

# Global Medical Device Nomenclature System - GMDN -

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# GMDN

- Work commenced in 1993
- Developed from -
  - NKKN (Norwegian system)
  - ISO Aids for the Disabled
  - EDMA system for IVD's
  - UMDN (ECRI) System
- Published as EN/ISO 15225 in 2001



# 1995 - 2001

- 70 Experts

IN

- 12 Teams

From

- 18 Countries

..... 40 man years of work



# Nomenclature is used by

- Regulators
- Manufacturers
- Health care providers

FOR

Data Exchange

Vigilance

Scoping of Certification

Product identification - purchasing  
e-Commerce



# GMDN

- 13 Categories of devices
- ~ 1000 **template** terms
- ~ 8500 **preferred** terms
- ~ 8000 **synonym** terms
- Maintenance Agency Policy Group to provide regular updates to the data base



# 13 Categories

- Active Implants
- Anaesthetic & respiratory
- Dental
- Electromechanical
- Hospital Hardware
- IVD's
- Non-active implants
- Ophthalmic & Optical
- Re-useable instruments
- Single Use devices
- Technical Aids for the disabled
- Radiation & X-ray
- Alternative therapy devices



# Maintenance Agency

- Holds copyright of original version of the code  
(English version)
  - Operational administration
  - Creates new terms
  - Modify & update existing terms
  - Administer and distribute user licences
- 
- Participants -
    - ISO (up to 5 experts)
    - CEN (up to 5 experts)
    - The European Commission
    - US FDA
    - MHLW (Japan)
    - GHTF



# Acceptance .....

- Currently being translated into
  - French
  - German
  - Japanese
  - Chinese (multiple dialects)
  - Spanish
  - Turkish
  - Spanish (including S'American variants)





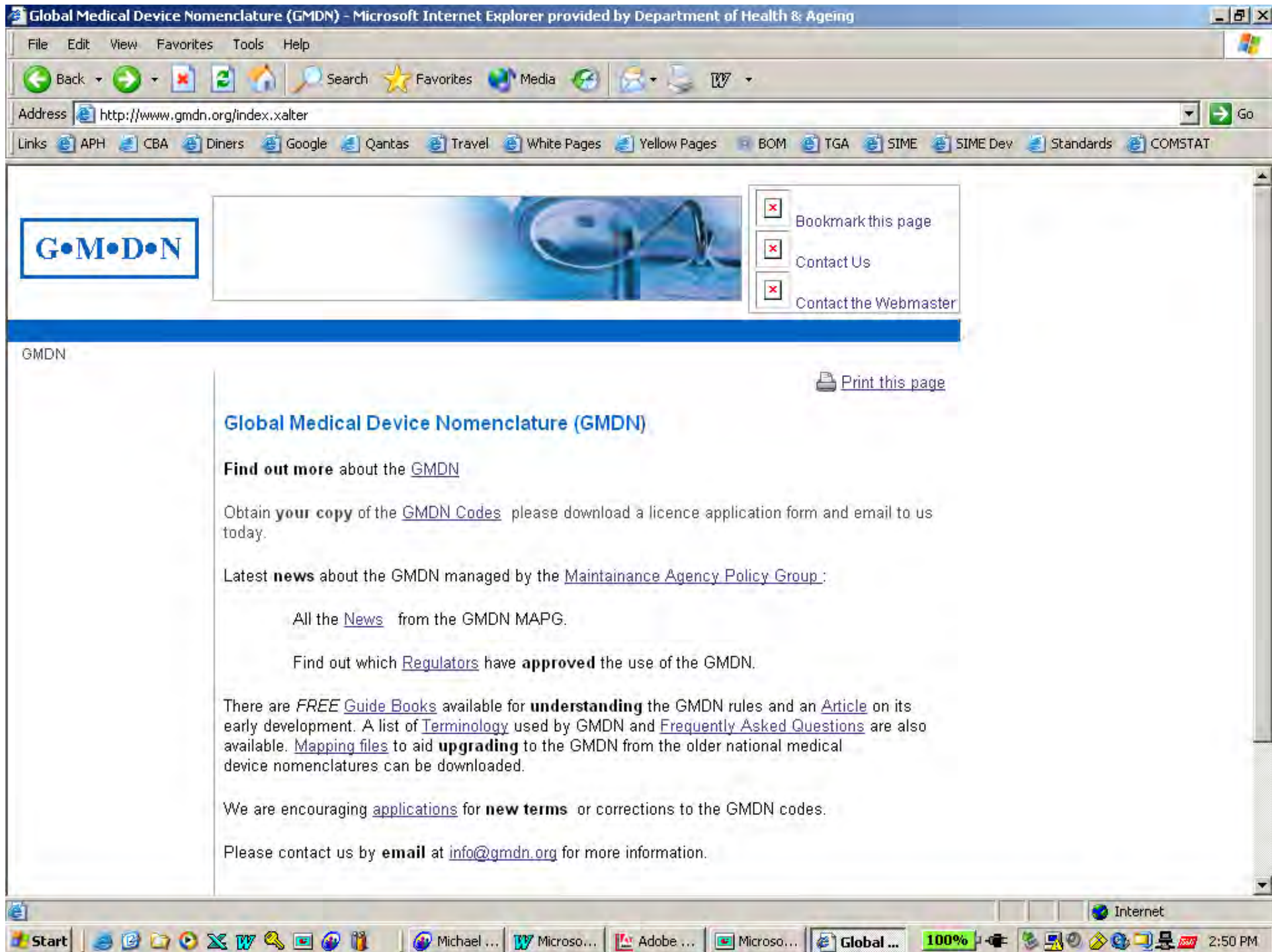
# Acceptance .....

