

# Towards standardized nomenclature of medical devices



GHWP annual meeting

Adriana Velazquez, team lead medical devices, WHO

1 December 2021

# WHO value chain to ensure improved access of safe, quality medical devices, **all require nomenclature. Goal better health care and patient safety.**

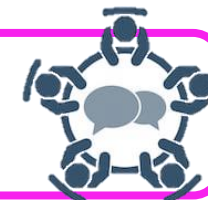
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- Academia and
- Medical devices industry



- Health Technology Assessment
- Priority medical devices lists and Essential in vitro diagnostics



- Regulation process of medical devices
- Lists of approved MD for marketing in country.

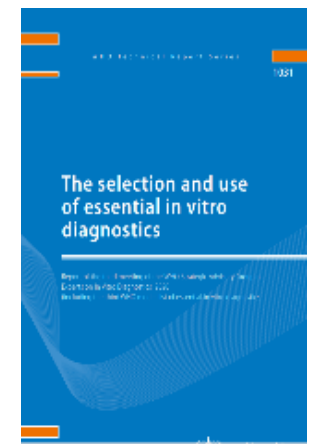
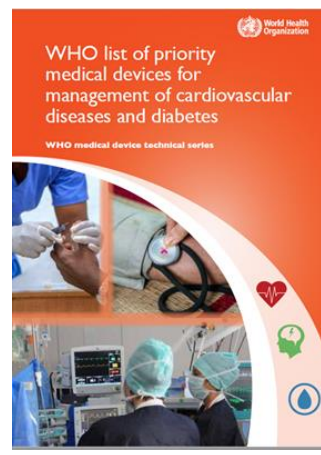
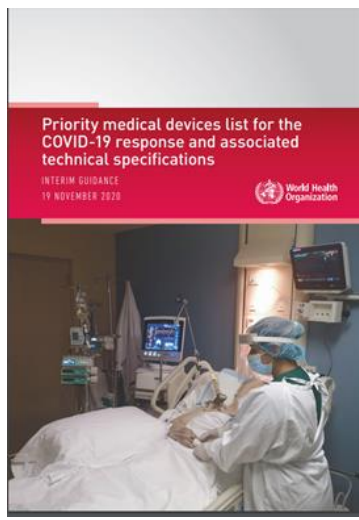
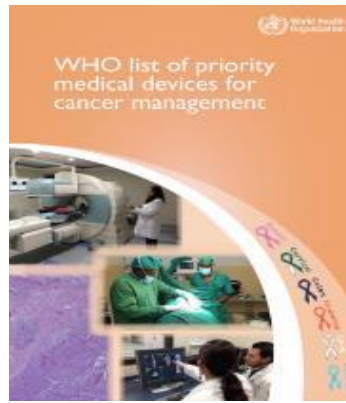
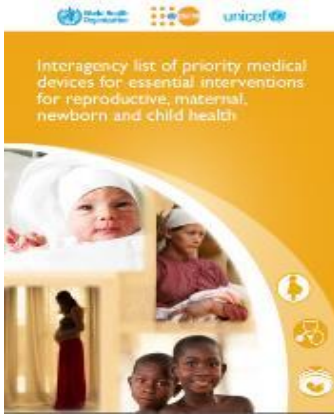


- Technical specifications, procurement and supply
- Installation, inventories, training, maintenance, operations
- Post market surveillance and adverse event report
- Decommissioning, Replacement
- Safe use

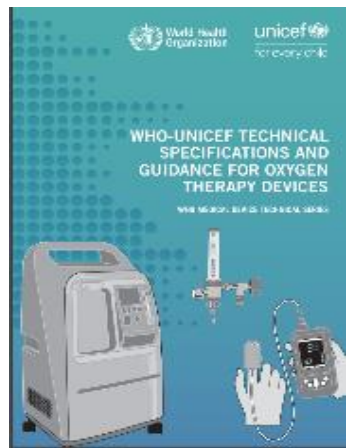


# WHO Publications of priority medical devices and essential in vitro diagnostics and related technical specifications of quality and safety to be available, affordable, acceptable, appropriate.

