

**UPDATE ON GLOBAL NOMENCLATURE  
(GMDN)  
OCTOBER 2007**

BY  
MAURICE F.FREEMAN

- Chair – GMDN Agency for Global Medical Device Nomenclature
- Past Chair – Study Group 1 of GHTF – 1995 to 2005
- Past EU Technical Expert – Medical Devices



**1991 – AUTUMN  
CONFERENCE IN BRUSSELS**

-----

**TO EXPLORE EXISTING M.D.NOMENCLATURES**

-----

**RESULT – NO CONCLUSION**

## **1992 – 1993 ADOPTION OF EUROPEAN MEDICAL DEVICE DIRECTIVE 93/42**

IDENTIFICATION OF NEED TO DEVELOP A GENERIC NOMENCLATURE TO IDENTIFY DEVICES ESPECIALLY FOR EXCHANGE OF INFORMATION WITH REGARD TO “DEVICE VIGILANCE” (OR ADVERSE EVENT REPORTING).

ALSO NEED TO EXCHANGE REGULATORY INFORMATION BETWEEN ALL MEMBER STATES IN EUROPE WITH REGARD TO CERTIFICATION AND REGISTRATION MATTERS ETC.

# **REVIEW OF EXISTING NOMENCLATURES**

**RESULT – NONE CONSIDERED TO BE COMPREHENSIVE ENOUGH FOR THE PURPOSE**

**EU COMMISSION PROVIDED MANDATE TO CEN FOR THE PREPERATION OF A STANDARD INDICATING THE STRUCTURAL NEEDS FOR A MEDICAL DEVICE NOMENCLATURE.**

**CEN COMMITTEE ESTABLISHED TO PRODUCE STANDARD WITH INVITATION FOR PARTICIPATION BY FDA/ISO**

1993-1995

STANDARD DEVELOPED GIVING STRUCTURE



RESULT EN/ISO 15225

# EUDAMED

EUROPEAN COMMISSION COMMENCED DEVELOPMENT OF **EUDAMED** – EUROPEAN DATABASE FOR MEDICAL DEVICES TO ESTABLISH REPORTING LINK BETWEEN ALL EUROPEAN UNION REGULATORY BODIES + EFTA COUNTRIES.

REQUIREMENT FOR APPROPRIATE MEDICAL DEVICE  
GENERIC NOMENCLATURE

# **FIRST NOMENCLATURE**

**EUROPEAN COMMISSION ISSUED MANDATE TO CEN TO DEVELOP THE FIRST GENERIC NOMENCLATURE FOR GLOBAL USE, UTILIZING EXISTING BASE NOMENCLATURES FROM SIX OTHER SOURCES.**

**EUROPEAN COMMISSION PROVIDED FUNDING TO COVER PROCESS AND A PROJECT TEAM LED BY BSI ON BEHALF OF CEN WAS FORMED TO PREPARE THE FIRST NOMENCLATURE.**

**TWELVE TEAMS OF EXPERTS COVERED DIFFERENT TECHNOLOGY AREAS.**

## **SOURCE NOMENCLATURES USED IN DEVELOPMENT OF GMDN**

- ECRI – UMDNS
- NKKN – NORWAY
- JFMDA – JAPAN
- FDA – PRO-CODES
- EDMA – IVD'S
- ISO – AIDS FOR DISABLED

**M.A.P.G**

**GROUP COMPRISES NOMINATED  
REPRESENTATIVES FROM:**

- **THE EUROPEAN COMMISSION (EC)**
- **US FOOD AND DRUG ADMINISTRATION (FDA)**
- **MINISTRY OF HEALTH & WELFARE (MHLW) – JAPAN**
- **GLOBAL HARMONISATION TASK FORCE (GHTF)**
- **UP TO 10 EXPERTS – FROM CEN AND ISO EXPERTS PLUS  
SPECIFIC TECHNOLOGY EXPERTS FROM  
MANUFACTURERS/REGULATORS ETC.**

# GMDN Agency

- Now constituted as a Company Ltd by Guarantee (a non-profit company) in May 2005 to carry out all functions for developing new terms, adjustment to existing terms + management of licencing and distribution of GMDN.
- Intellectual property rights/Copyright devolved to agency by CEN/EU Commission

