Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

GMDN UPDATES, 2024

CHINANISO MAJONI, SENIOR NOMENCLATURE DEVELOPER & QUALITY LEAD

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28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

Global Harmonization Working Party
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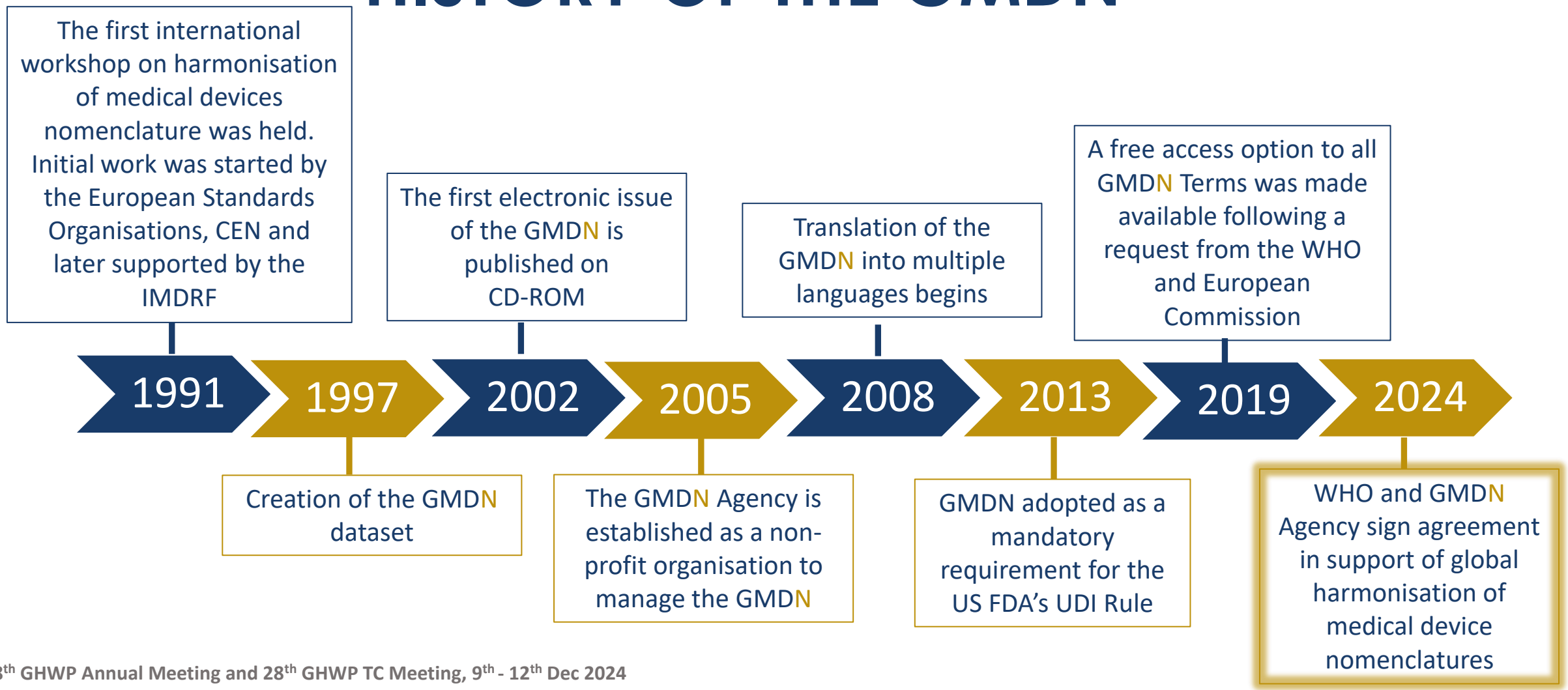
HISTORY OF THE GMDN



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Global Medical Device Nomenclature (GMDN)

A NON-PROFIT CHARITY

Name and Group All Medical Devices

- Well-defined mutually-exclusive concepts
- Grouping at many levels of granularity
- Up-to-date
- Trainings and Term Enquiry service for all users

Access to GMDN

- Register to GMDN, become a Member
- Free access for all Regulators/Governments, Healthcare Providers/Hospitals https://www.gmdnagency.org
- Membership options (incl. free of charge) are available

Globally Recognised and Independent

- ~12,000 users
- >70 Regulatory systems
- Users in >145 countries
- UDID used since 2013 (FDA's GUDID).UDI programs: US, UK, AU, CA, BR, CO
- Self-funded, independent, guided by Regulators

