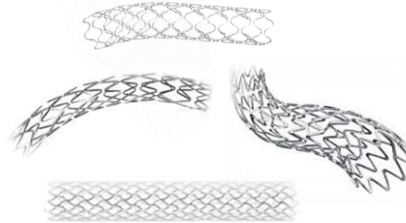
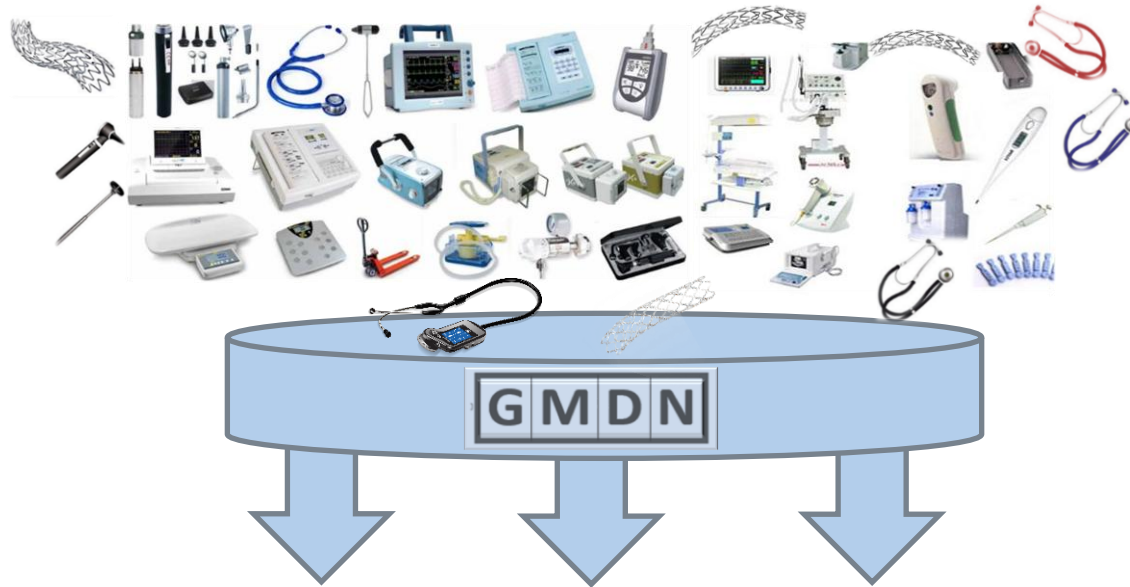

Global Medical Device Nomenclature (GMDN)

GMDN as a Trending Tool

Edward Glenn
GMDN Agency



GMDN – a medical device sorting machine



GMDN term example

GMDN Term

13755

Mechanical stethoscope

A mechanical listening device designed for listening to sounds from the heart, lungs, and/or gastrointestinal tract. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the users ears. Mechanical stethoscopes are typically found in two variants 1) a general-purpose stethoscope used for clinical/ward activities; or 2) a reinforced stethoscope used by cardiologists.

CTs (Broader groups)

CT267 Stethoscopes and associated devices

CT1930 Stethoscopes

CT149 General hospital devices



What's the GMDN Process?

THE GMDN TERM

13755 Mechanical stethoscope

A mechanical listening device designed for listening to sounds from the heart, lungs, and/or gastrointestinal tract. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the users ears. Mechanical stethoscopes are typically found in two variants 1) a general-purpose stethoscope used for clinical/ward activities; or 2) a reinforced stethoscope used by cardiologists.

is assigned to

THE DEVICE



by

THE MANUFACTURER



for

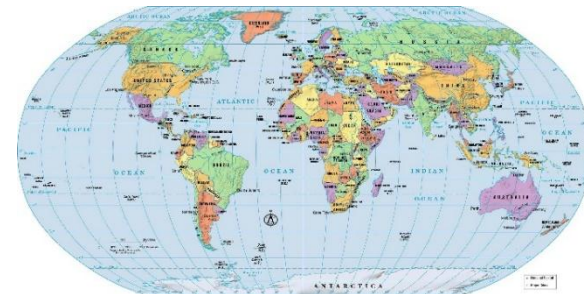
REGULATORS

and

HOSPITALS



WORLDWIDE



What about UDI?