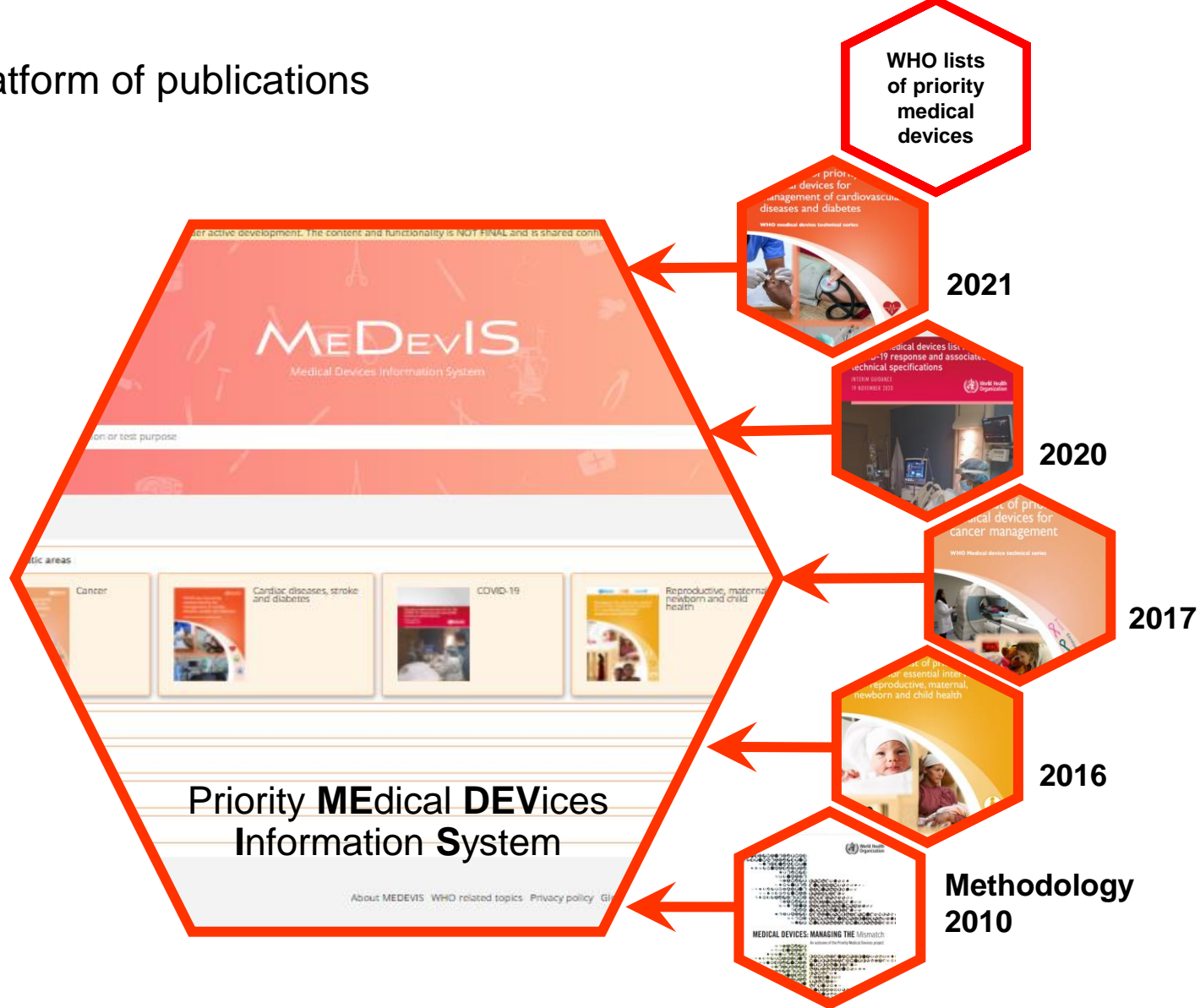
List of essential/ priority



Technical specifications



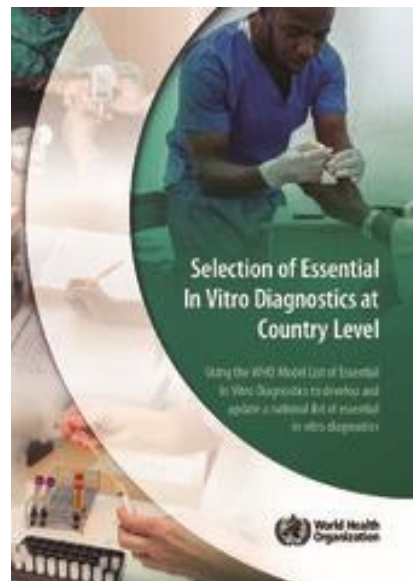
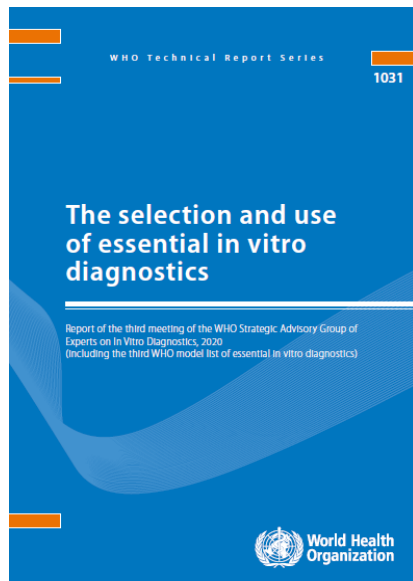
# Electronic platform of publications