- Licences issued to 26 National Regulators
- Endorsed by GHTF as global nomenclature for generic device descriptors
- FDA has indicated it is mapping to the GMDN from it's existing nomenclature
- Endorsed by EU MDEG for device identification in support of the Device Directives
- Written in to Australian legislation to identify devices for entry on to the Australian Register of Therapeutic Goods



GMDN	Term	Synonym	T/Char	Definition
31813	Tweezers, dental, articulation paper	0	0	A dental instrument having two spring-loaded jaws which is used for holding articulation paper.
31814	Tweezers, dental, dressing	0	0	A hand-held dental instrument having two narrow, pointed spring-loaded jaws. When these are approximated (closed), the instrument is used to grasp a dressing which is being applied orally.
35420	Tweezers, <specify>	0	10	A hand-held instrument having two spring-loaded jaws. When these are approximated (closed), the instrument is used to grasp an object. The shape of the jaws may be pointed, rounded or flat, according to the intended purpose for which the instrument is designed.
35079	Forceps, <specify>	0	9	A surgical instrument designed with two blades, which are closed upon the object to be held. The handles may be permanently joined together (pivoted as a pinsett, tweezers or scissors) or conjoined, usually by pressure, during use, e.g. some kinds of obstetric forceps.
39186	Forceps, articulation paper	31813	0	
11775	Forceps, biopsy	0	0	A scissors-like, ring handled surgical instrument whose blades distal to the pivot point are extended in length. The distal tip is specially designed to remove samples of tumours or other tissues to enable analysis.
15670	Forceps, bone	0	0	A surgical instrument with strong blades and teeth used for grasping, cutting, or crushing bone.
38791	Forceps, dental, <specify>	0	17	A hand-held dental instrument used in the mouth for different gripping applications.
35851	Forceps, dental, rubber dam clamp	0	0	A dental instrument used to apply and remove rubber dam clamps.
35552	Forceps, dental, tooth extraction	0	0	A dental instrument shaped like a kind of pincers for the extraction of teeth.
32136	Forceps, disconnect	35079	0	
39187	Forceps, dressing, dental	31814	0	





Thank you .....



.....Time for Questions

