



# WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices

WHO Medical device technical series





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WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices (WHO Medical device technical series)

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# Acronyms and abbreviations

<b>AHWP</b>	Asian Harmonization Working Party
<b>ASEAN</b>	Association of Southeast Asian Nations
<b>ATMP</b>	advanced therapy medicinal products
<b>CAB</b>	conformity assessment body
<b>CLSI</b>	Clinical and Laboratory Standards Institute
<b>FSCA</b>	field safety corrective action
<b>GDP</b>	good distribution practice
<b>GHTF</b>	Global Harmonization Task Force
<b>GMDN</b>	Global Medical Device Nomenclature
<b>IEC</b>	International Electrotechnical Commission
<b>IMDRF</b>	International Medical Device Regulators Forum
<b>ISO</b>	International Organization for Standardization
<b>IVD</b>	in vitro diagnostic medical device
<b>NRA</b>	national regulatory authority
<b>QMS</b>	quality management system
<b>SF<sup>1</sup></b>	substandard and falsified medical products
<b>SUMD</b>	single-use medical device
<b>UN</b>	United Nations
<b>UNFPA</b>	United Nations Population Fund
<b>US FDA</b>	United States Food and Drug Administration
<b>WHO</b>	World Health Organization
<b>WHA</b>	World Health Assembly

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<sup>1</sup> The Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products has recommended the World Health Assembly to adopt a simplified terminology for substandard and falsified (SF) medical products (EB140/23, Annex, Appendix 3 (dated 10 January 2017)).

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