Member States Information Session on Standardization of medical devices nomenclature

5th March, 2024

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World Health Organization

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Agenda

1. Why is nomenclature important?
2. Responding to Member States.
3. Searching a solution having 2 systems.

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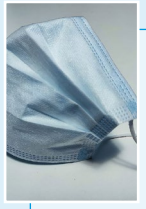
There are thousands of types of Medical devices… used at all levels of health care.

In vitro diagnostic, laboratory

Surgical instruments

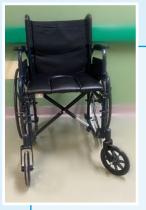
Implantable medical devices



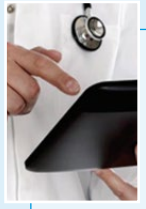
Some personal protective equipment

Medical equipment

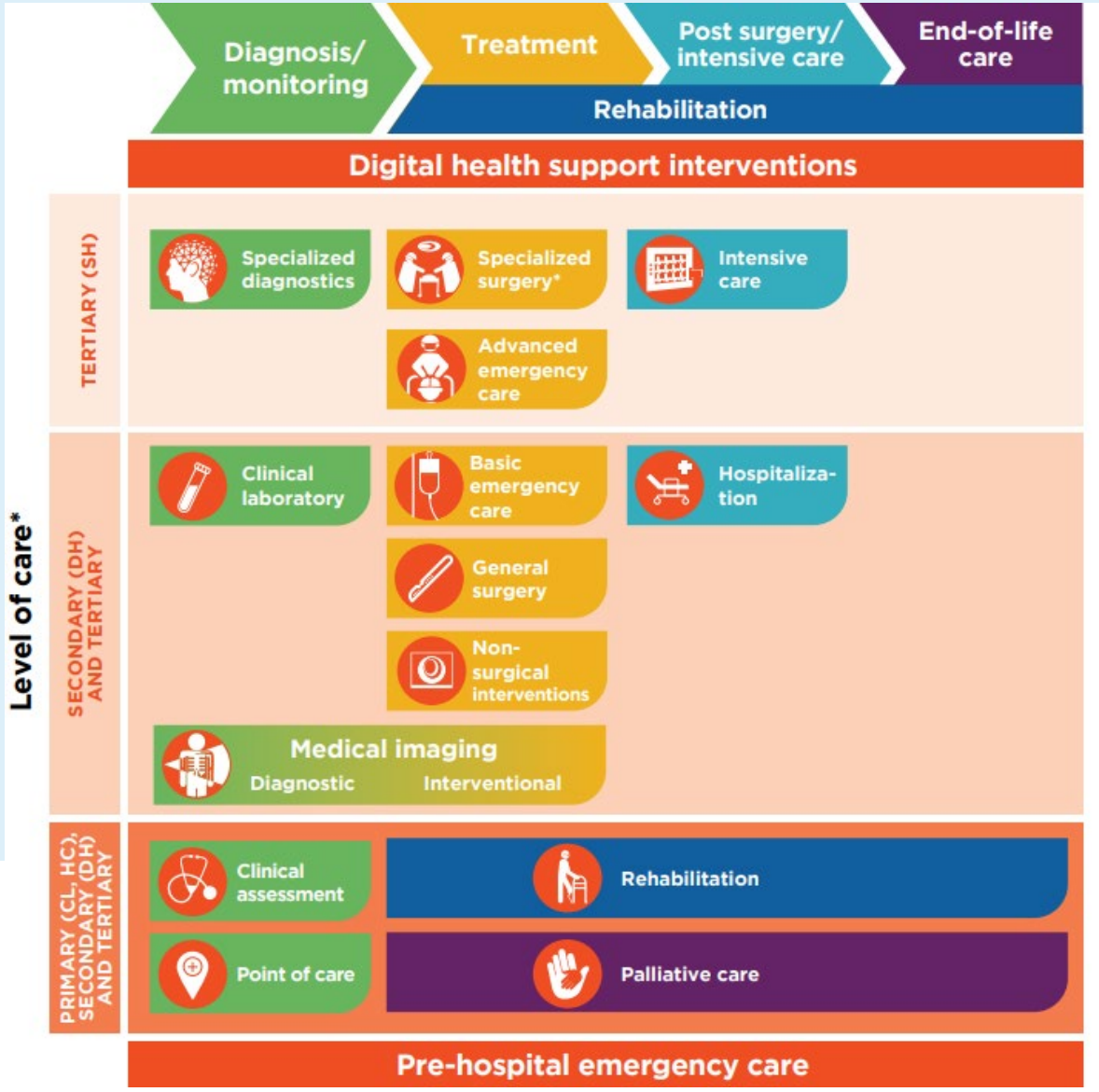
Single use medical devices



Some assistive devices



Software as medical device



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Harmonized Nomenclature improves access to safe, quality, affordable medical devices, towards increased quality of health care everywhere

R&D

Regulations

Assessment

Management

MD NOMENCLATURE

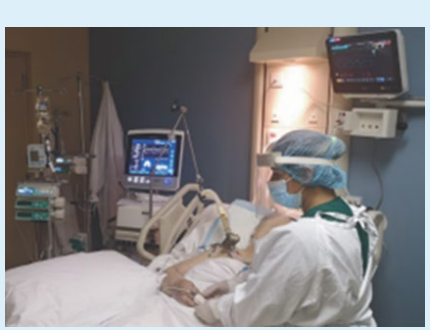
- **Academia and Industry**
- Manufacturing and trade

- **National Regulatory Agencies**
- Lists of approved MD for marketing in country.

- **MOH** (HTA): Selection of National Lists of MDs for reimbursement or procurement
- Health care benefit packages, national policies
- *(WHO Essential in vitro Diagnostics and Priority Medical Devices)*

- **Health care providers**
- Procurement, Installation, training, maintenance, safe use, operating costs
- Post-market surveillance and adverse event report
- Decommissioning, Replacement

Patient safety
Quality of health care



Save lives
Increase quality of life

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We have come a long way, uphill, approaching, but still not there… need to ensure everyone has access to naming system for medical devices, to avoid multiple developments

Med Devices Global Fora

- 2010 1st GFMD
- 2013 2nd GFMD
- 2017 3rd GFMD

2018

WHO principles: towards governance, transparent process, access as global public good

2019

- EB 145/3
- MS requested WHO **not** to develop yet another nomenclature but to work with the available ones.

