

Global Medical Device Nomenclature (GMDN)

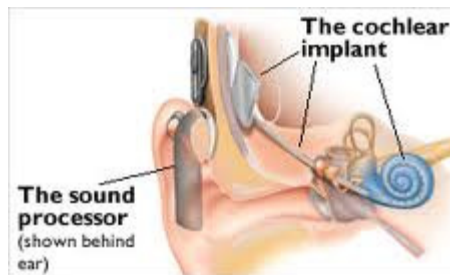
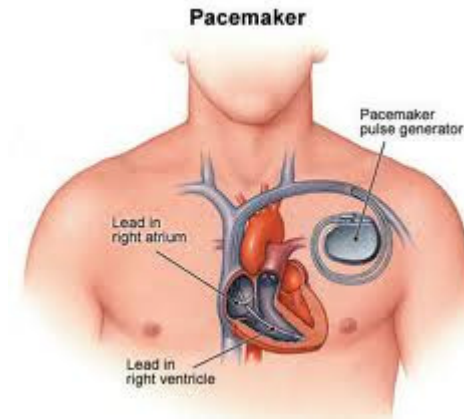
GMDN – A Requirement for UDI

Mark Wasmuth – CEO, GMDN Agency

G•M•D•N

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

What is the GMDN?

Global Medical Device Nomenclature (GMDN)

- ❑ The international standard for naming Medical Devices
- ❑ Uses the **ISO 15225** structure
- ❑ Used by over 60 national Medical Device Regulators
- ❑ Translated into **25 languages**
- ❑ Over **20,000 Preferred Terms** with Definitions

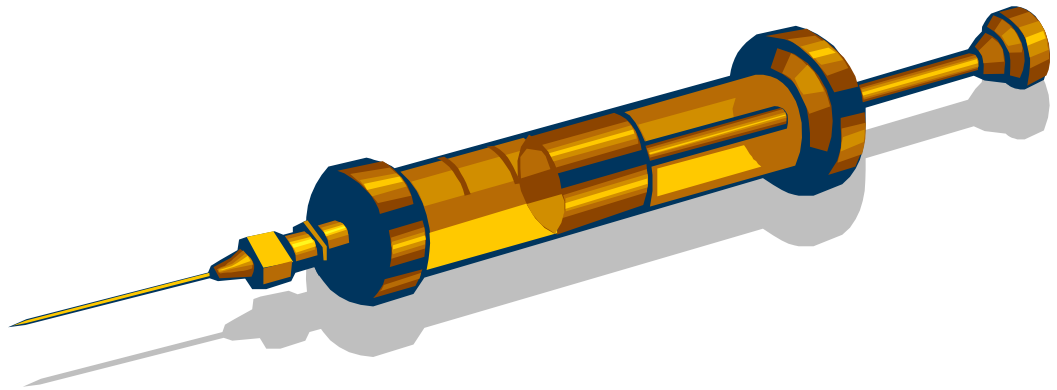
Global acceptance?

- ❑ 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:** Insulin syringe, fixed-needle
- **Definition:** A device consisting of a small, calibrated, hollow barrel (cylinder) and a moveable plunger with a permanently-attached needle (usually capped for user protection) that is used to administer an injection of insulin to a patient subcutaneously...
- **Code:** 38501



How can you find GMDN Codes?

www.gmdnagency.org

The screenshot shows the GMDN Agency website homepage. At the top, there is a navigation menu with links for "GMDN Home Page", "About GMDN", "Membership", "FAQ", "Contact Us", and "Login". A language selector 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. The main content area is divided into four sections:

- 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](#)

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How can you find GMDN Codes?

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 :

How can you find GMDN Codes?