[https://www.who.int/health-topics/medical-devices#tab=tab\\_1](https://www.who.int/health-topics/medical-devices#tab=tab_1)

# Essential in vitro diagnostic WHO Model List (do not include nomenclature)

1. WHO Technical Report Series The selection and use of essential IVDs
2. Electronic EDL (eEDL)
3. Technical specifications to support selection and procurement of IVD products



The eEDL website is currently under active development. The content and functionality is NOT FINAL and shared as a beta version.

World Health Organization WHO Model List of Essential In Vitro Diagnostics Search by name, indication or test purpose

FILTERS clear

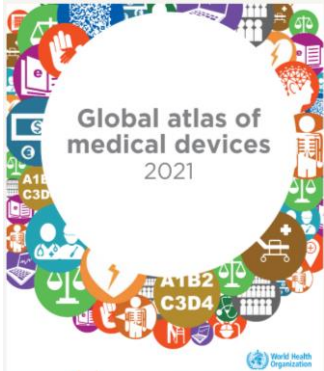
- Disease/health condition
- Setting
- Assay format
- IVD purpose
- Specimen type
- Year of WHO recommendation

Found 14 recommendations for 9 in vitro diagnostics Export results

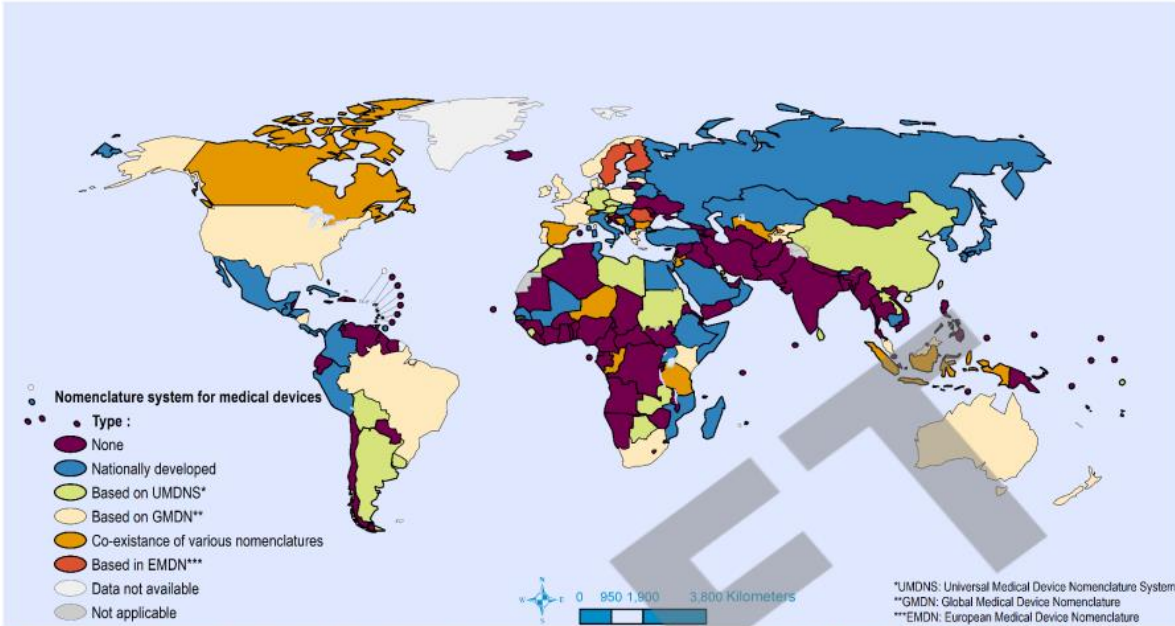
- Antibodies to Plasmodium spp.
- Antibodies to T. pallidum
- HIV 1/2 antibody (anti-HIV Ab)  
Antibodies to HIV-1/2 (anti-HIV Ab)  
HIV infection
- Facility level
- Blood screening laboratory
- Diagnostic tests
  - RDT
  - Particle agglutination assay
  - Immunoassay
- Hepatitis B surface antigen (HBsAg)
- Hepatitis C antibodies + HCV core antigen (HCV cAg)
- Hepatitis C antibody (Anti-HCV Ab)
- Plasmodium spp.
- Plasmodium spp. antigens
- To screen for other blood-transmitted microorganisms