2021

- EB 148/13
- 2021 WHA74
- 2021 Multiple consultations with nomenclature agencies MS, NGOs
- Member States update of Global Atlas of Medical Devices

2022

- EB150 **Decision EB150(10)**
- 2022 Consultations and pilot mapping EMDN- GMDN- UMDNS- UNSPSC
- 2022 WHA75 **Decision WHA75(25)**
- Upon request Of some MS, use of EMDN codes and terms in WHO publications and electronic platforms

2023

- EB152
- Cross reference EMDN- GMDN
- Work with GMDN upon request of some Member States during WHA and EB.
- 2023 WHA76

2024

- Agreement WHO with GMDN towards open policy access.
- Addition of GMDN terms, codes and definitions in WHO platforms. (2500 types of devices)
- **MS info session 5th March 2024.**

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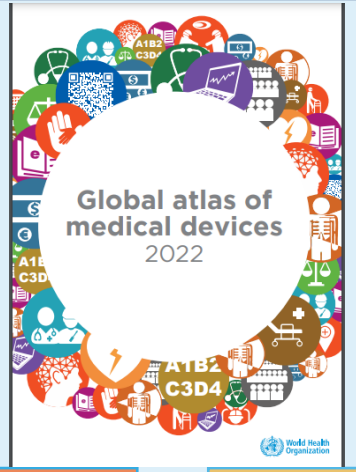
Decision approved 28 May 2022 in WHA 75 on Standardization of medical devices nomenclature: WHA75(25)

- Member States request to the Director General:
- to integrate **available** information related to medical devices, including **terms, codes, and definitions**, in the web-based database and clearinghouse established in line with resolution WHA60.29 (2007) and now available as the Medical Devices Information System (MEDEVIS); and to **link this to other WHO platforms**, such as the International Classification of Diseases, (ICD-11) to serve as a reference to stakeholders and Member States;
- (2) to submit a substantive report on progress made in implementing this decision to the Executive Board at its 152nd session in January 2023, and **its 156th session in January 2025**

Medical Devices Nomenclature systems most used.



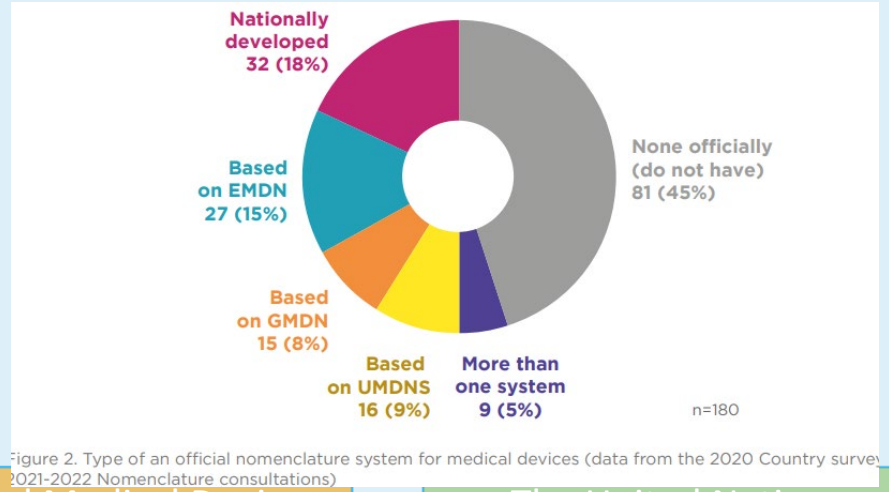


Figure 2. Type of an official nomenclature system for medical devices (data from the 2020 Country survey 2021-2022 Nomenclature consultations)

European Medical Devices Nomenclature (EMDN)

- Last update September 2021.
- ongoing public consultation until March 2024.
- Has free access of information for everyone.
- Governed by MDCG.
- Anyone can comment.

Global Medical Devices Nomenclature (GMDN),

- Continuous updates
- About 25,000 codes
- Requires membership and the system and accepts licence.
- Free for some, including governments and public health providers.

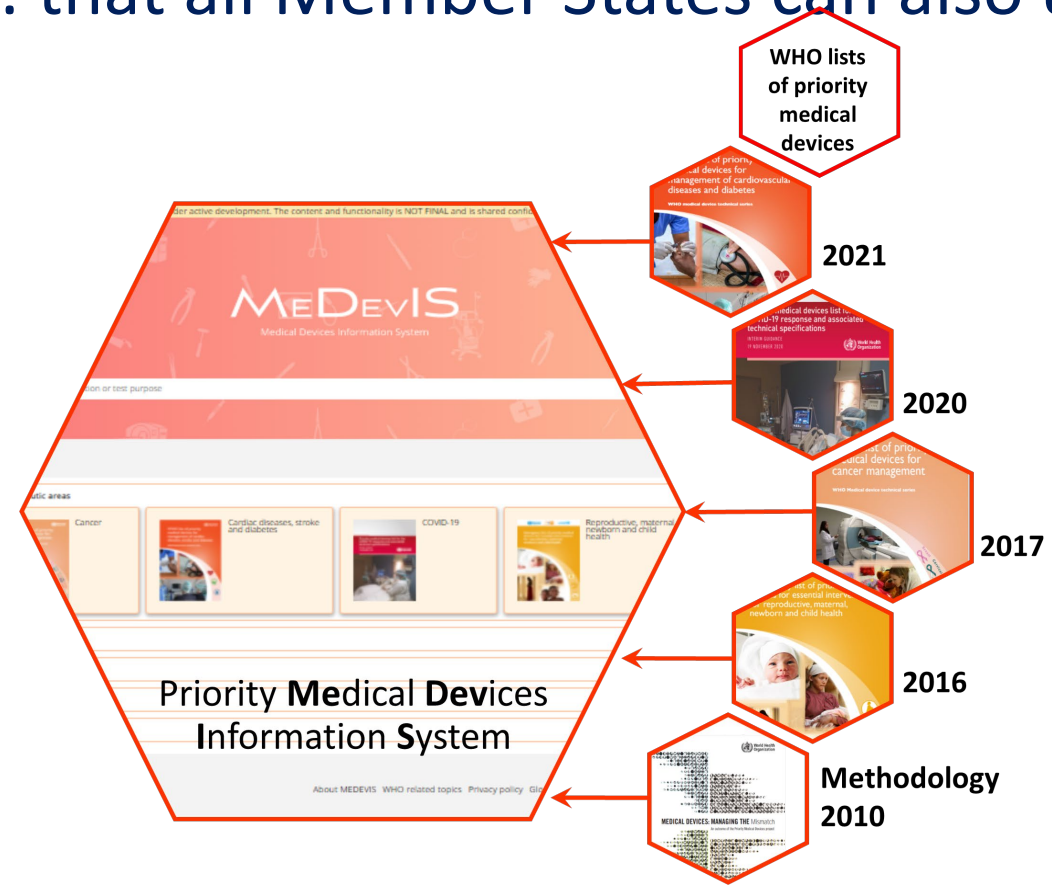
Universal Medical Devices Nomenclature System (UMNDS),

