

# Global Medical Device Nomenclature (GMDN)

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GMDN – A Requirement for UDI

Mark Wasmuth – CEO, GMDN Agency

G•M•D•N

# What we will be discussing

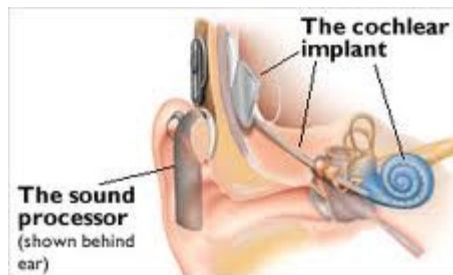
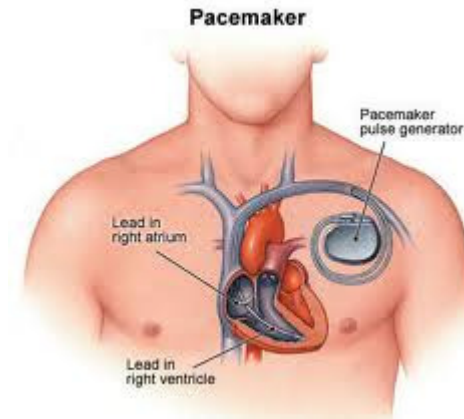
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- Why is the GMDN needed
- GMDN data structure
- How to find GMDN terms
- UDI & GMDN Relationship
- New, Modified & Obsolete Terms
- Examples of use
- Questions?

# Why the need for Device names?

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Large variety of devices!



# Why is consistent naming important?

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- ❑ 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?

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## 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?

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## 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?

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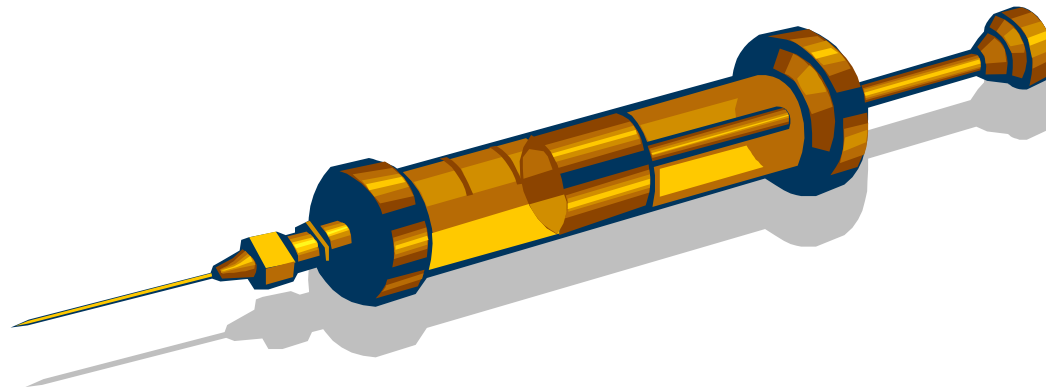
- ❑ GHTF (now **IMDRF**) proposes GMDN for UDI
- ❑ EC proposes GMDN for the **EUDAMED** (market surveillance database)
- ❑ **EUCOMED** supports the use of GMDN in meeting the needs of European manufacturers
- ❑ EC has translated the GMDN into **20 languages**
- ❑ **WHO & MSF** use GMDN in guidance for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

# GMDN Term Structure

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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 menu 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 prominently displayed on the left. The main content area is divided into four sections: 'News (click on a link below)' with four news items; 'I am a GMDN member' with a login form and a 'Forgot your password?' link; 'GMDN Agency Service' with a list of services provided; and 'Actions' with six options, each with a 'Continue' link.

**GMDN Home Page** About GMDN Membership FAQ Contact Us Login English **Select Language**

**G·M·D·N AGENCY**

**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

**Login** [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

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[My GMDN](#) [Terms](#) [Search](#) [Navigator](#) [Information](#) [Basket](#)

**Show results with one or more options**

Search text :

syringe general

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 :

Words only in term

# Review the Results

**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)
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- Translation Code(s)

In :

**Search Terms**

Records 1-1 from 1

Term	Type	GMDN Code	Definition
1. <b>General-purpose syringe</b> Categories: 10 Single-use devices			
<b>General-purpose syringe</b>	P	 <a href="#">Add To Basket</a>	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 designed to have anti-sticking properties (internally pre-coated with a lubricant) to facilitate manual or by a syringe pump. This is a single-use device.

# More detail

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## 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

# How can you find GMDN Codes?

**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 :

**Search Terms**

Records 1-1 from 1

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

[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 Luer-Lock) (hub) of a hypodermic needle or an administration set. It is typically used to administer medication. It has anti-sticking properties (internally pre-coated with silicone) and can be used manually or by a syringe pump. This is a single-use device.

# Reveal the GMDN Code

**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 :

**Search Terms**

Records 1-1 from 1

Term	Type	GMDN Code	Definition
1. <u>General-purpose syringe</u> Categories: 10 Single-use devices			
<u>General-purpose syringe</u>	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 Luer-lock type) or 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

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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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## Collective Terms

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



# Using Collective Terms to search

The screenshot shows a web interface for searching GMDN terms. The top navigation bar includes 'My GMDN', 'Terms', 'Search', 'Navigator', 'Information', 'Basket', and 'Request a Code'. The 'Search' tab is active. Below the navigation bar, there is a summary of selected terms: 'High-Level Device Groups - CT309 Syringes/Injectors and associated devices - CT1943 Syringes'. A checkbox for 'Apply filter immediately' is checked, along with 'Apply Filter', 'Reset', and 'View Help' options.