# Survey and desk review for consultation 2021.

*Please review and submit comments before 5<sup>th</sup> December.*



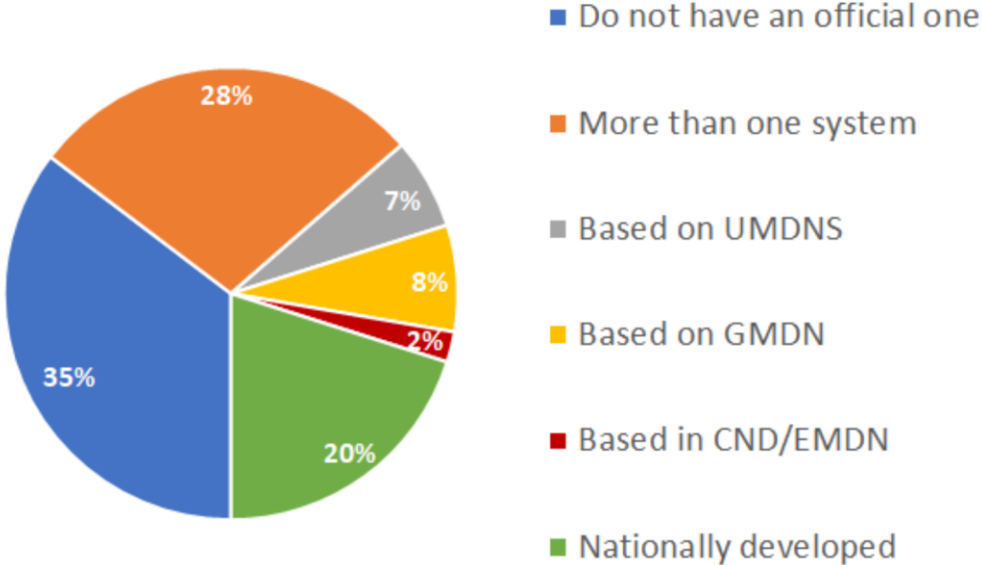
**Nomenclature system for medical devices -5 types- (status as of 2021; data collected from 2013 to 2021).**



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: Baseline Country Surveys of Medical Devices: 2013; 2017; 2021.  
 Map Production: WHO MHP/HPS/MDD unit (Oct 2021)  
 World Health Organization  
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**Existence and type of an official nomenclature system for medical devices (data from the MD 2021 country consultation verified by desk-review 2021)**



<https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature>

# Discussion on standardization of nomenclature in the WHA74, May 2021



[Seventy-fourth World Health Assembly \(who.int\)](http://who.int)

## Requests by Member States

Importance of nomenclature, coding and classification of medical device to support regulation, procurement, assessment

**Should be transparent, harmonized and evidence based, open systems to be accessible for all**

**Requested WHO not to create a new nomenclature to avoid duplications**

**Concerns of EMDN not harmonized with GMDN**

**Request to: Map EMDN to GMDN**

## WHO response

WHO confirms will not create a new nomenclature.

Information and consultation sessions in 2021 to report to Executive Board 150, January 2022.

WHO requires support by Member States and stakeholders, to find agreements of nomenclature systems to map, have a transparent system to assign codes, and make information openly available, with no IP or fee restrictions.