- Monthly updates.
- About 43,000 terms
- Requires that user registers in their system and accepts licence.
- Not free
- Mostly used in hospitals for health technology management

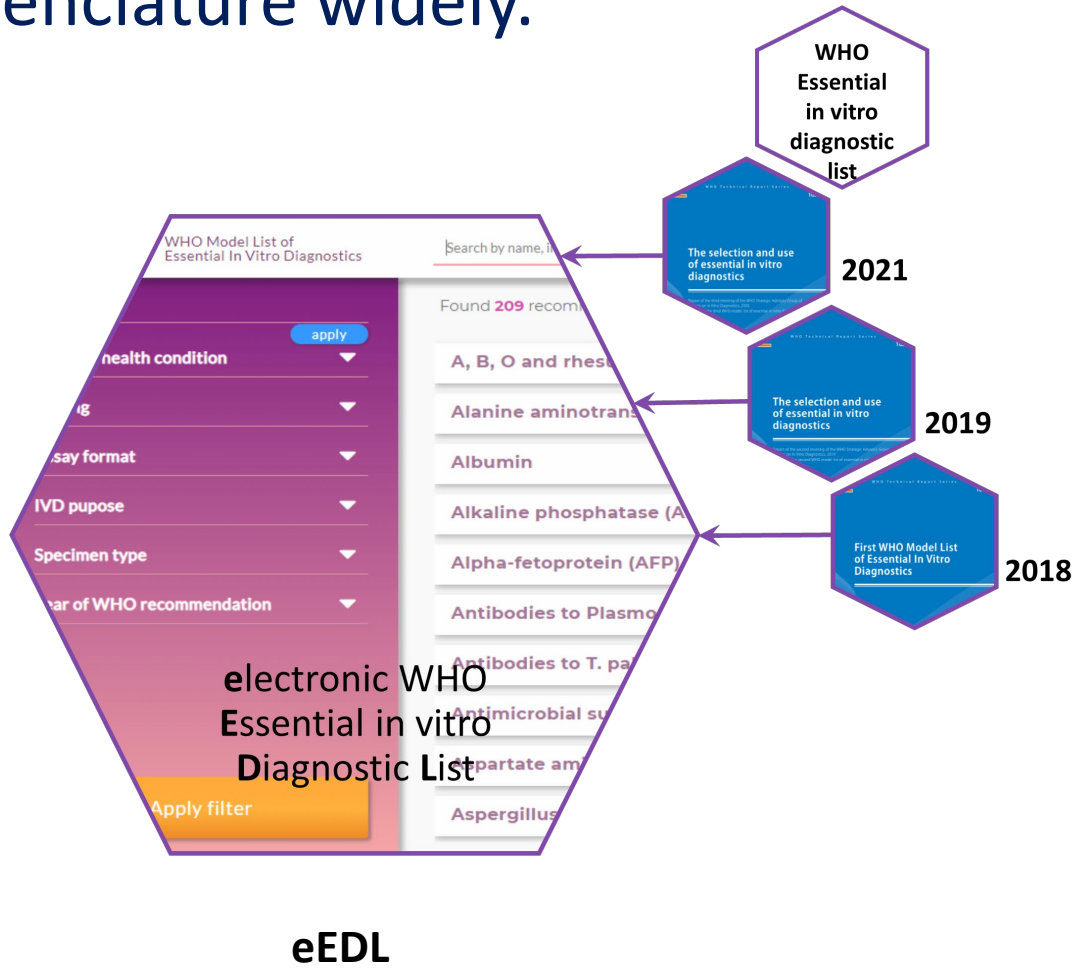
The United Nations Standard Products and Services Codes (UNSPSC),

- includes medical devices plus other multiple types of products and services.
- Mostly used for procurement.
- UNGM.

Goal:1. to include naming, codes, definitions in all WHO publications and electronic platforms, for public reference and
2. that all Member States can also use nomenclature widely.



MeDevIS



eEDL

https://medevis.who-healthtechnologies.org/

Mapping process and results

- **Goal:** 5,200 EMDN-GMDN pairs
- **Source**: initially: AccessGUDID and EUDAMED
- **Time:** 7 months (finalize September 2023)
- **Method applied**: Automatic matching tools, similarity of term/definitions
- **Final result**: 7,500 pairs (table available to MS only as reference)
- **Challenges:** Multiple:
  - The continuous updating of the GMDN nomenclature code/terms, unless it continues in real time with everyone's collaboration.
  - Unable to perform automated creation of EMDN-GMDN pairs using UDI system as a source.
  - It is possible to establish relationships between nomenclatures, even though the different granularity of the nomenclature, but it would not be one to one.

Collaboration with EMDN 2023.

Meetings Medical devices policy officers EC to:

Agree on the use of the EMDN codes and terms in all WHO publications.

- Shared the outcomes of the mapping exercise and challenges faced.

Q3

EMDN codes and terms were added to all the WHO Priority Medical Devices and in Medevis,

with the corresponding disclaimer

and link to the EMDN page.

28 September

Presented the status of work on nomenclature to the IMDRF management committee, upon request of the EC as chair.

22 November

WHO presented update to The EC Medical Devices Coordination Group (MDCG-NOM) and agree to future collaboration.

WHO provide input to MDCG NOM, on annual revision

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Collaboration with GMDN 2023-24

Meetings to share concerns and define collaboration

- March to December 2023
- Definition of technical and legal aspects
- Scope

Agreement:

- Licence open access, noncommercial, for publicly available information, reached February 2024.
  WHO adding disclaimer and link to GMDN website.

