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
Global acceptance?

- IMDRF (previously GHTF) proposes GMDN
- EC proposes GMDN for the EUDAMED (market surveillance database)
- EUCOMED / EDMA / ADVAMED supports the use of GMDN in meeting the needs of manufacturers
- EC has translated the GMDN into **20 languages**
- WHO & MSF use GMDN in their guidance documents for developing countries
- Aligned with **Snomed CT** standard for patient records
- 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
Reveal the GMDN Code

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
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>
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<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)</td>
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<td>(e.g., medication) into, and/or withdraw fluids/gas from, the lumen. The</td>
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<td>end of the barrel is a male connector (typically a Luer-lock type) needle</td>
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<td>or an administration set. It is typically made of plastic (internally</td>
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<td>precoated with compatible substances) allowing it to be connected to a</td>
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<td>single-use device.</td>
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G•M•D•N
GMDN and UDI Relationship

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

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

Hudson

Brooks

Woods

12345678909874

19876543218976

32345678908765
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
Thank you for listening

Any questions?

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