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 :

Records 1-2 from 2

Term	Type	GMDN Code	Definition
1. <u>Insulin syringe, fixed-needle</u> Categories: 10 Single-use devices , 11 Assistive products for persons with disability			
<u>Insulin syringe, fixed-needle</u>	P	38501	A device consisting of a used to administer an in (internally precoated with the pharmaceutical from
<u>Syringe, piston</u>	MS		
<u>Syringe, insulin</u>	S		
2. <u>Insulin syringe, retractable-needle</u> Categories: 10 Single-use devices , 11 Assistive products for persons with disability			
<u>Insulin syringe, retractable-needle</u>	P	Add To Basket	A device consisting of a of insulin to a patient su substances) allowing sn providing protection aga
<u>Syringe, antistick</u>	MS		
<u>Syringe, insulin, shielded-needle</u>	S		

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Poly-Hierarchical Structure

GMDN uses **Collective Terms** to provide:

- Attributes adding context
- Variable / Optional Hierarchies
- Important common features
- Flexible to meet Regulator future needs
- Can be added without changing GMDN Term meaning

Collective Terms

Device group hierarchy

AND / OR

Materials (Inert, Latex, Animal)

Invasiveness (Internal / External)

Sterility (Supplied Sterile / non-sterile)

Use Frequency (Single Use / Reusable)

Powered by (mains, battery, air, etc.)

English

Term Details

Product Identifier

Created 17/05/2004 13:42:56, Last Modified 01/02/2012 03:00:30

Term Insulin syringe, fixed-needle

GMDN Code **38501**

Definition A device consisting of a small, calibrated, hollow barrel (cylinder) and a moveable plunger with a permanently-attached needle (usually capped for user protection) that is used to administer an injection of insulin to a patient subcutaneously. It is typically made of plastic and silicone materials and will have plunger anti-sticking properties (internally pre-coated with compatible substances) allowing smooth plunger movement. It can be used by healthcare personnel or patients, and will allow for the aspiration of the pharmaceutical from its container for direct administration to the patient or via an intravenous (IV) port, heparin lock, or saline lock. This is a single-use device.

Related bulletins [Insulin syringe term is obsolete. Use more recent developed P terms or alternative active P terms such as: Insulin syringe, retractable-needle, Insulin syringe, fixed-needle](#)

Categories

10 Single-use devices

11 Assistive products for persons with disability

Collective Terms

- Device Applications
 - CT1000 Disability-assistive products
 - CT695 Personal medical treatment assistive products
- Device Attribute Assortment
 - CT315 Home-use
 - CT325 Pharmaceutical
 - CT335 Single purpose
 - CT334 Single-patient use
 - CT338 Subcutaneous
 - CT700 Hypodermic
- Device Invasiveness
 - CT983 Surgical invasive
 - CT320 Transient surgical invasive
- Device Materials
 - CT979 Inorganic materials
 - CT177 Metals
 - CT201 Synthetic polymers
 - CT179 Plastics
 - CT212 Silicone
- Device Power/Operation
 - CT326 Manually powered/operated
- Device Sterility
 - CT336 Sterile

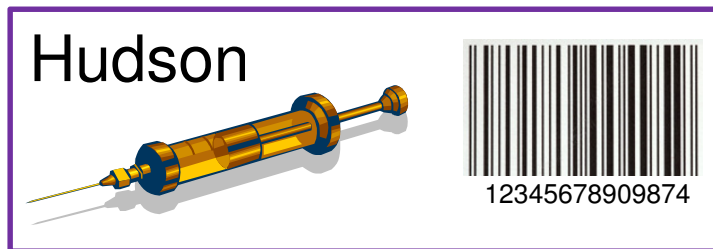
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What's the process?

- ❑ 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 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.)



GMDN and UDI Relationship

- The GMDN code is one of 22 core data elements identified in the **GHTF UDI Guidance Document** and adopted by US FDA in 2012.
- From scanning the bar code, the GMDN Term can be identified from the public **UDI Database** (UDID). Data is provided by the device manufacturer.

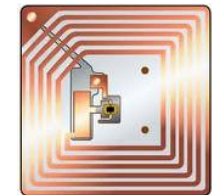


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UDI requires a Carrier & Reader

□ Product Label (Carrier)

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



□ Hardware to read labels

- Bar code Reader
- Image Scanner
- RFID Scanner

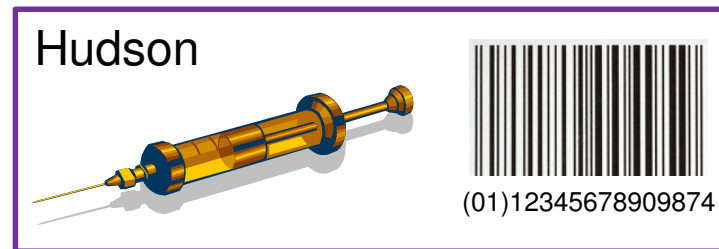


* Requires 'image' scanner

GMDN and UDI Relationship

Pack / Device – UDI [unique number]