The scope:

- Terms, codes and definitions of the WHO selected medical devices.
- 1. WHO model list of essential in vitro diagnostics
- 2. WHO Priority Medical Devices lists, other associated subsets.
- 3. WHO would not publish the whole GMDN list

Funding:

- Financial compensation to GMDN for the management of 3,000 initial codes, annual expansion.

License of MeDevIS, using Creative commons non commercial was agreed to host the GMDN codes, terms and definitions.

Status of nomenclature (terms and codes) of medical devices (22 February)
Outcomes of mapping has been shared with the 3 agencies (EMDN, GMDN, UMDNS).

WHO-EMDN

- Codes and terms already used in all WHO MeDevIS data since 2023.

WHO- GMDN

- Inclusion of codes, terms and definitions in WHO MEDEVIS (tests in February 2024)
- Approval for WHO open access, using Creative Commons non commercial licence.

WHO- UMDNS

- **In pause.**
- ECRI still does not have a publicly available nomenclature system

WHO- UNSPSC

- WHO secretariat will contact in Q3. 2024.
- They are interested.

The way forward, by WHO in 2024

- Organize consultations and monthly webinars*
- With the agreements achieved place codes, terms and definitions in WHO resources and make them publicly available.
- Use the nomenclature systems for any new device added in WHO Lists and publications.
- Continue collaboration with EMDN and GMDN to support MS, co-existing as the measurement system…

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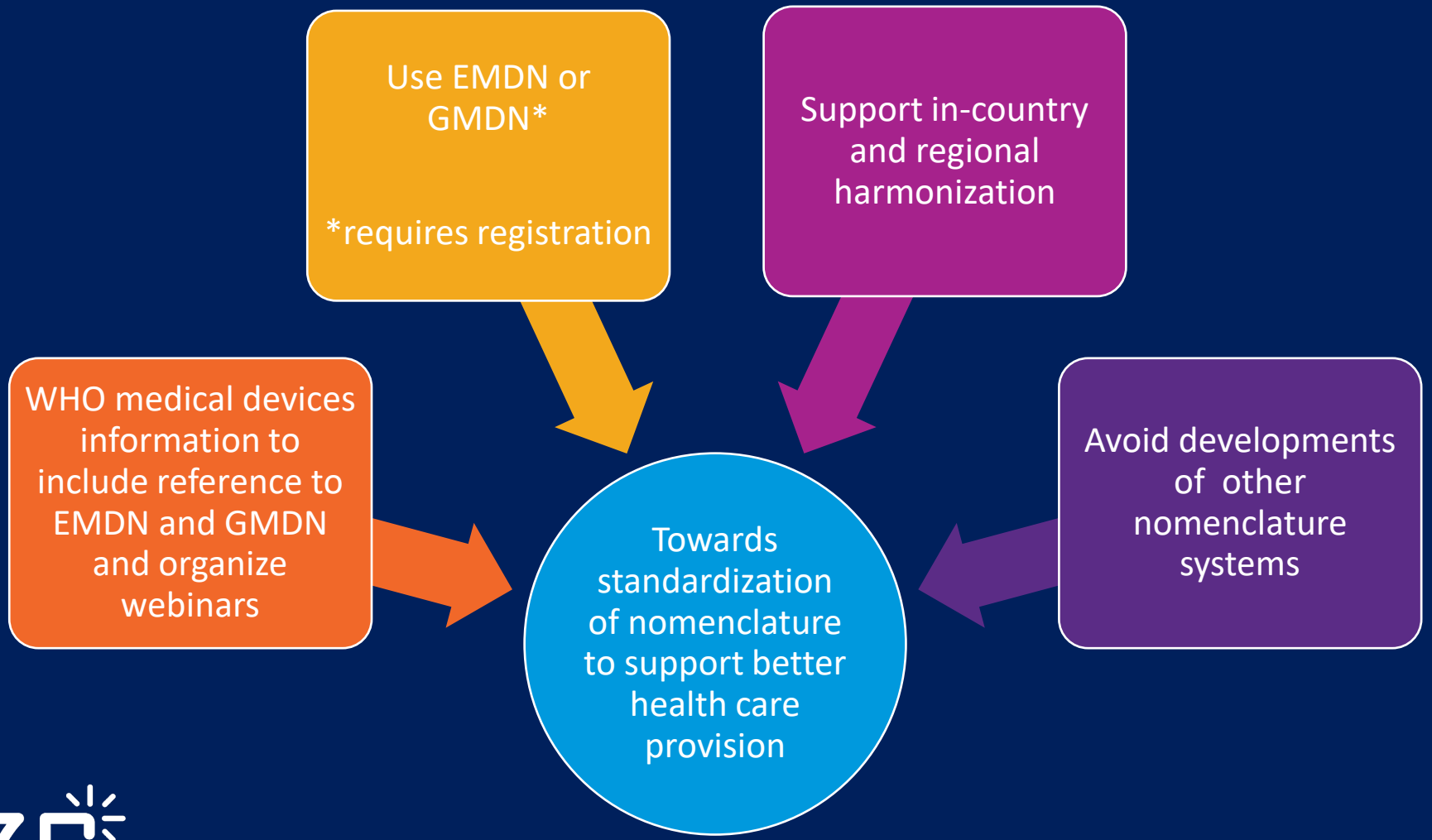
Next steps: Proposal to have monthly webinar on nomenclature of medical devices

1. When? First Tuesday of every month at 13:00 CET to be available to all countries.
Webinar, in Teams, open to all participants

3. **Who?** Member States, NGOs, nomenclature agencies, etc..