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GLOBAL REACH

NATIONAL REGULATORS/GOVERNMENT DEPARTMENTS WITH GMDN MEMBERSHIP (AS OF NOVEMBER 2024)

NORTH AMERICA
- Canada
- Mexico
- United States

EUROPE
- Belgium
- Bosnia and Herzegovina
- Czech Republic
- Denmark
- Estonia
- France
- Germany
- Iceland
- Ireland
- Netherlands
- Norway
- Portugal
- Serbia
- Slovakia
- Slovenia
- Switzerland
- Ukraine
- United Kingdom

ASIA
- Armenia
- Azerbaijan
- Bahrain
- Bhutan
- India
- Iran
- Japan
- Kazakhstan
- Kuwait
- Kyrgyzstan
- Lebanon
- Malaysia
- Mongolia
- Mordovia
- Oman
- Pakistan
- Russia
- Saudi Arabia
- Singapore
- South Korea
- Thailand
- Turkey
- Uzbekistan
- Vietnam

SOUTH AMERICA
- Argentina
- Brazil
- Chile
- Colombia
- Cuba
- Ecuador
- El Salvador
- Guyana
- Honduras
- Peru
- Uruguay

AFRICA
- Burkina Faso
- Botswana
- Egypt
- Eritrea
- Ethiopia
- Ghana
- Kenya
- Mozambique
- Nigeria
- Rwanda
- South Africa
- Sudan
- Tanzania
- Uganda

OCEANIA
- Australia
- New Zealand

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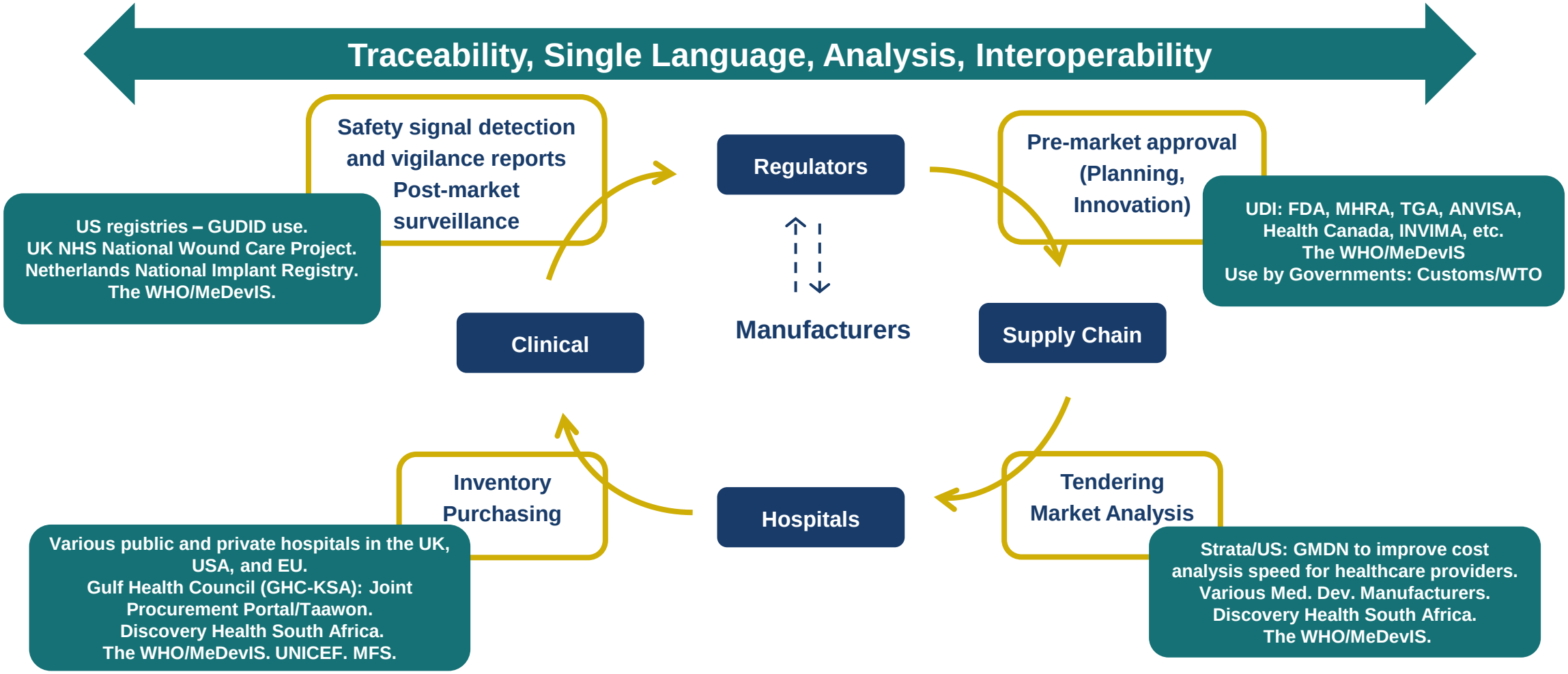
USE CASES