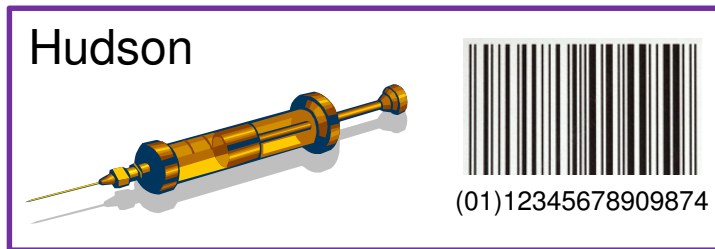
(e.g. 12345678909874)



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GMDN and UDI Relationship

Pack / Device – UDI [unique number]
(e.g. 12345678909874)



Generic Device Group - GMDN Term
(e.g. GMDN Code **38501**)



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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 Form
 - Attach your product datasheet / pictures
 - We discuss the draft Term with you
 - Takes about 3 weeks

Modifying or Obsoleting Terms?

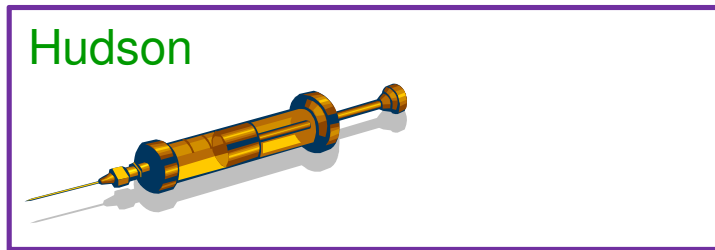
- We modify existing Terms
 - To increase the scope
 - Improve the definitions
- Make Terms Obsolete
 - To remove inadequate Terms
 - Reducing over time
- Notifications by email to Members

Use 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



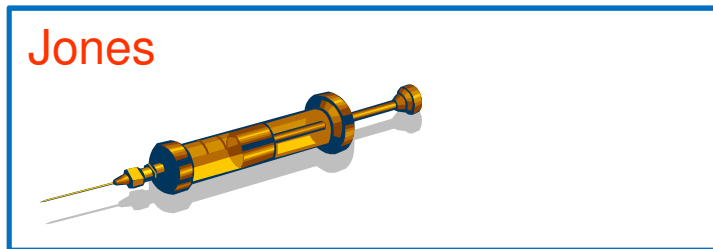
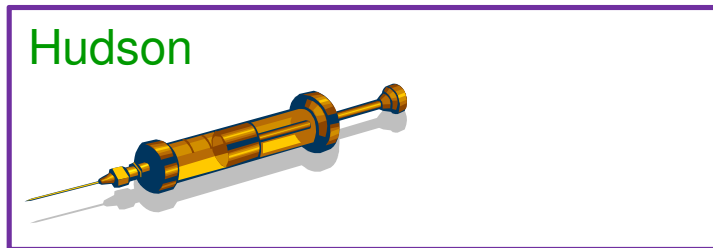
Regulator Device Register

GMDN	Make	Test Method	Date	Approval
38501	Hudson			

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GMDN speeding up pre-market approval

New Applicant



Previously Approved Device

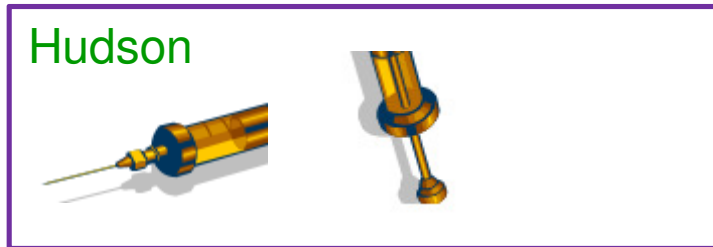
Regulator Device Register

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

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GMDN speeding up product recall

