

G.M.D.N
GLOBAL MEDICAL DEVICES
NOMENCLATURE

REPORT ON CURRENT SITUATION

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G.M.D.N

A NOMENCLATURE OF APPROX 15,000 TERMS



GENERIC TERMS TO IDENTIFY DEVICES



G.M.D.N

APPROXIMATELY 7000 PRIMARY TERMS + DEFINITIONS

APPROXIMATELY 1000 TEMPLATE TERMS + DEFINITIONS

APPROXIMATELY 7000 SYNONYMS



G.M.D.N

FOR USES INCLUDING:

**GENERIC DESCRIPTORS FOR EXCHANGE OF
INFORMATION IN VIGILANCE INVESTIGATIONS
(INCIDENT REPORTS)**

**FOR DATA EXCHANGE BETWEEN PUBLIC AUTHORITIES
AS A BASIS FOR E-COMMERCE – AS GENERIC
REFERENCE FOR MORE DETAILED MANUFACTURER
MODEL-SPECIFIC INFORMATION.**

**(USED FOR INVENTORY, PURCHASING, TRACEABILITY
PURPOSES)**



THE STANDARD

**EN/ISO 15225 – STRUCTURAL SYSTEM FOR
NOMENCLATURE**

THE NOMENCLATURE

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

BOTH REPORTS PUBLISHED 1ST NOV. 2001



**G.M.D.N
MAINTENANCE AGENCY**

**COPY-RIGHT OF ORIGINAL ENGLISH
VERSION OF NOMENCLATURE
ADMINISTERED BY: -**

M.A.P.G



M.A.P.G

**GROUP COMPRISES NOMINATED
REPRESENTATIVES FROM:**

THE EUROPEAN COMMISSION (EC)

FEDERAL DRUG ADMINISTRATION (FDA)

**MINISTRY OF HEALTH & WELFARE (MHLW) –
JAPAN**

GLOBAL HARMONISATION TASK FORCE (GHTF)

UP TO 5 EXPERTS – CEN

UP TO 5 EXPERTS - ISO



M.A.P.G

APPOINTS SECRETARIAT TO DISTRIBUTE GMDN
PREPARES LICENCE AGREEMENTS FOR THOSE
WISHING TO USE NOMENCLATURE

CONSULTS WITH REGULATORY BODIES –
SUBSEQUENT ENDORSEMENT OF SELECTED BODY
TO TRANSLATE AND DISTRIBUTE FOR OTHER
LANGUAGE VERSIONS

SETS APPROPRIATE FEES FOR LICENCE TO USE
NOMENCLATURE FOR COMMERCIAL PURPOSES

INVITES VOLUNTARY SPONSORSHIP FROM
REGULATORY BODIES



PROGRESS OF MAPG

HAS ESTABLISHED EXPERT GROUP TO ACTION
THE MAINTENANCE PROCESS (CHANGE TERMS-
CORRECT TERMS – ADD NEW TERMS)

DRAFTED LICENCE AGREEMENTS AS NEEDED

FOR: - MANUFACTURERS

REGULATORS

CONFORMITY ASSESSMENT BODIES

SOFTWARE SUPPLIERS

OTHERS



PROGRESS OF MAPG CONTINUED.

- DISCUSSED WITH REGULATORY AND OTHER BODIES THE USE OF GMDN AS BASIS FOR E-COMMERCE ETC.
- ARRANGING FOR MODIFIED DATA BASE TO BE OPENED FOR CONTROL OF NOMENCLATURE DEVELOPMENT
- DISCUSSIONS WITH WHO TO ENCOURAGE GLOBAL USAGE OF GMDN FOR ALL MEDICAL DEVICE REGULATORS



PRESENT WORK OF MAPG

QUESTIONS

- Finalising licence documents -
- Information on costs -
- When can I order? -
- How? -
- Expert Group-Update Nomenclature -
- Any Problems? -
- Links with other Base Nomenclatures- -
- Instructions for use of GMDN -
-
- Translations of GMDN-Endorsement-

ANSWERS

- June 2002
- Mostly available now
- Contact Secretariat
- Order Form Available
- Finalising Data-Base for this purpose
- Especially Costs
- Mostly Available
- Summary supplied with Licence.
- Full Manual being completed
- Document under Preparation