**THE STANDARD**  
**EN/ISO 15225 - STRUCTURAL SYSTEM FOR**  
**NOMENCLATURE**

-----

**THE NOMENCLATURE**  
**CEN TECHNICAL REPORT – CR14230 =**  
**ISO TECHNICAL SPECIFICATION – TS20225**

**BOTH REPORTS PUBLISHED 1<sup>ST</sup> NOV. 2001**

# FIRST NOMENCLATURE

G•M•D•N

-----

DISTRIBUTED THROUGH STANDARDS BODIES ON CD-ROM

UPDATED VERSIONS DISTRIBUTED THROUGH  
MAINTENANCE AGENCY

LICENCE MECHANISM INTRODUCED TO CONTRIBUTE  
TOWARDS THE COST OF UPDATING PLUS ADDITION OF  
NEW TERMS

LICENCE COST DEPENDING ON SIZE OF MANUFACTURER  
WITH SMALL CONTRIBUTION FROM OTHER USERS

## **NEW DATABASE**

MAINTENANCE AGENCY RAISED FINANCE TO ESTABLISH A NEW DATABASE FOR INTERNET ACCESS BY LICENCED MEMBERS TO THE ENLARGED DATAFILE OF 20,000 APPROX TERMS (APPROXIMATELY 10,000 PREFERRED TERMS FOR PRODUCT IDENTIFICATION AND 10,000 OTHER TERMS, SYNONYMS AND TEMPLATE HEADER TERMS).

NEW DEVELOPMENTS INCLUDE THE ADDITION OF COLLECTIVE TERMS AS ORIGINALLY MANDATED BY THE COMMISSION, ADDITIONAL AIDS TO NAVIGATION.

**G•M•D•N**

EN ISO 15225

Search:  
template terms  
~~G•M•D•N~~  
synonym terms  
multiple syn.

**Device Category**

**Code**

**Code**

**Generic  
Device  
Group**

**P Term**

**Definition**

Device label:

