

Global Medical Device Nomenclature (GMDN)

GMDN – A Requirement for UDI

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G•M•D•N

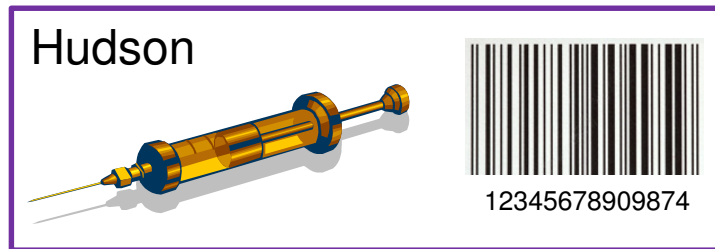
What is the GMDN?

Global Medical Device Nomenclature (GMDN)

- The international standard (ISO 15225) for naming Medical Devices
- Used by 70 national Medical Device Regulators - Backed by IMDRF
- Over 4000 Manufacturers worldwide
- Translated into 25 languages
- 22,000+ Preferred Terms (product groups)
- Controlled distribution and updating
- International acceptance

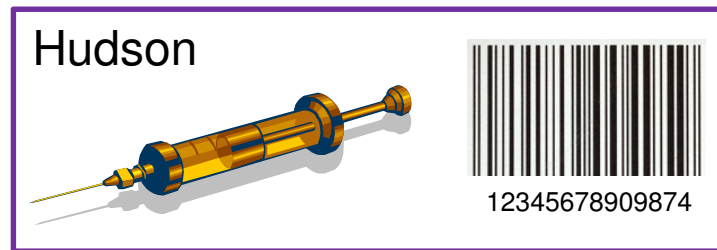
GMDN and UDI Relationship

**Pack / Device -
Unique Device Identifier**
(e.g. 12345678909874)

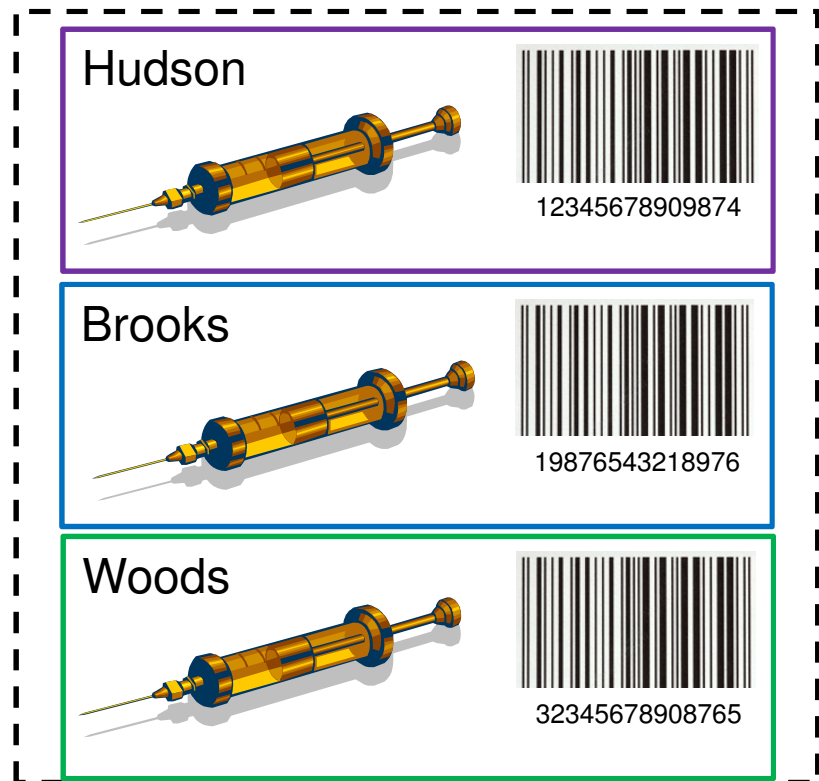


GMDN and UDI Relationship

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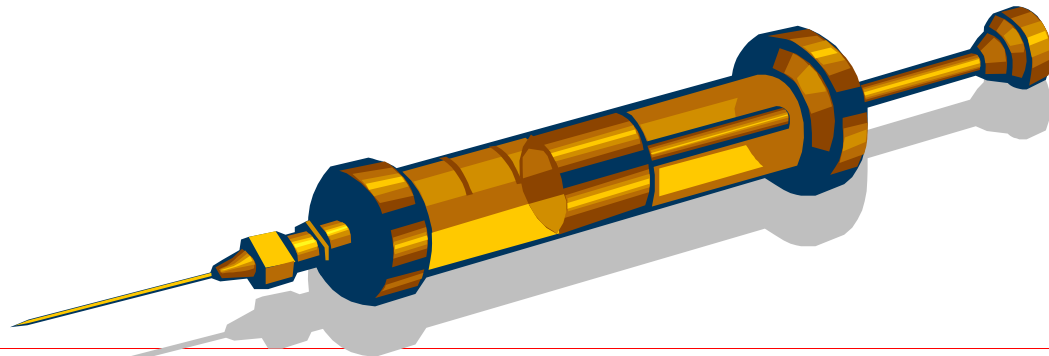
**Generic Device Group -
GMDN Term**
(e.g. GMDN Code 47071)