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US FDA GUDID

GMDN Code and status now visible on every GUDID entry.

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Supera™
Version or Model: S-70-060-120-P6
Commercial Distribution Status: In Commercial Distribution
Catalog Number: S-70-060-120-P6
Company Name: ABBOTT VASCULAR INC.
Device Description: Supera™ Peripheral Stent System 7.0 mm x 60 mm x 120 cm 6 F

Primary DI Number: 08717648344268
Issuing Agency: GS1
Commercial Distribution End Date:
Device Count: 1
Labeler D-U-N-S® Number*: 964569052 *Terms of Use

CLOSE

DEVICE CHARACTERISTICS

GMDN [?]

GMDN© Term Code, Names and Definitions (*Terms of Use): **GMDN®** is a registered trademark of The GMDN Agency. All rights reserved. Used under licence from The GMDN Agency Ltd.

GMDN Term Code	GMDN Term Name	GMDN Term Definition	GMDN Term Status [?]	Implantable?
47932	Peripheral artery stent, bare-metal	A non-bioabsorbable tubular device intended to be implanted in a peripheral artery (excludes aorta, coronary, and intracranial arteries) to indefinitely maintain patency and improve luminal diameter in patients with atherosclerotic disease, or following the recanalization of a total occlusion. It may additionally be intended to be implanted in an obstructed biliary duct; it is not dedicated to carotid artery implantation. The stent is made entirely of metal [e.g., nickel-titanium alloy (Nitinol) mesh structure] and is typically implanted by a dedicated instrument where it self-expands upon release or is balloon expanded.	Active	true

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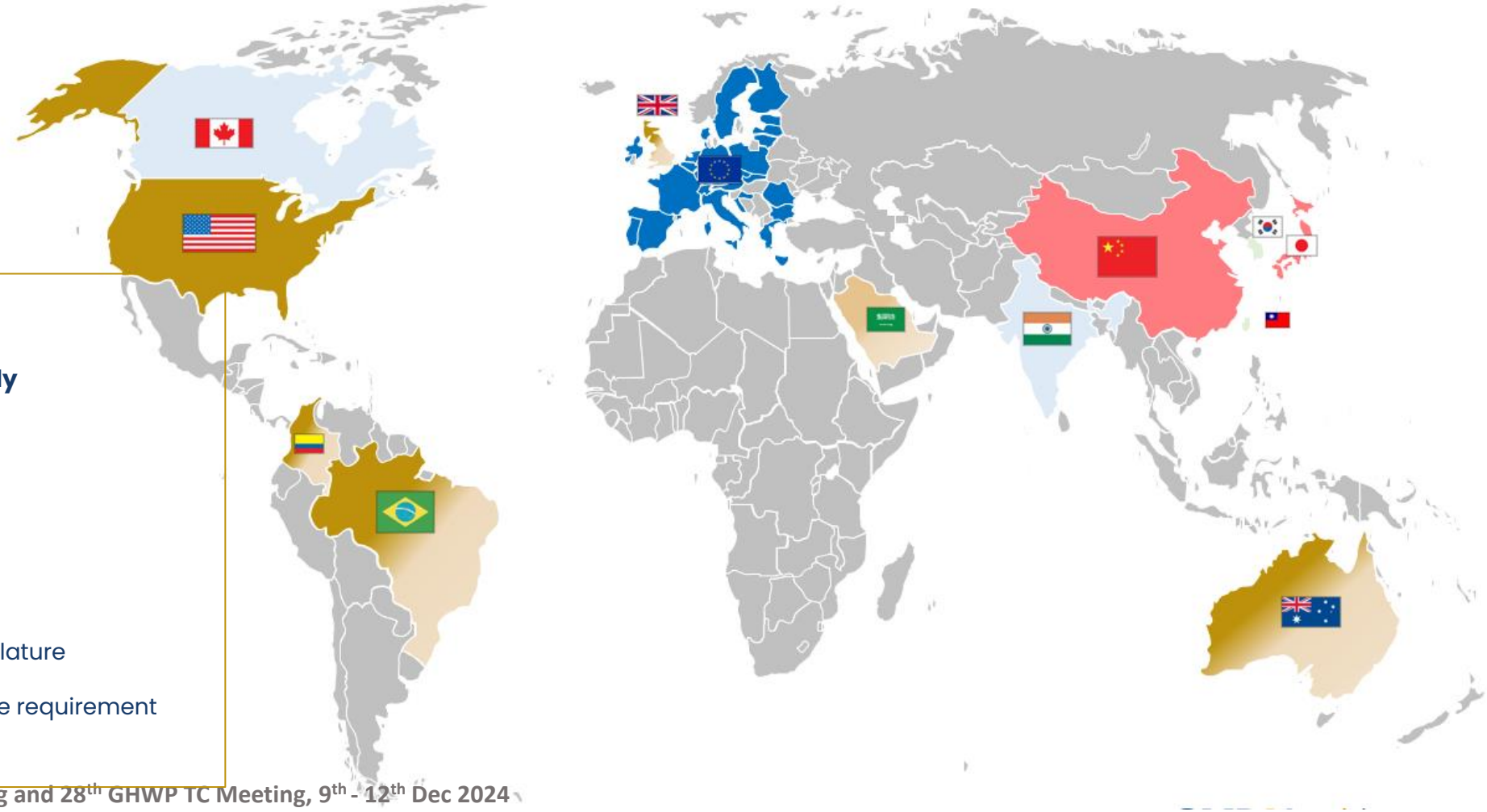
GLOBAL UDI DATABASES AND NOMENCLATURE REQUIREMENTS