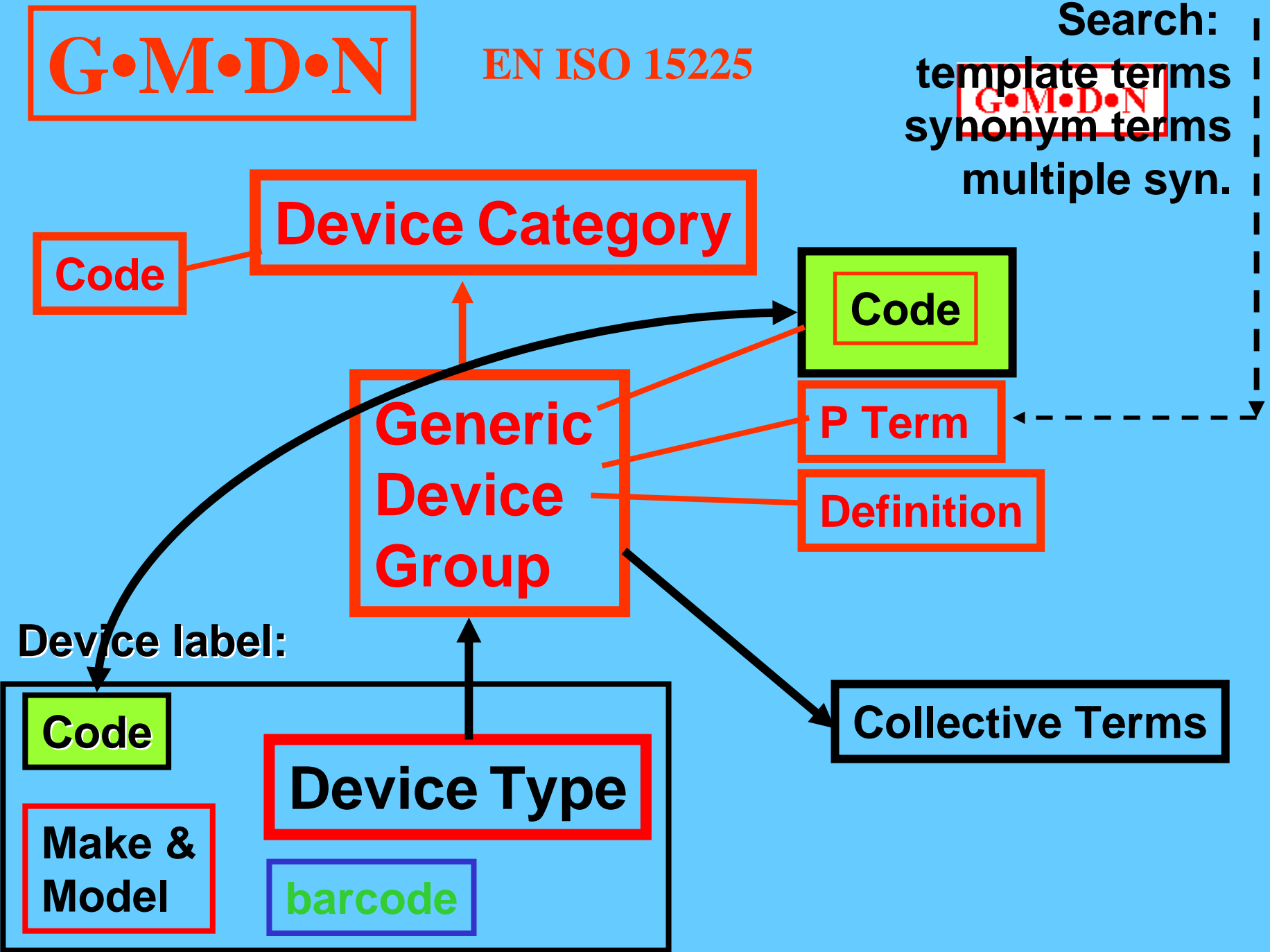
**Code**

**Make & Model**

**Device Type**

**barcode**

**Collective Terms**



## OTHER USER - e.g. Hospitals

- Searching the market
- Tender procedure
- Purchasing
- Acceptance control
- Stock-keeping
- Maintenance and use records
- Preparedness
- Equipment Management Systems

**e - commerce**

# GHTF and GMDN

Now the basis for  
development of regulations  
in all parts of the globe

## **GLOBAL ACCEPTANCE OF GMDN**

**AFTER SOME THREE YEARS OF  
HESITATION BY REGULATORY BODIES,  
MANUFACTURERS AND HOSPITAL  
AUTHORITIES, THE ACCEPTANCE OF  
GMDN IS NOW RECOGNISED IN MOST  
PARTS OF THE WORLD AND FORMAL  
ADOPTION NOW IS ESTABLISHED**

## **EUROPEAN ACCEPTANCE OF GMDN**

- **THE GMDN DATAFILE IS NOW LOADED INTO THE EUROPEAN DATA EXCHANGE MECHANISM – EUDAMED, SOON TO BE FORMALLY INTRODUCED**
- **EUROPEAN COMMISSION IS IN THE PROCESS OF INITIATING TRANSLATION OF GMDN INTO 21 EUROPEAN OFFICIAL LANGUAGES**

# USA

THE USA FDA IS IN THE PROCESS OF MAPPING THE FDA PROCODES TO THE RELEVANT GMDN TERMS, AND MANY US MANUFACTURERS ARE MEMBERS OF GMDN FOR IDENTIFICATION OF THEIR DEVICES BOTH IN USA AND WORLD MARKETS.

# GLOBAL ACCEPTANCE

GMDN IS BEING TRANSLATED INTO  
LANGUAGES FOR USE IN COUNTRIES  
IN MOST REGIONS OF THE WORLD.

# PERSONNEL

GMDN AGENCY IS GRATEFUL FOR THE DEDICATION OF THOSE INVOLVED OVER THE YEARS IN INTRODUCING THE CONCEPT, IN PROVIDING FREELY IN MOST CASES A WEALTH OF INFORMATION AND EXPERIENCE TO ACHIEVE THIS COMPREHENSIVE AND VERSATILE NOMENCLATURE WHICH WILL BE INVALUABLE FOR THE FUTURE DEVELOPMENT, CONTROL AND UNDERSTANDING OF MEDICAL DEVICES THROUGHOUT THE WORLD IN THE INTERESTS OF SAFETY FOR USERS AND PATIENTS.