4**. What?** Nomenclature use cases, lessons learned and challenges, examples:
April: WHO tools, EMDN, GMDN
May: Ministries of Health, policies, national lists
June: Regulatory agencies: registration, to post market surveillance
July: Procurement and supply management, NGOs and humanitarian agencies
August: UDI, unique device identifier
September: At facility level: inventories, maintenance, CMMS
October: HS, harmonized code, WCO,
November: Med tech industry
December: creation of communities of practice

Way forward: Nomenclature of medical devices



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Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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WHO

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Medical devices website:
https://www.who.int/health-topics/medical-devices#tab=tab_1

Comparison of EMDN and GMDN vs. WHO principles (Feb 24)

	WHO Principles medical devices nomenclature	EMDN	GMDN
•Governance	1.Organizational and review structures should be in place to ensure that all stakeholders from different regions are able to provide feedback according to global needs.	MDCG, EC, and website	GMDN agency with their advisory groups and members only
•Classification, coding and nomenclature characteristics	1. a transparent methodology and processes;	Open website	For members only
	1. a transparent mechanism for regular updates (e.g. once per year);	open to input from all stakeholders	Continuous update and for members only
	1. hierarchies grouped into categories and subcategories to meet stakeholder needs;	Yes	Yes
	1. medical devices used outside highly regulated countries;	Yes	Yes
	1. mutually exclusive terms;	Yes	Yes
	1. availability of terms in other languages	In process	Yes
•Access to information	1. be capable of being referenced and used by regulators, procurers, managers and all users of medical devices (hospitals/health care workers and patients);	Yes	Yes for internal institutional use, publicly limited to licence
	1. be freely available and considered a global public good;	Yes	Limited
	1. support unique device identifier system;	Yes	Yes
	1. be accessible through simple and intuitive search;	Yes	Yes
	1. be available for use in all health-related data base systems.	Yes	Limited to licence
More information	https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature	https://webgate.ec.europa.eu/udi-helpdesk/en/other-relevant-information/emdn-codes.html	https://www.gmdnagency.org/

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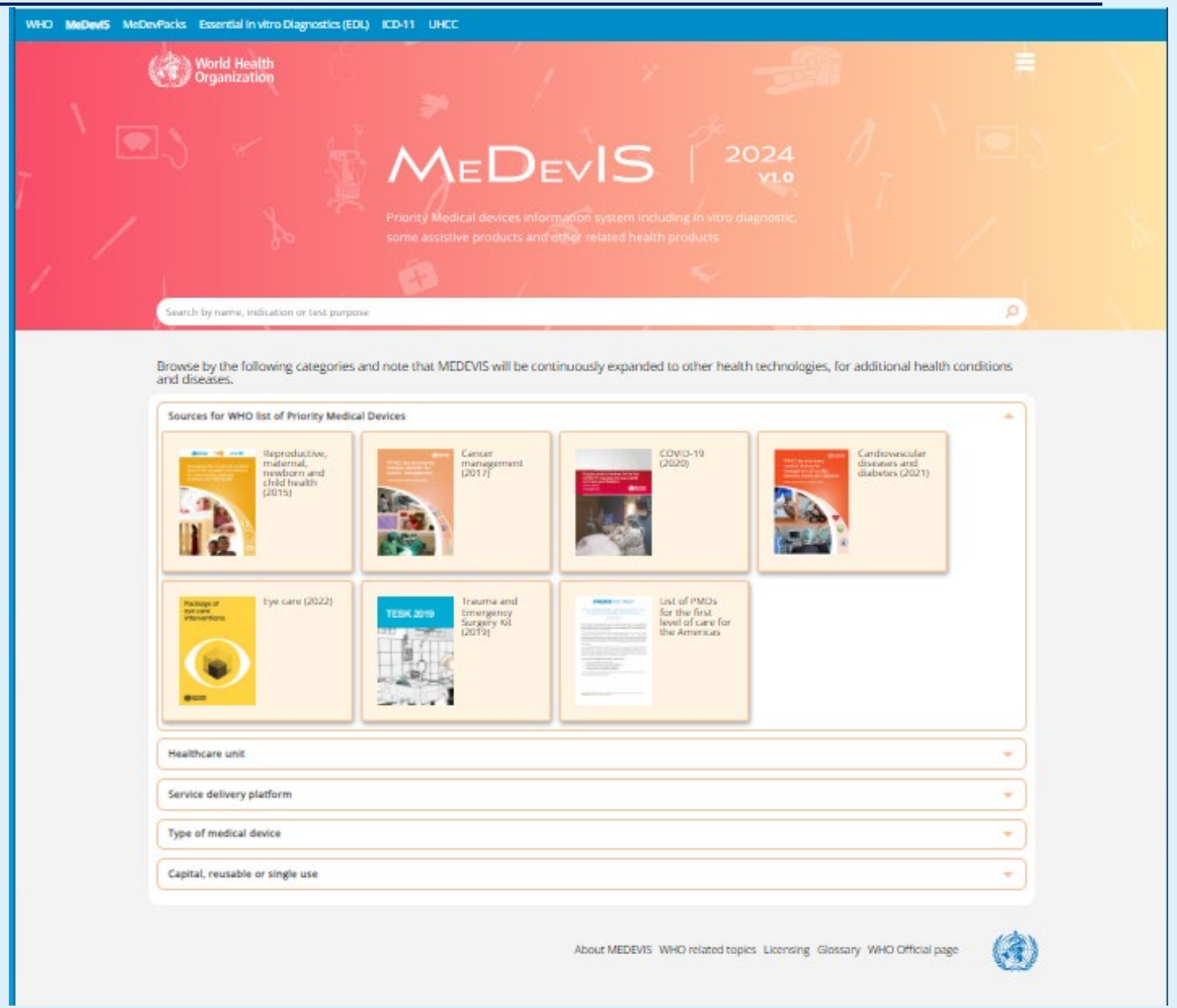
Background

- The World Health Assembly Report by the Director-General WHA75/11 and the Decision WHA75(25).
- The Executive Board report EB152/11
- The WHA76 Consolidated report by the Director General, section 13.7
- The WHA76 - Committee A, twelfth session, on 27/05/2023, 09:15-11:30 hrs. webcast MS discussion, including Dr. Nakatani's ADG Access to Medicines to Medicines and Health Products.