The search interface is divided into two main sections: 'CT Wizard' and 'Search Results'. The 'CT Wizard' section includes a 'CT Finder' tab and a 'CT Quick Finder' form. The 'CT Quick Finder' form has a text input field containing 'syringe' and an 'Apply' button. Below the form, a list of records is displayed, showing 'Records 1-6 from 6'. The records are as follows:

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

The 'Search Results' section includes a 'PT Search' tab and a list of search results. The results are numbered 15 through 23. The 19th result, 'General-purpose syringe', is circled in red and has the number '47017' next to it. The other results are:

- 15. Dental irrigation/aspiration syringe
- 16. Ear syringe
- 17. Embolization implant syringe
- 18. Gas/liquid chromatography syringe
- 19. General-purpose syringe (47017)
- 20. Hazardous fluid syringe
- 21. Heparin lock flush syringe, reprocessed
- 22. Heparin lock flush syringe, single-use
- 23. High performance liquid

# What's the process?

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- ❑ 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)**

# UDI Database

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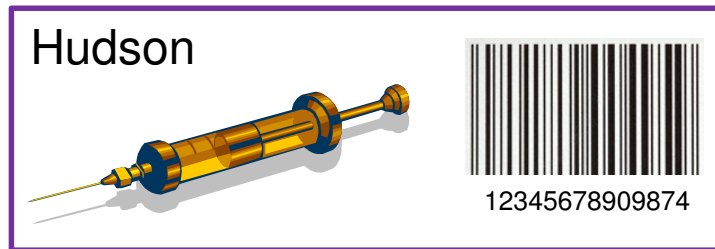
- The GMDN code is one of the 25 mandatory core data elements identified in the **IMDRF ‘UDI System for Medical Devices’** *draft* Guidance Document.
- Data for each device is provided by the manufacturer to the **UDI Database** (*FDA GUID*).
- The UDID data could be distributed by:
  - Public access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

# GMDN and UDI Relationship

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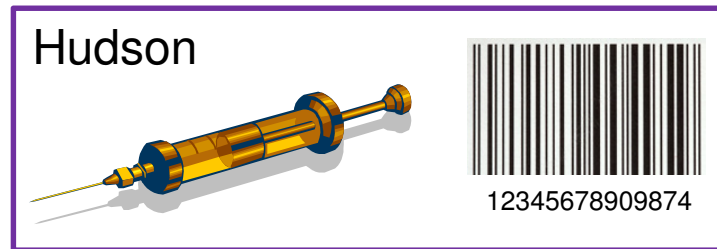
**Pack / Device – Unique Device Identifier**

*(e.g. 12345678909874)*

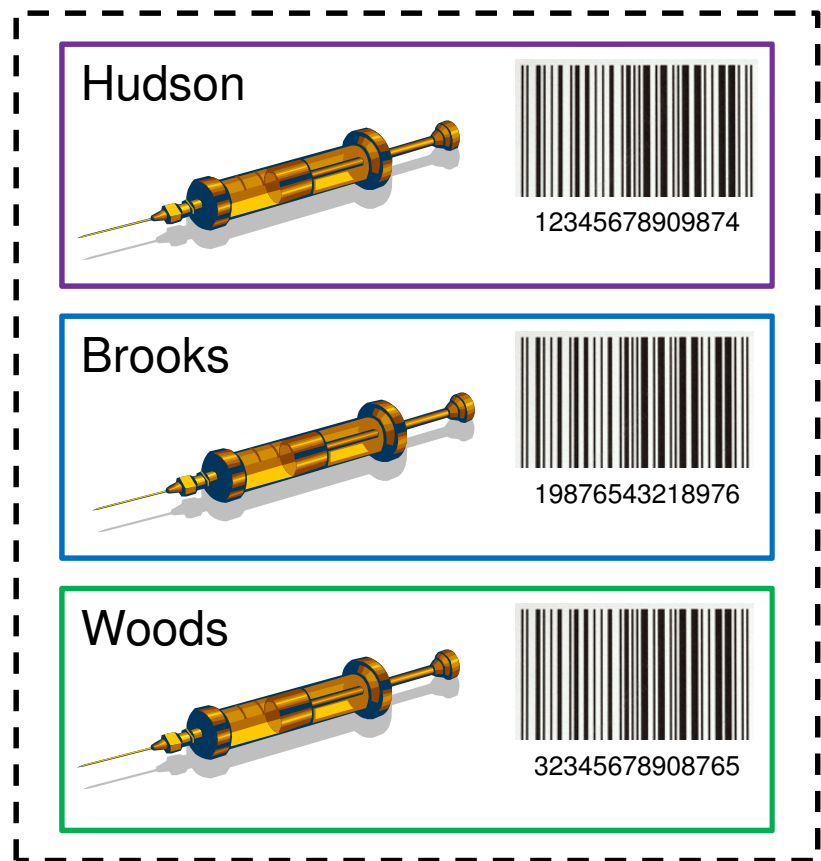


# GMDN and UDI Relationship

**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?

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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?

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- 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

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- 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



# Example of GMDN & UDI 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

# Thank you for listening

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Any questions?

[enquiries@gmdnagency.org](mailto:enquiries@gmdnagency.org)

[mark.wasmuth@gmdnagency.org](mailto:mark.wasmuth@gmdnagency.org)