Date	Activity	Expected outcome
May-June	WHA74 and EB149	-----
24 June, 13 and 16 September	<i>IMDRF teleconference</i>	<i>Briefing of WHA and next steps</i>
16, 20 July, 3 September	WHO HQ meetings, <i>ICD-11, MeDeVIS</i>	Status, ongoing activities, nomenclature convergence platform possibilities
19 July, 23 August	<b>WHO Regional Advisors</b>	Status, plan and their input
22 July, 26 August 21 September	<b>Medical devices industry</b> Medical devices industry and Regional WHO Meeting with industry and UN	<b>GMTA, DITTA</b> , Discussion of the outcomes of survey Status, ongoing activities
30 July, 27 August 1, 3 September 15 October	<b>UN agencies and NGOs</b> UN agencies and NGOs and Regional Advisors UNICEF, Global Fund UNOPS	Nomenclature and tech specs uses Discussion of the outcomes of the survey Nomenclature used, catalogue and codes used, challenges UNOPS collaboration on feasibility study
1 <sup>st</sup> round: 29 and 30 of July, 03 August 2 <sup>nd</sup> round: 24 and 25 August 8 September 3 <sup>rd</sup> round: 15 September 4 <sup>th</sup> round: 3 and 4 November 5 <sup>th</sup> round: 9 November From 15 November: weekly meetings	<b>Nomenclature agencies</b> Nomenclature agencies and Regional WHO All 4 nomenclature agencies together  Each nomenclature agency ( <b>EMDN, GMDN, UMDNS, UNSPSC</b> ) All 4 nomenclature agencies together	Single agencies and all agencies. Willingness to map, transparent process, fees and copyright issues. Discussion of the outcomes of the survey Findings on bilateral meetings, willingness to map, brainstorm, Symmetric Willingness to share survey, to nomenclature pilot and to participate in MS session Agreements forward collaboration on feasibility study Updates on feasibility study
29 July, 26 August 22 September	<b>Biomedical and Clinical engineers</b> Biomedical and Clinical engineers and Regional Advisors	Use of nomenclature in health care facilities Discussion of the outcomes of the survey
21 September,	<b>Regional regulators and MOH AFRO and EURO</b>	Nomenclature uses and challenges Global Atlas for Medical Devices 2021 review.
23 September	<b>Member States information session</b>	<b>Report on the consultation sessions and defining next steps</b>
TBC (October to December)	<b>Other country and regional consultations</b>	Nomenclature uses and challenges



# Road map towards the EB Jan 2022

WHA74  
request for  
consultations  
, mapping  
and costs.

WHO MS  
information  
session (23  
Sept)

WHO MS  
information  
session (16  
December)

WHO EB  
Discussion in  
Executive  
Board  
(January  
2022)

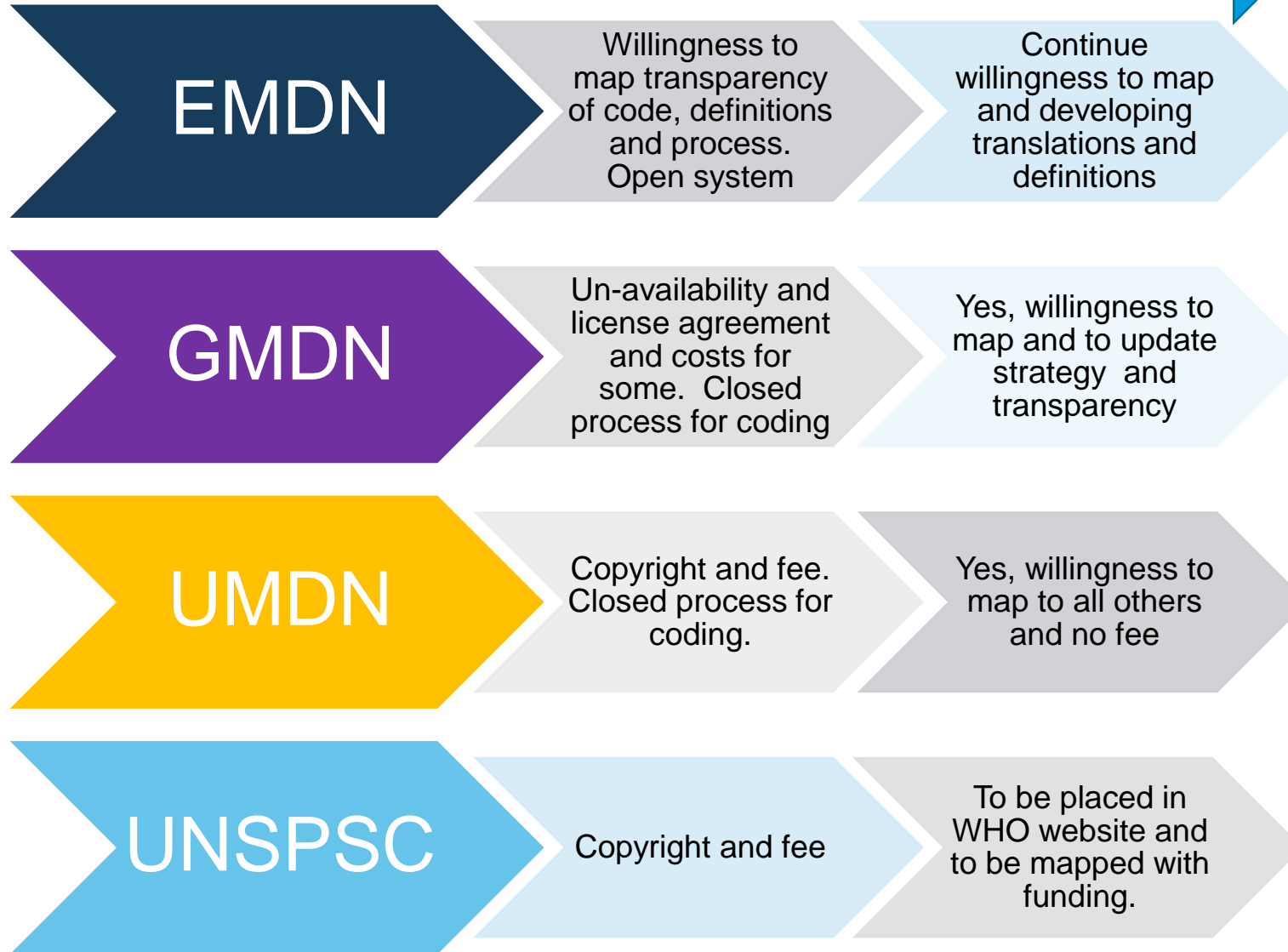
- Country data
- Consultations to UN , nomenclature agencies, med tech industry