Additional complementary slides 5th March 2024

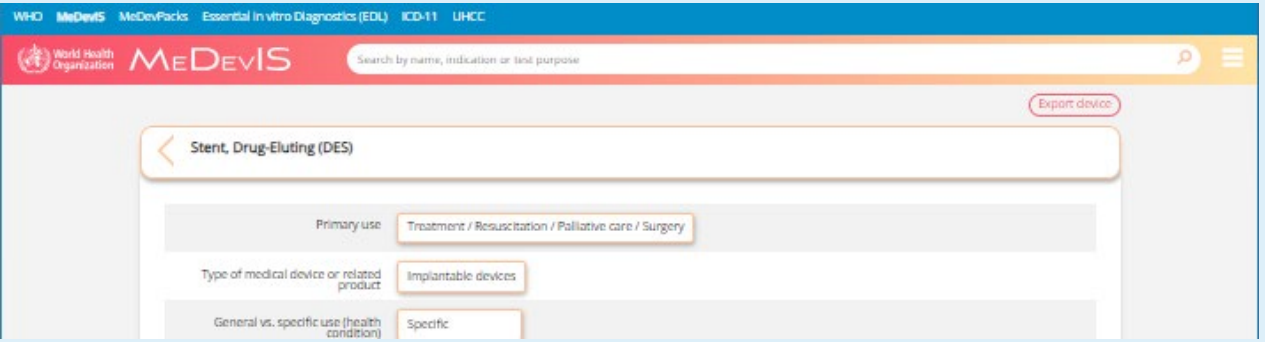
MeDevIS, 2024 v 1.0
is being released today.

As per decision WHA75(25),
"to integrate available information related to medical devices, including terms, codes, and definitions, in the web-based database and clearinghouse…"



https://medevis.who-healthtechnologies.org/

Including EMDN and GMDN codes, terms, disclaimer, link to their website.



EMDN related code(s)

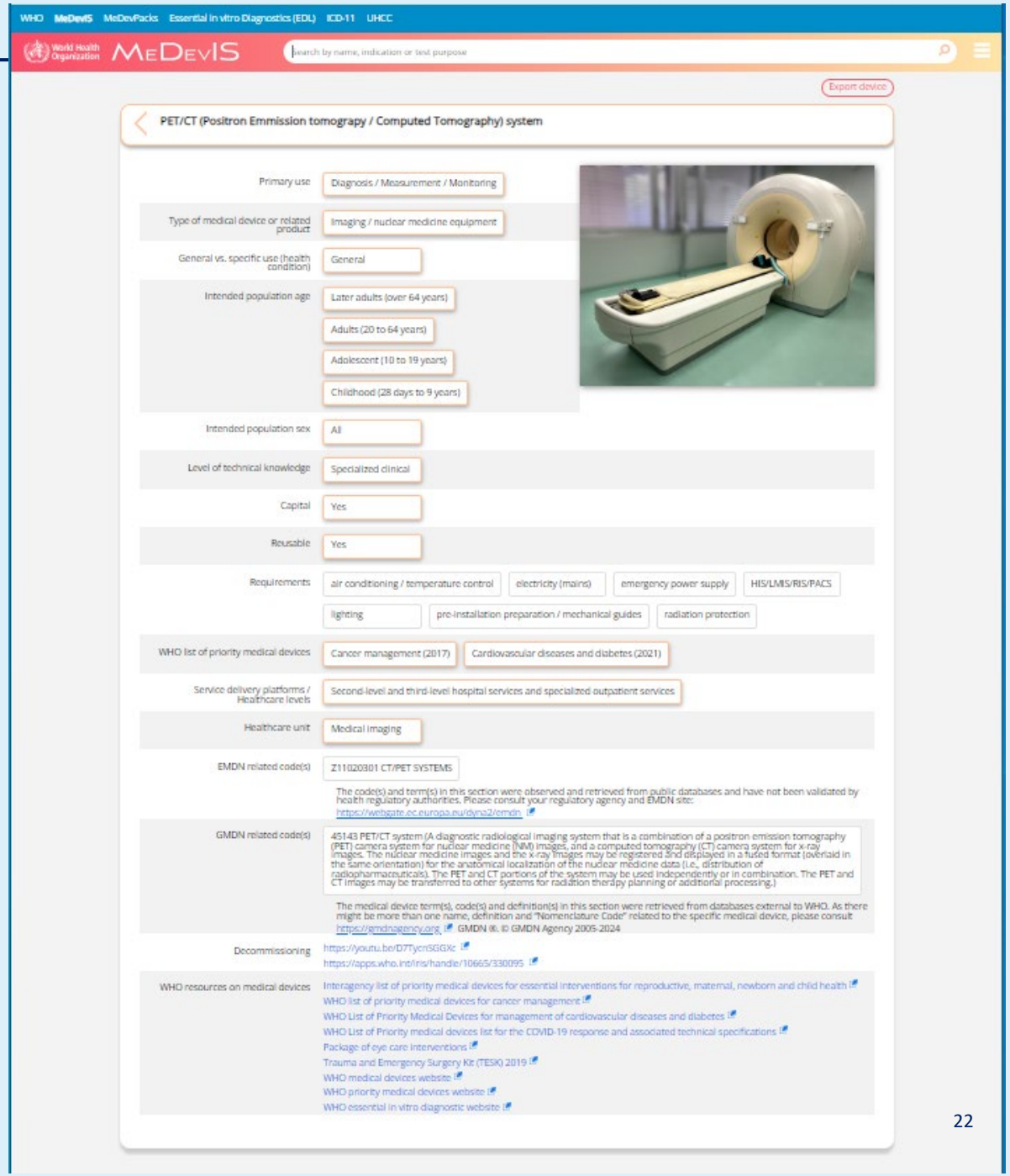
P0704020103 CORONARY DRUG ELUTING STENTS (DES)

The code(s) and term(s) in this section were observed and retrieved from public databases and have not been validated by health regulatory authorities. Please consult your regulatory agency and EMDN site:
https://webgate.ec.europa.eu/dyna2/emdn

GMDN related code(s)

56304 Drug-eluting coronary artery stent, fully-bioabsorbable (A bioabsorbable tubular or coil-shaped device with a drug coating intended to be implanted, via a delivery catheter, into a de novo or restenotic native coronary artery during a percutaneous coronary intervention (PCI) to temporarily maintain its patency, typically in patients with symptomatic atherosclerotic heart disease. The drug coating is intended to inhibit restenosis by reducing vessel smooth muscle cell proliferation. The device is made of a material capable of being degraded and absorbed by body tissues (e.g., bioabsorbable polymer) and is designed to remain in the vessel to provide support for the stenosed lesion until it degrades.)

