Global Medical Device Nomenclature (GMDN)

GMDN – A Requirement for UDI

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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

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

Hudson

12345678909874

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

Hudson

12345678909874

Brooks

19876543218976

Woods

32345678908765
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
Search using product description

**Search text:** syringe general

**For:**
- All the words
- Any of the words
- The exact phrase
- None of these words

**In:** Words only in term

**Search Terms**

Records 1-1 from 1

<table>
<thead>
<tr>
<th>Term</th>
<th>Type</th>
<th>GMDN Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>General-purpose syringe</td>
<td>P</td>
<td>47017</td>
<td>A sterile device that consists of a calibrated hollow barrel (cylindrical) for injecting or withdrawing fluids/gases, often used in medical procedures such as administering medications. It is typically made of plastic and is a single-use device.</td>
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</tbody>
</table>
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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