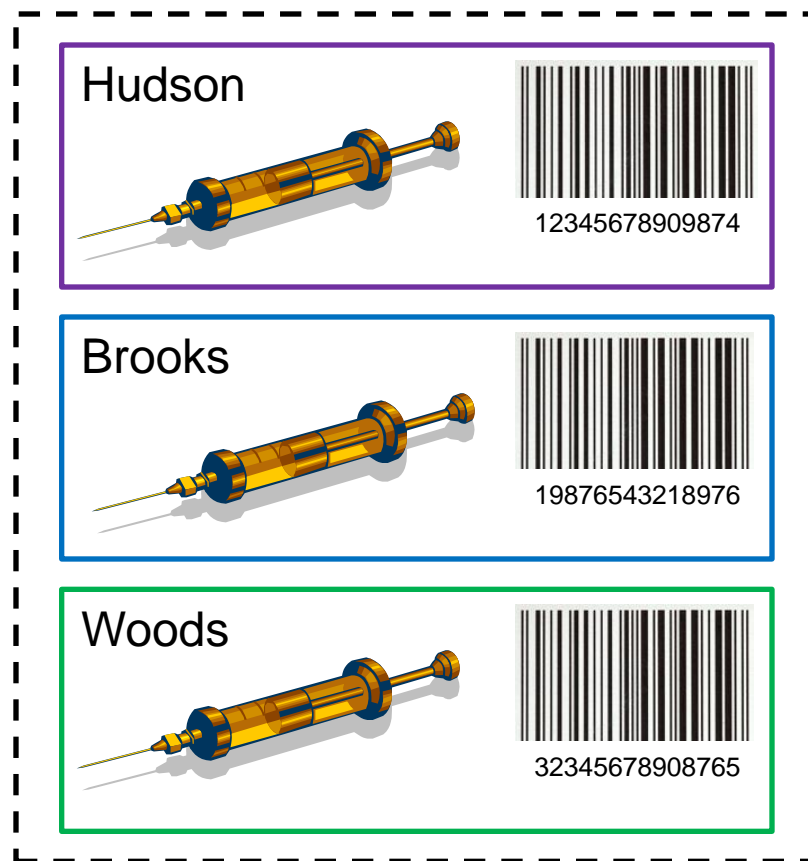
GMDN and UDI Relationship

Pack / Device – Unique Device Identifier

(e.g. 12345678909874)



Generic Device Group - GMDN Term
(e.g. GMDN Code **47071**)



When you can't find a Term?

If you can't find a GMDN Term for your product:

1. Ask us for assistance
2. Apply for a new Term:
 - On-line Request Application
 - Attach your product datasheet / pictures
 - We discuss the draft Term with you
 - Two week public comment period
 - Database updated daily

Modifying or Obsoleting Terms?

- We modify existing Terms
 - To increase the scope
 - Improve the definitions
- Make Terms Obsolete
 - To remove inadequate Terms
 - Reducing over time
- Notifications by email to Members

Example of GMDN & UDI for Regulation

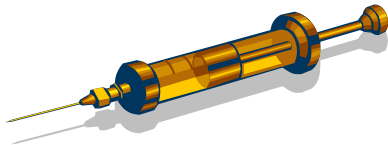
- Post Market surveillance
 - Identify systematic (generic) product failure
 - Support rapid product recall
- Better Regulation
 - Speed up Pre-market approval
 - Identify products quickly
 - Detailed information on imports and exports
 - Quickly identify trends about new equipment use and problems

GMDN speeding up pre-market approval

New Applicant

Regulator Device Register

Hudson



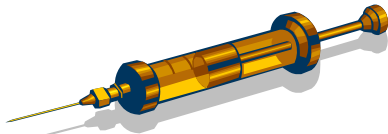
GMDN	Make	Test Method	Date	Approval
38501	Hudson			

GMDN speeding up pre-market approval

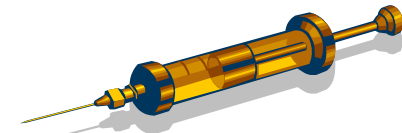
New Applicant

Regulator Device Register

Hudson



Jones



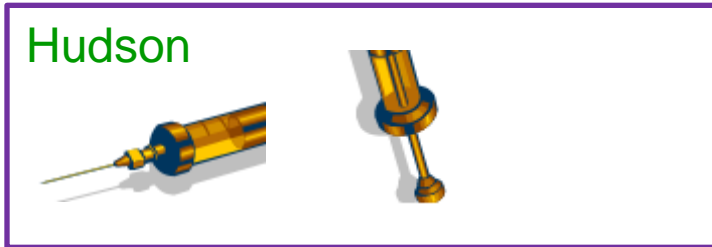
GMDN	Make	Test Method	Date	Approval
38501	Hudson			
38501	Woods	ISO 7886	2009	✓
38501	Brooks	ISO 7886	2008	✓
38501	Jones	ISO 7886	2010	✓