The medical device term(s), code(s) and definition(s) in this section were retrieved from databases external to WHO. As there might be more than one name, definition and "Nomenclature Code" related to the specific medical device, please consult
https://gmdnagency.org GMDN ®. © GMDN Agency 2005-2024



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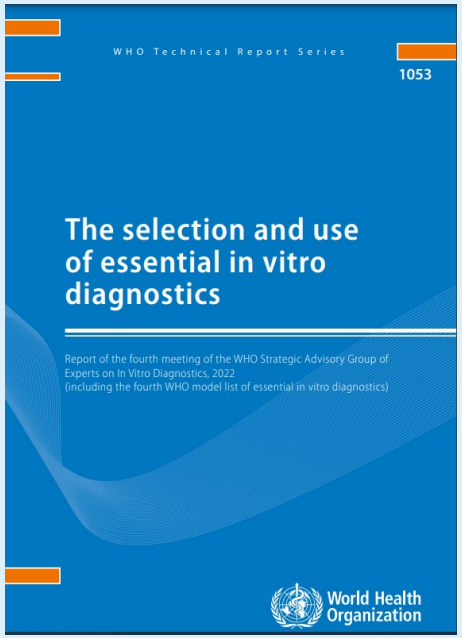
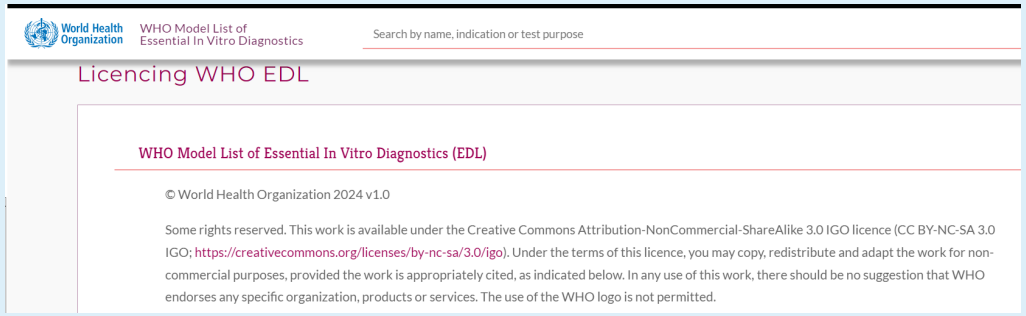
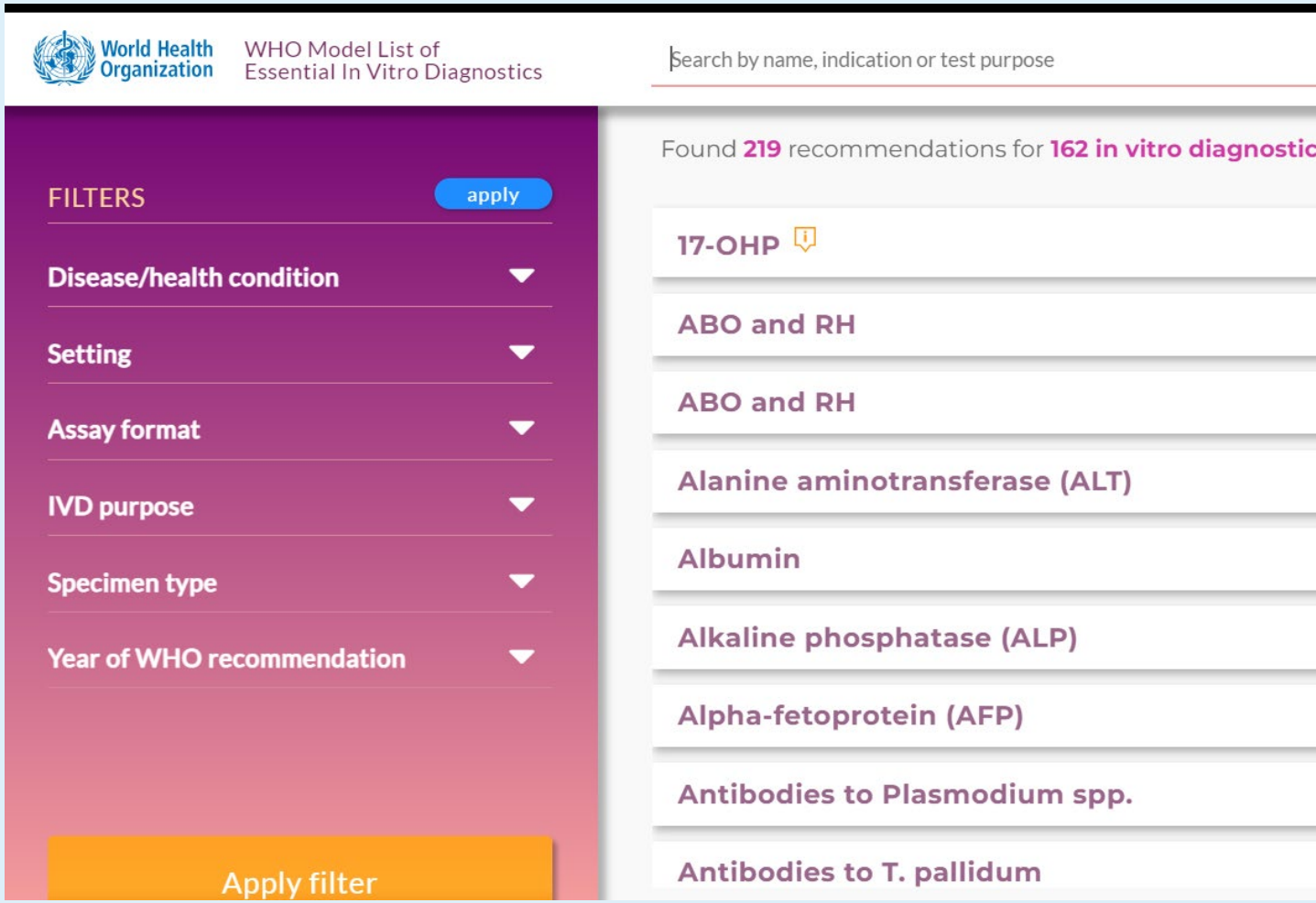
4th WHO model list of Essential in vitro diagnostic (EDL) is included in eEDL 2024, v 1.0







https://www.who.int/publications/i/item/9789240081093

https://edl.who-healthtechnologies.org/

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4th Essential in vitro diagnostic list is being classified with EMDN and GMDN codes. Work in progress.