- MOH and Regulators consultations
- Define mapping costs
- Feasibility study to map EMDN to GMDN, UMNDS, UNSPSC
- Webinars 13,14 December

# WHO work convening the 4 nomenclature agencies:



June 2021 to ... November 2021



# Mapping Crosswalk - Details

EUDAMED



ACCESS  
**GUDID**  
IDENTIFY YOUR MEDICAL DEVICE

554 items have this combination of nomenclature assignment

Regulatory Nomenclature Assignments

Non-regulatory Nomenclature Assignments

EMDN – H010101010201  
POLYGLYCONATE AND DERIVATIVES  
MONOFILAMENT WITH NEEDLE

UNSPSC - 42312201  
Sutures

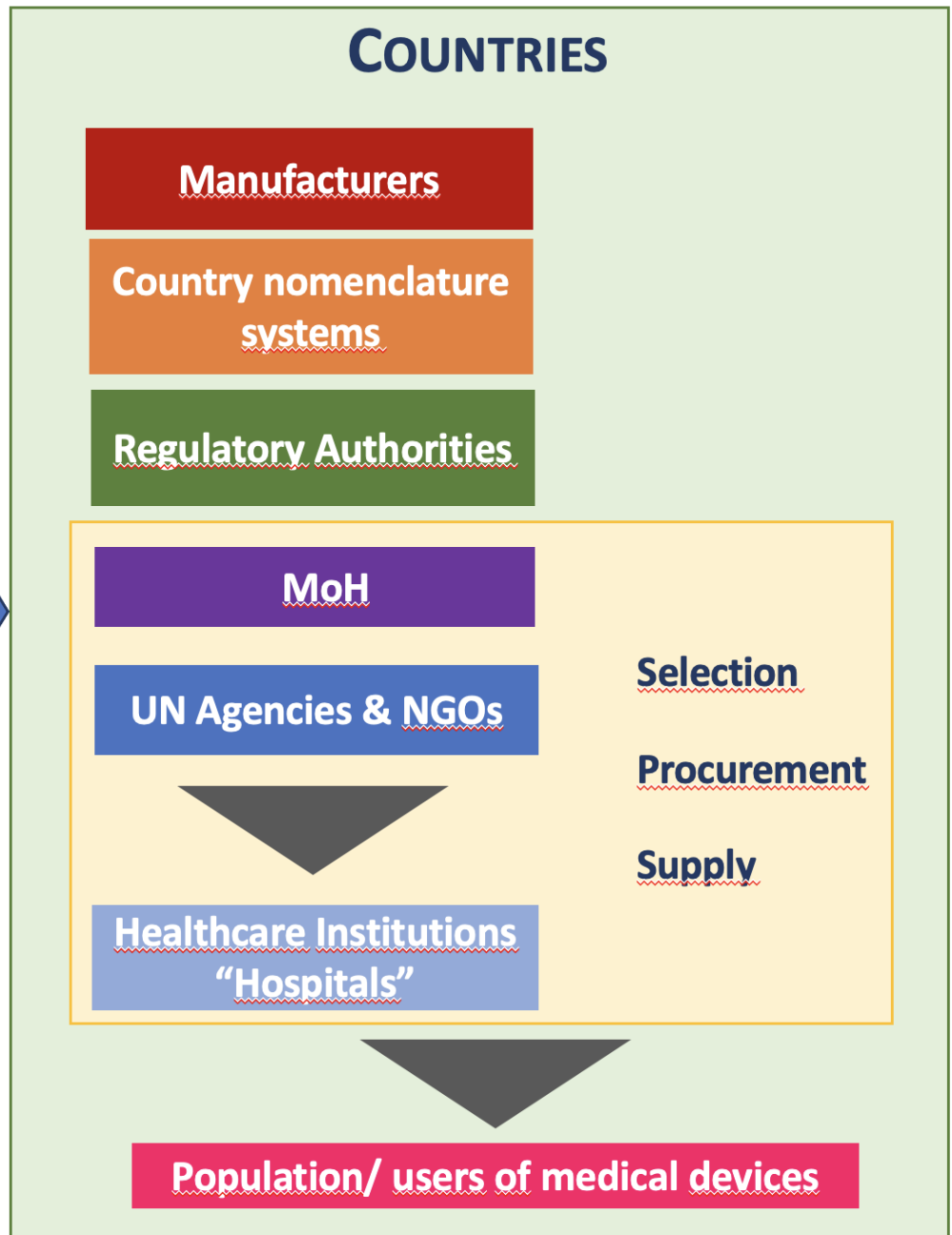
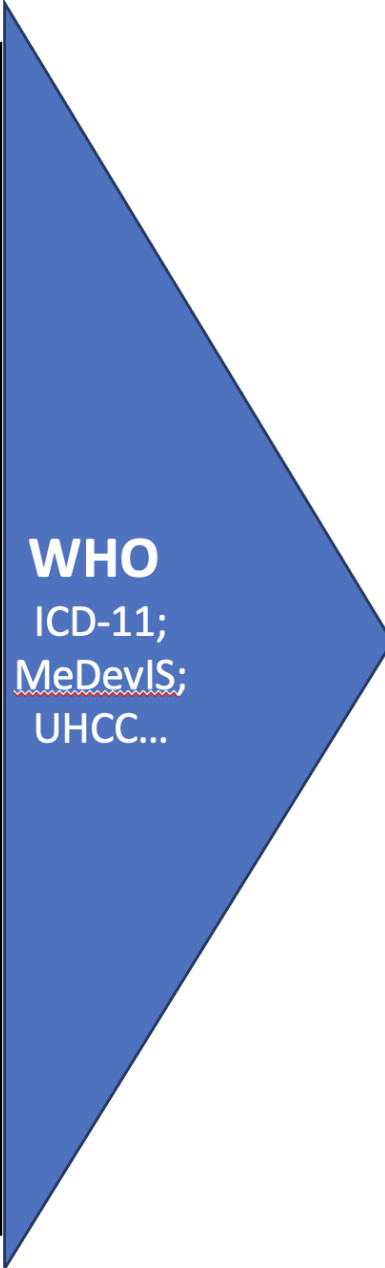
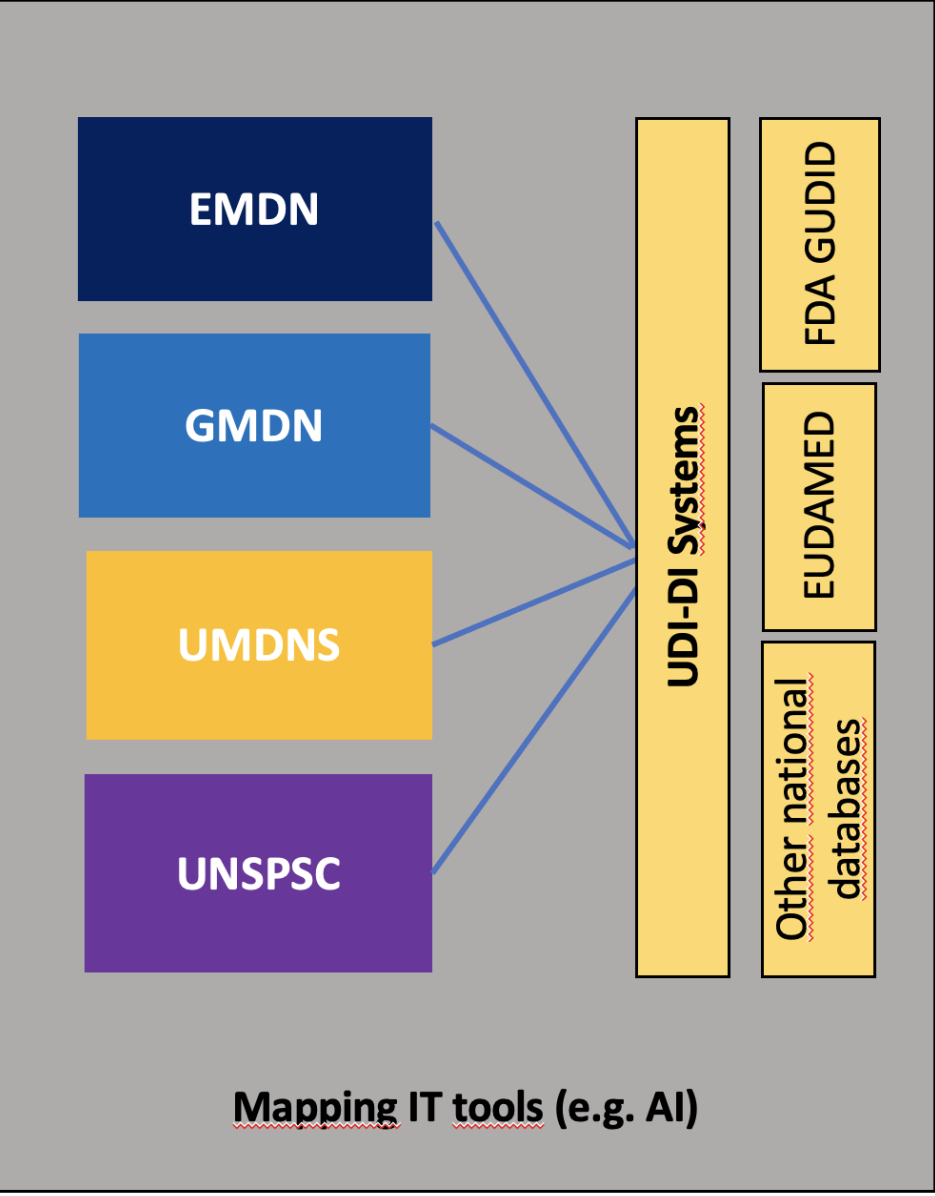
GMDN- 16584  
Polyester suture, bioabsorbable, monofilament, non-antimicrobial