THE COST OF ACHIEVING THIS IS ONLY NOW STARTING TO BE COVERED BY THE SUPPORT OF USERS.

## TERM CONSTRUCTION

IT IS IMPORTANT FOR ALL TO NOTE THAT ALL MAIN GMDN PREFERRED TERMS HAVE A FULL DEFINITION.

THIS DEFINITION IN ALL CASES IS THE TRUE INDICATOR OF THE FEATURES OF A GIVEN DEVICE, WHICH IS REPRESENTED BY THE DEVICE TERM USING THE MAIN HEADER AND QUALIFIERS.



## The Global Medical Device Nomenclature

The Global Medical Device Nomenclature (GMDN) provides the use of generic descriptors for the identification of medical devices and other Healthcare related products. All aspects of the nomenclature system are managed by the [GMDN Agency](#)

Dear Jacob Nordan,  
Welcome to GMDN Database

## GMDN Agency Service

Services provided by the GMDN Agency are:

- Access to the GMDN data file and codes via this Internet site through a license agreement and/or by

## Actions

- I would like to search GMDN Database [Continue](#)
- I would like to view My GMDN terms [Continue](#)





	GMDN Code	Term	Definition	Original Term	S
1.	S 32234	<a href="#">Abdominal binder</a>		BINDER, ABDOMINAL	FC
2.	P 33721	<a href="#">Absorbent tipped applicator, non-sterile</a>	A device intended for <b>medical</b> purposes which include, to apply medications to, or to take specimens from, a patient or an object. It is typically designed as an absorbent, non-sterile, swab on a wooden, paper, or plastic stick. This is a single-use device.	APPLICATOR, ABSORBENT TIPPED, NON-STERILE	FC
3.	P 33722	<a href="#">Absorbent tipped applicator, sterile</a>	A device intended for <b>medical</b> purposes which include, to apply medications to, or to take specimens from, a patient or an object. It is typically designed as an absorbent, sterile, swab on a wooden, paper, or plastic stick. This is a single-use device.	APPLICATOR, ABSORBENT TIPPED, STERILE	FC
4.	MS 31241	<a href="#">Absorber, carbon-dioxide</a>		ABSORBER, CARBON-DIOXIDE	FC
5.	P 40704	<a href="#">Accelerator system chair</a>	A seat, typically with legs, that is a component of a therapeutic accelerator system, and used to support and position a seated patient during radiation therapy treatments involving the use of either a <b>medical</b> linear accelerator or non-linear accelerator.		
6.	P 36502	<a href="#">Accelerator system computer</a>	A dedicated mainframe computer,	Radiotherapy, linear accelerator	N



GMDN Code	Term	Definition	Original Term
S 17550	<a href="#">Mask, mouth-to-mask, resuscitation training</a>		Masks, Mouth-to-Mask, Resuscitation Training
P 36066	<a href="#">Resuscitation mask, mouth-to-mask</a>	A flexible, form-shaped device that is placed over a patient's or person's mouth to administer exhaled air from the user to a patient/person during cardiopulmonary resuscitation (CPR). The device is designed to replace mouth-to-mouth resuscitation therefore avoiding cross-contamination. It is also used on <b>manikin</b> training by students during CPR training; again to minimize the risk of cross-contamination. The device may include an airway, one-way valve or other components, e.g., a bacteria filter. This is a reusable device.	Masks, Mouth-to-Mask, Resuscitation Training
S 36326	<a href="#">Teaching aid, manikin</a>		Teaching aid, <b>manikin</b>
S 17697	<a href="#">Training aid, haemodynamic monitoring</a>		Training Aids, Hemodynamic Monitoring
S 15666	<a href="#">Training manikin</a>		Training Manikins
S 15309	<a href="#">Training manikin, cardiopulmonary resuscitation</a>		Training Manikins, Cardiopulmonary Resuscitation
P 35540	<a href="#">Training model, anatomical, resuscitation</a>	A specially constructed doll with respiratory and circulatory (heart) functions used for educational/instructive teaching in techniques, e.g., "mouth-to-mouth" resuscitation, heart compression or manual pulse registration. This device is commonly known as a <b>Manikin</b> .	
P 35740	<a href="#">Training model,</a>	A system of instruments, <b>manikin</b> , and software representing physiological	Training Aids,