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



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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 side of the header. Below the header, the page is divided into four main sections:

- News (click on a link below):** This section contains four links: "GHTF endorses GMDN for global use", "US FDA outlines recommendations for UDI", "New GMDN Terms for Complementary Therapy", and "European Regulators are using GMDN".
- I am a GMDN member:** This section features a login form with fields for "Login" and "Password", a "Login" button, and a "Forgotten your password?" link.
- GMDN Agency Service:** This section lists services provided by the GMDN Agency, including access to the GMDN data file and codes, a link to the GMDN database, application forms for new terms or modifications, access to GMDN terminology and information, guidance on how to use the GMDN, access to Collective Terms and codes, and a GMDN translation software tool.
- Actions:** This section lists several actions users can take, each with a "Continue" link: "I would like to become a member of GMDN", "I would like to submit a proposal for a GMDN term", "I would like to learn about the GMDN", "I would like to contact the GMDN Agency", "I would like a free copy of the GMDN User Guidance", and "I would like to bookmark this page".

Search using product description

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

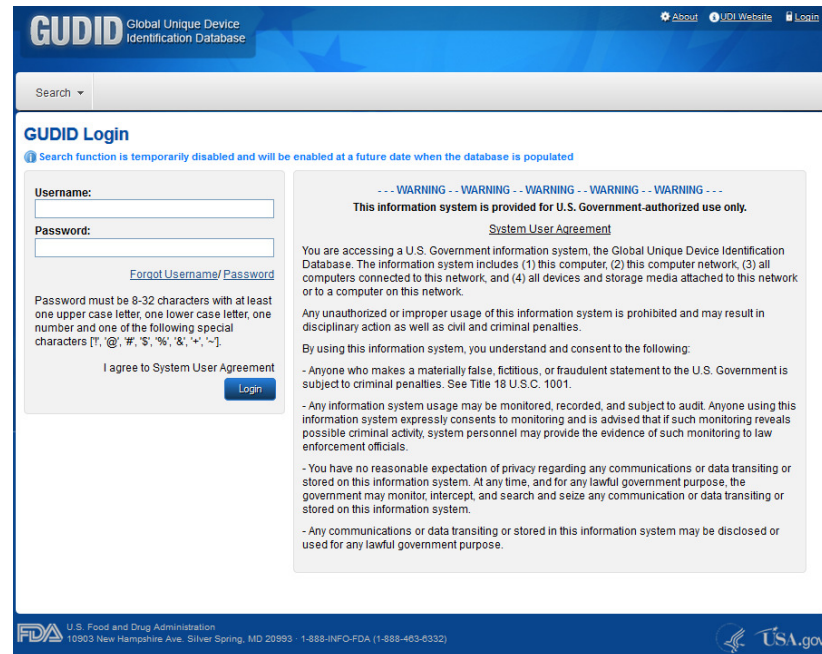
Records 1-1 from 1

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.

FDA GUDID Inputs

Two methods of entering data into the FDA Global UDI Database:

1. FDA GUDID web interface
2. HL7 SPL submission (up to 500 records per time)



GMDN Code & FDA PT Code?

To overcome the need to be a GMDN Member the FDA have a facility to assign a GMDN term to your Device record, within the GUDID Website:

1. Users can use the 'Find FDA PT Codes' module to search GMDN terms
2. The related **FDA PT Code** can be used to assign the GMDN term name to a device within the Device record.

This is not needed if you already have your GMDN Code.

GMDN Codes or FDA PT Codes will be needed in advance if using the HL7 SPL submission.

GMDN Term Structure - Reminder

Each GMDN Term consists of 3 parts:

- ❑ **Term Name:** General-purpose syringe
- ❑ **Definition:** A sterile device...
- ❑ **GMDN Code:** 47017

- ❑ GMDN Code is equivalent to **FDA PT Code** (WXYZ)

- ❑ 'FDA PT Codes' will only work in the US FDA GUDID
- ❑ If your product is not found when using use the 'Find FDA PT Codes' module you will be directed by the FDA to obtain one from the GMDN Agency

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
- GMDN Members are kept up-to-date with email notifications

Thank you for listening

Any questions?

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