	DIAGNOSTIC TEST	TEST PURPOSE	ASSAY FORMAT	GMDN CT	GMDN CT NAME	GMDN CODE	GMDN TERM NAME	GMDN TERM DEFINITION
81	Combined HIV antibody/p24 antigen (antiHIV/p24 Ag)	To screen blood donations for HIV	Immunoassay	CT284	Human immunodeficiency virus (HIV) IVDs	48445	HIV1/HIV2 antigen/antibody IVD, kit, enzyme immunoassay (EIA)	A collection of reagents and other associated materials intended to be used for t and/or quantitative detection of antigens from and antibodies to human immunode virus 1 and 2 (HIV1/HIV2) in a clinical specimen, using an enzyme immunoassay (EIA) n.
82	Haematocrit (Hct)	To diagnose and monitor anaemia. *Note: Result time sensitive for emergency and critical care*	method (if automated haematology analyser not	CT561	Haematology analyser IVDs	56696	Haematocrit analyser IVD	An electrically-powered automated or semi-automated laboratory instrument intended to be used to determine the red cell haematocrit or packed red cell volume of a whole blood specimen, using technology which may incorporate centrifugation, photometry or electrometry
83	Haematocrit (Hct)	To diagnose and monitor anaemia. *Note: Result time sensitive for emergency and critical care*	Haematology analyser (preferred)	CT561	Haematology analyser IVDs	56696	Haematocrit analyser IVD	An electrically-powered automated or semi-automated laboratory instrument intended to be used to determine the red cell haematocrit or packed red cell volume of a whole blood specimen, using technology which may incorporate centrifugation, photometry or electrometry
84	Haemoglobin (Hb)	To diagnose and monitor anaemia. To monitor the safety of certain drugs (e.g. zidovudine for HIV infection). To screen potential blood donors	Haemoglobinometer	CT1945	Haemoglobin analyser IVDs	32435	Haemoglobin analyser IVD, point-of-care	A mains electricity (AC-powered) instrument, which may include internal rechargeable batteries, intended to be used by health professionals at the point-of-care, and often also in the laboratory, to determine the concentration of haemoglobin in a clinical specimen, using technology which may include colorimetry, electrometry or photometry.
85	Haemoglobin (Hb)	Clinical marker for certain severe infections (e.g. malaria, viral haemorrhagic fevers). To aid in the diagnosis of intravascular haemolysis, renal conditions, rhabdomyolysis (myoglobinuria)	Dipstick	CT880	Hemoglobin IVDs	64807	Urine haemoglobin IVD, kit, rapid colorimetric, clini	and/or (semi-)quantitative screening of urine for haemoglobin within a short period, relative to standard laboratory testing procedures, using a rapid colorimetric method. This is a rapid test commonly used in the laboratory or in point-of-care analyses. It is not intended to be use for self-testing.
86	Haemoglobin (Hb)	To diagnose and monitor anaemia and polycythaemia. To monitor the safety of certain drugs (e.g. zidovudine for HIV infection). To screen potential blood donors. Clinical marker for certain severe infections (e.g. malaria, viral haemorrhagic fevers). To aid in the diagnosis of intravascular haemolysis, renal conditions, rhabdomyolysis (myoglobinuria). *Note: When used for emergency or critical care, results are time-sensitive.*	Optical methods, haemoglobinometer, if automated haematology analyser not available	CT880	Hemoglobin IVDs	55872	Total haemoglobin (totHb) IVD, kit, spectrophotometry	A collection of reagents and other associated materials intended to be used for the qualitati and/or quantitative determination of total haemoglobin (totHb) in a clinical specimen, using spectrophotometry method.
	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Handheld and small analysers	CT833	Clinical chemistry substrate/metabolite (non-drug/non-hormone) IVDs	63151	Glycated haemoglobin (HbA1c) IVD, kit, spectrophot	A collection of reagents and other associated materials intended to be used for the qualitati and/or quantitative detection of glycated haemoglobin (HbA1c), also known as glycosylated haemoglobin, in a clinical specimen, using a spectrophotometry method.
	bin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Immunoassay	CT883	Clinical chemistry substrate/metabolite (non-drug/non-hormone) IVDs	61010	Glycated haemoglobin (HbA1c) IVD, kit, chemiluminescent immunoassay	A collection of reagents and other associated materials intended to be used for the qualitati and/or quantitative detection of glycated haemoglobin (HbA1c), also known as glycosylated haemoglobin, in a clinical specimen using a chemiluminescent immunoassay method

A	B	D	E	F	G	I	J	K
No.	*EDL TEST*	*SETTING*		*Assay format*	Specimen type	Tag	EMDN code	EMDN term
1	A, B, O and rhesus factor (Rh)	No laboratory	To determine A, B and O groups and Rh type	Slide agglutination test	Capillary whole blood, Venous whole blood	EDL-001	W0103030299	RHESUS TYPING ASSAYS OTHER
2	Alanine aminotransferase (ALT)	Laboratory	To aid in the diagnosis of liver disease as a marker of liver injury.	Optical methods on semi-automated or automated chemistry analysers	Serum, Plasma	EDL-002	W01010103	ALANINE AMINO-TRANSFERASE
3		No laboratory	To detect or monitor kidney disease	Dipstick	Urine	EDL-003	W01010201	ALBUMIN (CC)
4	Albumin	Laboratory	To aid in the diagnosis and monitoring of diseases affecting protein metabolism (synthesis, loss, intake, absorption) e.g. liver disease, kidney disease, severe malnutrition, malabsorption, burns, etc.)	Optical methods on semi-automated or automated chemistry analysers	Serum, Plasma	EDL-004	W01010201	ALBUMIN (CC)
			To monitor kidney function	Optical methods on semi-automated or automated chemistry analysers	Urine	EDL-004	W01010201	ALBUMIN (CC)
	aline phosphatase (ALP)	Laboratory	To aid in the diagnosis of hepatobiliary and bone disorders	Optical methods on semi-automated or automated chemistry analysers	Serum, Plasma	EDL-005	W01010105	ALKALINE PHOSPHATASE - TOTAL

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MEDEVIS WEBSITE

https://medevis.who-healthtechnologies.org/