Product Failure



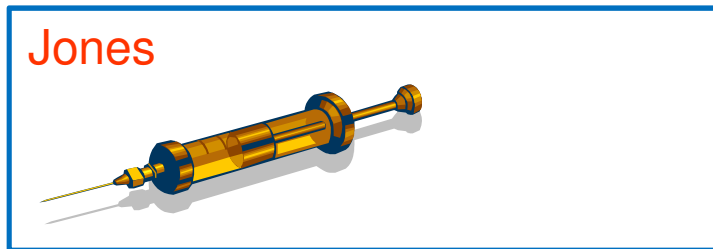
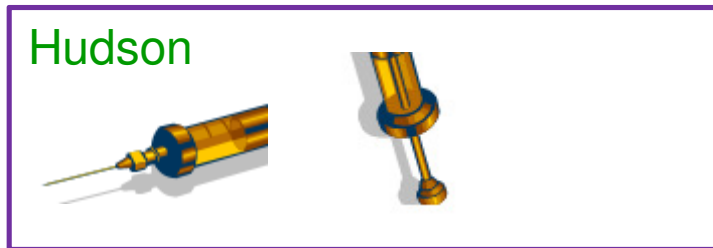
Regulator Device Register

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

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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?

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Use of GMDN & UDI in Hospitals

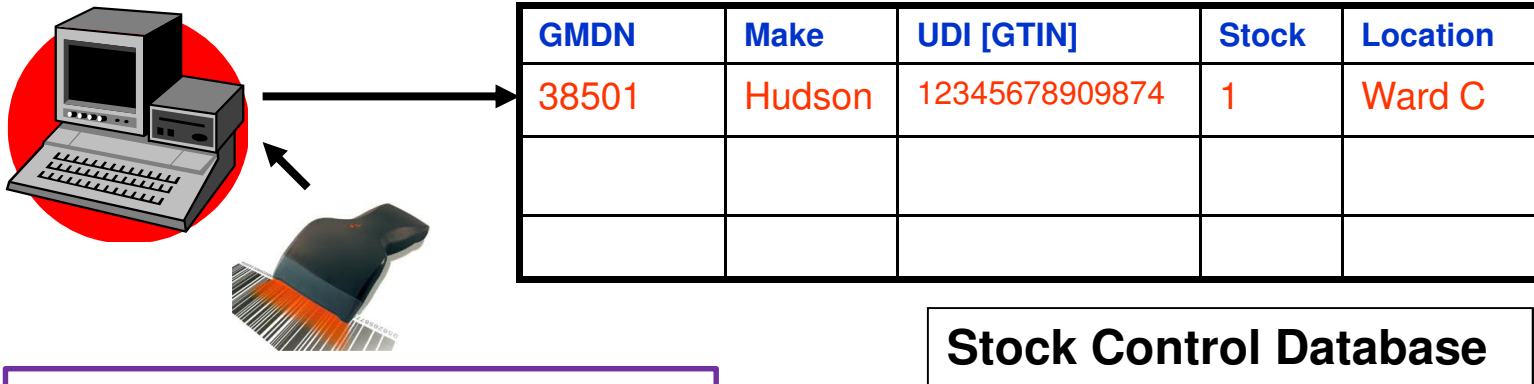
Asset Management

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

Inventory Control

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

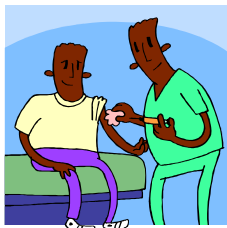
Use the GMDN to find missing stock



Hudson

(01)12345678909874

20 Needed in Ward C



Use the GMDN to find stock



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Nottingham University Hospital

□ Clinical Engineering application

The screenshot shows the Medusa Clinical Engineering application running in Internet Explorer. The browser address bar shows the URL: <http://csqmedusa.nuh.local/medusa/medusa/framework/index.aspx>. The application interface includes a navigation menu on the left with options like 'My Team's Equipment', 'All Equipment', 'New Equipment', and 'Mass Update'. The main content area is titled 'Medusa Service Delivery' and features a search bar and a table of 'Search Device Code Elements'. The table lists various equipment codes and descriptions, such as 'Electrophoresis anal...', 'Gas chromatography a...', and 'High performance liq...'. The table has columns for 'Code', 'Description', 'Device Coding Standa...', and 'Code Element Level'. The 'Code Element Level' column shows 'Device type' for all entries. The table also indicates that 1392 records were found.

Code	Description	Device Coding Standa...	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

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Thank you for listening

Any questions?

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