Mature UDI
USA – GMDN

UDI in development/early implementation
UK – GMDN
Brazil – GMDN
Colombia - GMDN
Australia – GMDN
Saudi Arabia – GMDN
European Union - EMDN
China - Other
Japan - Other
South Korea – no nomenclature requirement
Taiwan – no nomenclature requirement
Canada – TBC
India - TBC

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WHO & GMDN COLLABORATION - MEDEVIS

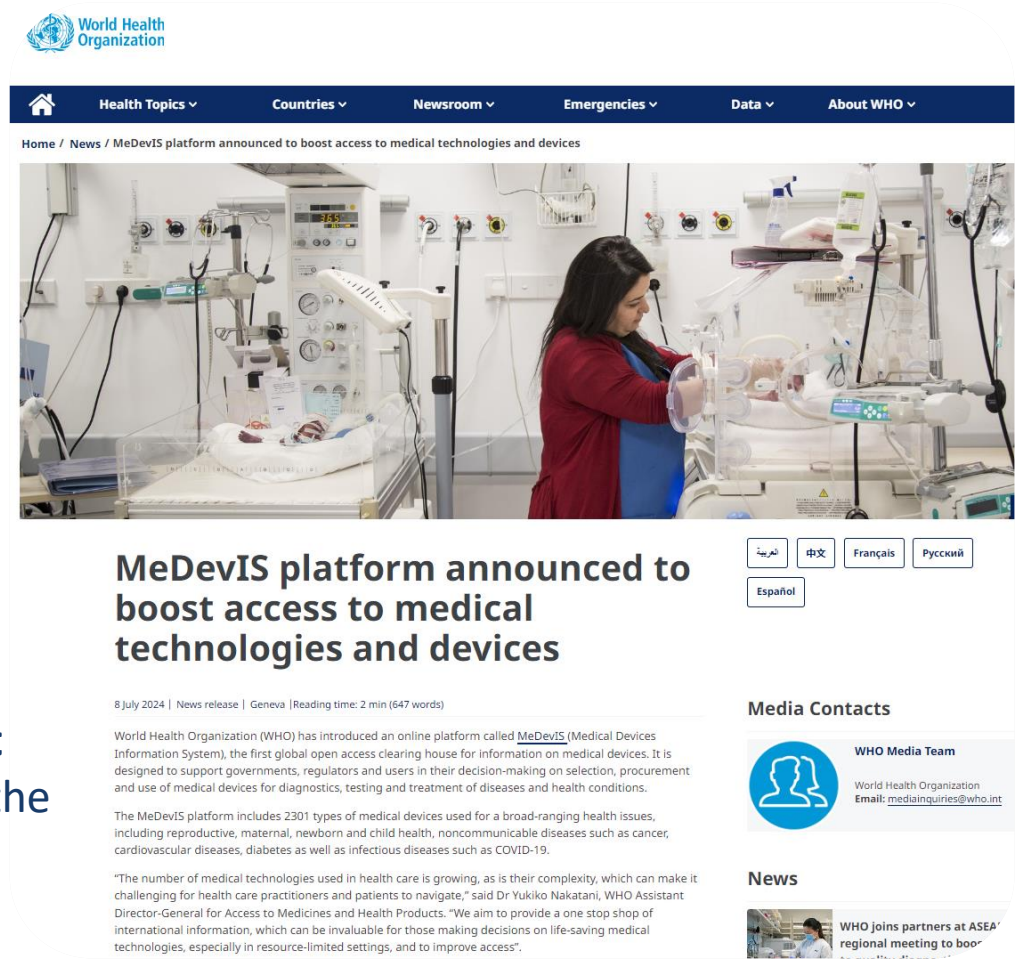
Use of GMDN Terms, Codes and Definitions within MeDevIS, including:

- Priority Medical Devices List
- Essential Diagnostics Lists (EDL)

GMDN providing support to WHO through:

- Consultation
- Database management
- Data analysis
- Any WHO platforms/publications that reference GMDN

With the aim of **supporting access** to medical devices and **patient safety, improving communication** about medical devices within the health sector, for **public health benefit.**



GHC – JOINT PROCUREMENT PROGRAM

New folderivucdsq | Google | Taawon Portal | Taawon Procureme... | MenaME - ... خدمات ا | LIMIT Clause | Muscat Stock Excha... | ...منصة تعاون التحريب | KSA Numbers - ...بح

Download ··· Tender Schedule 2024.pdf Info 1 / 1

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

جدول مناقصات برنامج الشراء الموّحد الخليجي لعام 2024م

Tenders Schedule of Gulf Joint Procurement Program for the Year 2024

Tender	التكميلي Supplementary Committee	البت والترسية Award Committee	فتح المظاريف Bids Opening Committee	طرح المناقصة Invitation for Bidding	لجان تحديث الدليل والاعداد Updating Directory Committee	المناقصة
Oral & Dental	9 May	15-18 Apr	26-27 Mar	7 Feb	9-11 Jan	لوازم رعاية الفم والأسنان
Orthopedic & Spine	25 Jun	26-30 May	22-24 Apr	20 Feb	22-25 Jan	لوازم جراحة العظام والعمود الفقري
Medical Rehabilitation	30 Jun	2-6 Jun	28-30 Apr	20 Mar	18-21 Feb	لوازم التأهيل الطبي
Ophthalmology	13 Nov	20-24 Oct	29 Sep 1 Oct	21 Aug	22-25 Jul	لوازم العيون
Otorhinolaryngology, Head & Neck	28 Nov	3-7 Nov	15-17 Oct	4 Sep	5-8 Aug	لوازم الانف والأذن والحنجرة
Linens & Medical Uniforms					10-11 Jul	الملبوسات والكساوي الطبية
Laboratories Sundries					25-29 Aug	لوازم المختبرات الطبية
Veterinary Pharmaceuticals	19 Dec	24-26 Nov	10-12 Nov	1 Oct	2-5 Sep	المستحضرات البيطرية
Cardiovascular Sundries					8-12 Sep	لوازم جراحة القلب
Human Pharmaceuticals					8-12 Dec	المستحضرات الصيدلانية
Hospital Sundries & Renal Dialysis Supplies					22-26 Dec	لوازم تجهيز المستشفيات

WHY GMDN IS IMPORTANT FOR PUBLIC HEALTH PROGRAMMES?

What does GMDN offer?

Significant improvement in **traceability** increases safety and efficiency

Single language avoiding confusion

More detailed **analysis**

Interoperability

- Empowers the **public** and all stakeholders to **understand** their **medical devices**
- Supports strategic planning and oversight of global **access to medical devices** – Especially in developing countries
- **Enables interoperability,** linking medical device data across different health systems and stakeholders
- **Complements UDI**:
  - **Traceability** in-country and across jurisdictions
  - Enables **early signal detection** of medical device performance issues: **Category-level analysis**; it lets us understand **trends across categories**
  - Enables **data analysis** - pooling data from pre-market and post-market surveillance programs
  - Enables to **identify** the **right technology for the patient**
- Improves decision-making and **operational effectiveness**

Thank you!

Questions?

www.gmdnagency.org