List of transitional WHO Listed Authorities for medical devices (tWLAs-MD)
as of 1 July 2026

This time limited transitional list of national or regional regulatory authorities is established to support and facilitate regulatory reliance on medical devices. It is part of the transformation from the term Stringent Regulatory Authorities (SRAs) to WHO-Listed Authorities (WLAs) for regulatory oversight of medical products, including medical devices. WLA Policy document is available at the following link https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/wla-policy_draft_second-edition.pdf

The ultimate responsibility and decision for use of tWLA-MD resides with the users (e.g., regulatory authorities, procurement agencies) and will depend on the specific context of its intended use. In no event shall the World Health Organization be liable for any damage arising from its use.

Transitional WHO Listed Authorities for medical devices (tWLAs - MD)		
Country	**National/Regional Regulatory Authority**	**Scope of designation**
1. Australia	Therapeutics Goods Administration (TGA)	Medical devices, including in vitro diagnostics
2. Brazil	Brazilian Health Regulatory Agency (ANVISA)	Medical devices including in vitro diagnostics
3. Canada	Health Canada	Medical devices including in vitro diagnostics
4. China	National Medical Products Administration (NMPA)	Medical devices including in vitro diagnostics
5. European Medical Devices Regulatory Network	European Medical Devices Regulatory Network [1]	Medical devices including in vitro diagnostics

Transitional WHO Listed Authorities for medical devices (tWLAs - MD)		
Country	**National/Regional Regulatory Authority**	**Scope of designation**
6. Republic of Korea	Ministry of Food and Drug Safety (MFDS)	Medical devices including in vitro diagnostics
7. Japan	Ministry of Health, Labour and Welfare (MHLW)/ Pharmaceutical and Medical Devices Agency (PMDA)	Medical devices including in vitro diagnostics
8. Russian Federation	Ministry of Health (MoH)	Medical devices including in vitro diagnostics
9. Switzerland	The Swiss Agency for Therapeutic Products (Swissmedic)	Medical devices including in vitro diagnostics
10. Singapore	Health Sciences Authority (HSA)	Medical devices including in vitro diagnostics
11. United Kingdom of Great Britain and Northen Ireland	Medicines and Healthcare products Regulatory Agency (MHRA)	Medical devices including in vitro diagnostics
12. United States of America	Food and Drug Administration (FDA)	Medical devices including in vitro diagnostics

'The European Medical Devices Regulatory Network is composed of the European Commission and the regulatory authorities of the following EU/EEA-EFTA countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

Notes:

1. *Precise scope of designation for tWLAs-MD will be further defined in agreement with each Regulatory Authority as part of the roadmap for being designated as a WLA for medical devices.*

2. *The list is built based on the existing list of Recognized Regulatory Authorities by the WHO Prequalification for medical devices and membership to Management Committee of the International Medical Devices Regulators Forum (IMDRF), as of 30 June 2026.*

3. *This tWLA-MD is a risk-based evaluation process and will be valid for a period of five years from the date of publication of the WHO guidance on the process and requirements for performance evaluation of candidate WLAs-MD.*