A UDI ISSUING AGENCY



provides THE MANUFACTURER



with A UNIQUE NUMBER

0) 1 0614141 012345678

to be put in

A BARCODE



for THE DEVICE



allowing accurate

RETRIEVAL



of

DEVICE DATA

DI number
SIZE
Brand name
GMDN code
Company info

from

A DATABASE



GMDN working with Regulators and Registries



UK- Working closely with MHRA

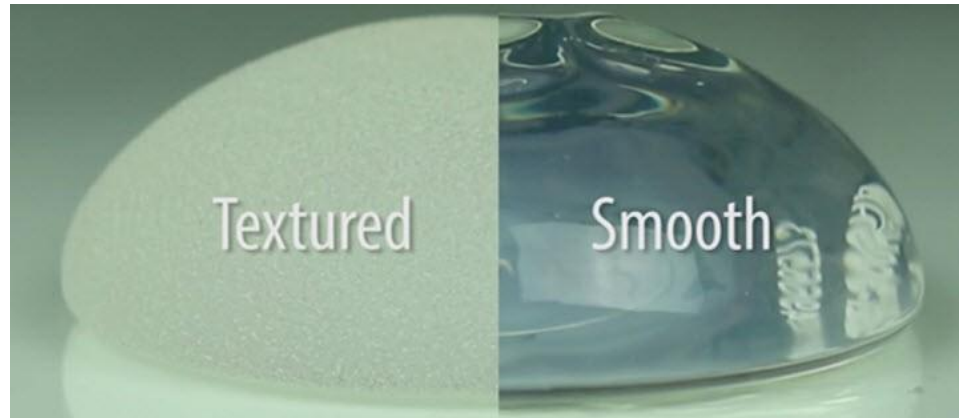
- Software (SaMD) terms
- Lower limb prostheses terms



US- Learning UDI Community

- Set up to establish non-regulatory uses for UDI
- FDA initiated and participant
- Managed by AHRMM – trade association for supply chain
- Device categorization work group
 - How can GMDN be used to leverage UDI data?
- **Projects:**
 - RAPID (vascular implant clinical evaluation project)/VQI (vascular implant registry)
 - Augmented UDI Data (AUDI)
 - Breast Implant registry

Working with Breast Implant registries



Working with Breast Implant registries

- ▶ CT244 Prostheses and associated devices
 - CT2274 Breast implant sizers
 - CT2630 Dental appliance fabrication materials
 - CT1377 External limb prosthesis sockets
 - CT1458 Implantable joint prosthesis trials
 - CT2273 Orthopaedic prosthesis implantation instruments
- ▶ CT1370 Prostheses
 - ▶ CT1371 External prostheses
 - ▶ CT446 Implantable prostheses
 - CT1373 Breast implants**
 - ▶ CT1374 Cardiovascular prostheses
 - ▶ CT1372 Implantable joint prostheses
 - ▶ CT1376 Implantable ocular prostheses
 - CT2302 Penile prostheses
- ▶ CT775 Plastic surgery and cosmetic devices
 - ▶ CT303 Breast implants and associated devices
 - CT2274 Breast implant sizers
 - CT1373 Breast implants**

1,777 of 2,087,581 products

10888628003132 - Allergan, Inc. -
NATRELLE 410 Highly Cohesive
Anatomically Shaped Silicone-Filled
Breast Implants

10888628002937 - Allergan, Inc. -
NATRELLE 410 Highly Cohesive
Anatomically Shaped Silicone-Filled
Breast Implants

10888628030459 - Allergan, Inc. -
Natrele Inspira Cohesive Breast Implants

10888628029774 - Allergan, Inc. -
Natrele Inspira Cohesive Breast Implants

10851795006060 - IDEAL IMPLANT
INCORPORATED - IDEAL IMPLANT

10851795006077 - IDEAL IMPLANT
INCORPORATED - IDEAL IMPLANT

10851795006022 - IDEAL IMPLANT
INCORPORATED - IDEAL IMPLANT

• • •

- CTs arranged in a hierarchy
- Allows for grouping at many levels

GMDN CTs  Devices

Working with Breast Implant registries

- ▶ CT244 Prostheses and associated devices
 - CT2274 Breast implant sizers
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- ▶ CT775 Plastic surgery and cosmetic devices
 - ▶ CT303 Breast implants and associated devices
 - CT2274 Breast implant sizers
 - CT1373 Breast implants**

8 of 23,772 terms

Saline-filled breast implant, internally-structured

Saline-filled breast implant, unstructured
Obsolete

Saline-filled breast implant, unstructured, smooth-surface

Saline-filled breast implant, unstructured, textured-surface

Silicone gel/saline-filled breast implant

Silicone gel-filled breast implant **Obsolete**

Silicone gel-filled breast implant, smooth-surface

Silicone gel-filled breast implant, textured-surface

4 of 2,087,581 products

00812790025480 - Sientra, Inc. - SIENTRA Silicone Gel Breast Implant

00812790025473 - Sientra, Inc. - SIENTRA Silicone Gel Breast Implant

00812790025466 - Sientra, Inc. - SIENTRA Silicone Gel Breast Implant

00812790025497 - Sientra, Inc. - SIENTRA Silicone Gel Breast Implant

New terms created to capture textured implant issue - Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)



Working with Breast Implant registries

Silicone gel-filled breast implant, textured-surface

GMDN Terms



Texture coarseness levels 1→6

Implant Registry terms

- Implant registries usually need even more granular groups (beyond the scope of the GMDN)
- Registries can use GMDN terms as a framework to then supplement with additional groups
- Improves data sharing /consistency



A powerful tool to consistently **name** and systematically **group** the **millions** of medical devices on the international market