World Health Organization

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

WHO Medical device technical series

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Contents

Acronyms and abbreviations

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

1 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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