UMDNS - 17246  
Sutures Synthetic Absorbable Polyglyconate

Study includes more than 13,000 items  
Intersection of data in  
AccesGUDID & Italian Ministry of Health (surrogate for EUDAMED)  
Mapped to items in MeDeVIS

# Automated Mapping

GUDID DATA	GMDN - FROM GUDID	EMDN - FROM ITALY CND -> EMDN Mapping	UMDNS	UNSPSC	Outliers
primary_di	gmdn	emdn	umdns	unspsc	is_outlier
04546540538437	13730-Sterilization/disinfection conta	V0402-CLINICAL USE TRAYS AND BOWLS	13730-Sterilization Containers	42281807-Sterilization indicator tapes	Outlier
00650862164008	63652-Thoracic suction collection cont	A060203-PLEURAL DRAINAGES WITH VALVE AND	10817-Drainage Systems Pleural	42295453-Surgical drains or drain sets	Not Outlier
10705034195438	46479-Surgical implant template, reus	V030299-DIMENSIONAL CLINICAL PARAMETERS	41918-Bone Depth Gauges	42293002-Surgical measuring gauges or rods	Not Outlier
10705034219097	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219103	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219110	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
04048675041610	42411-Neonatal/adult intensive-care v	Z1203010502-ADULT PULMONARY VENTILATORS	17429-Ventilators, Intensive Care	42272220-Ventilator accessories	Not Outlier
10705034219141	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219158	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219165	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219172	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10705034219219	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10705034219226	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10705034219233	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10884521181229	17148-Pulse oximeter, line-powered	Z1203020408-PULSE OXIMETERS	17148-Oximeters, Pulse	42181918-Multiparameter vital sign unit acce	Not Outlier
10603295116691	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42295100-Surgical equipment and accessorie	Not Outlier



# Conclusions

- WHO has developed lists and specifications of medical devices including IVDs
- Nomenclature is indispensable for all medical devices process.(industry, regulation, supply and use)
- WHO recognizes 4 nomenclatures and is developing mapping to support use by MS towards Standardization
- MS voice is indispensable to advance forward, MS information session 16 December.

**Gracias**  
**Thank you**  
**Merci**  
**Shokran**  
**Xie xie**  
**Spasiva**



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Medical devices

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website: [https://www.who.int/health-topics/medical-devices#tab=tab\\_1](https://www.who.int/health-topics/medical-devices#tab=tab_1)