Previously Approved Device

GMDN speeding up product recall

Product Failure

Regulator Device Register

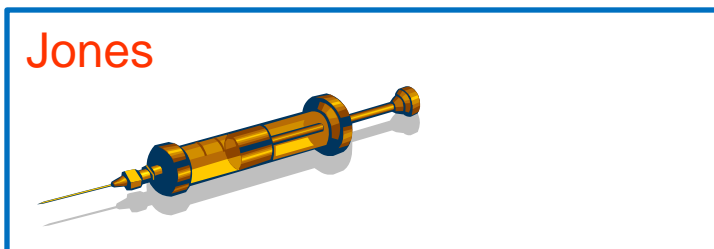
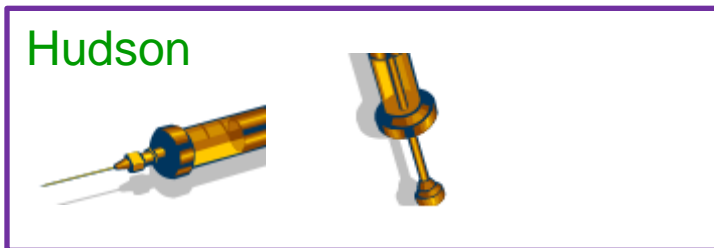


GMDN	Make	UDI [GTIN]	Date	Recall
38501	Hudson	12345678909874	2011	✓

GMDN speeding up product recall

Product Failure

Regulator Device Register



GMDN	Make	UDI [GTIN]	Date	Recall
38501	Hudson	12345678909874	2011	✓
38501	Woods	32345678908765		✗
38501	Brooks	19876543218976		✗
38501	Jones	58746528415424		?

Investigate this product too?

Example of GMDN & UDI in Hospitals

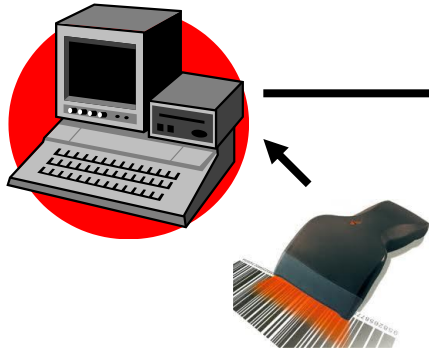
□ Asset Management

- Support equipment commissioning
- Help identify equipment location
- Support maintenance programmes

□ Inventory Control

- Reduce wastage
- Translate product labels with poor descriptions
- Improve stock control


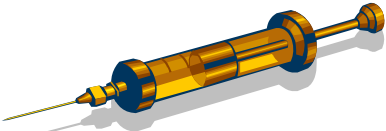
Use the GMDN to find missing stock



GMDN	Make	UDI [GTIN]	Stock	Location
38501	Hudson	12345678909874	1	Ward C

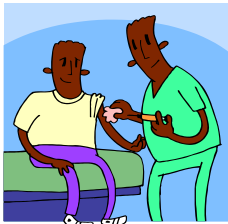
Stock Control Database

Hudson

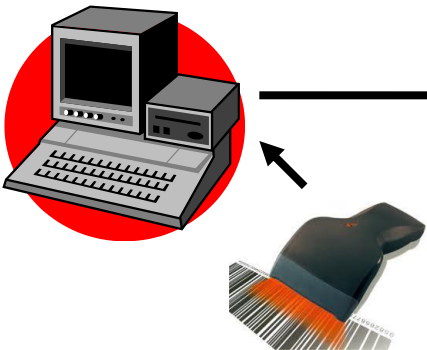


(01)12345678909874

20 Needed in Ward C




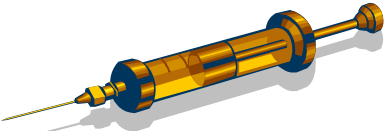
Use the GMDN to find stock



GMDN	Make	UDI [GTIN]	Stock	Location
38501	Hudson	12345678909874	1	Ward C
38501	Woods	32345678908765	2	Ward E
38501	Brooks	19876543218976	100	Ward H

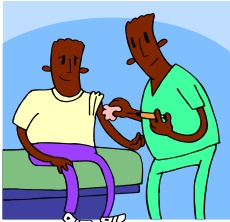
Stock Control Database

Hudson




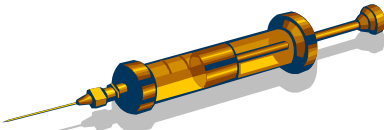
(01)12345678909874

20 Needed in Ward C



100 Located in Ward H

Brooks



(01)19876543218976

Nottingham University Hospital

□ Clinical Engineering application

Medusa Service Delivery

Search [] Clear [] Add new [] Edit List Columns []

Search Device Code Elements

Code Element Key [] Device Coding Standard []

Name []

Code Element Level [Device Group]

List max [All] records: Number of records found: 1392

Code	Description	Device Coding Stand...	Code Element Level
57838	Electrophoresis anal...	GMDN	Device type
57843	Gas chromatography a...	GMDN	Device type
57845	High performance liq...	GMDN	Device type
57863	Microplate reader IV...	GMDN	Device type
57866	Microplate washer IV...	GMDN	Device type
57869	Fluorescent spectrop...	GMDN	Device type
57928	Surgical diode-pumpe...	GMDN	Device type
58000	CT contrast medium i...	GMDN	Device type
58019	Otoacoustic emission...	GMDN	Device type
58029	Foot-switch, pneumat...	GMDN	Device type

Thank you for listening

Any questions?

enquiries@gmdnagency.org

mark.wasmuth@gmdnagency.org