AHWP/GHWP

25th Online Annual Meeting and 25th TC Meeting

30th Nov and 1st Dec 2021

CB Sponsors:

Summary of TC Work Progress (Workgroups 1 - 9)

Alfred KWEK, AHWP/GHWP Technical Committee Co-Chair (Industry)

30 Nov 2021

ASIAN HARMONIZATION WORKING PARTY

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

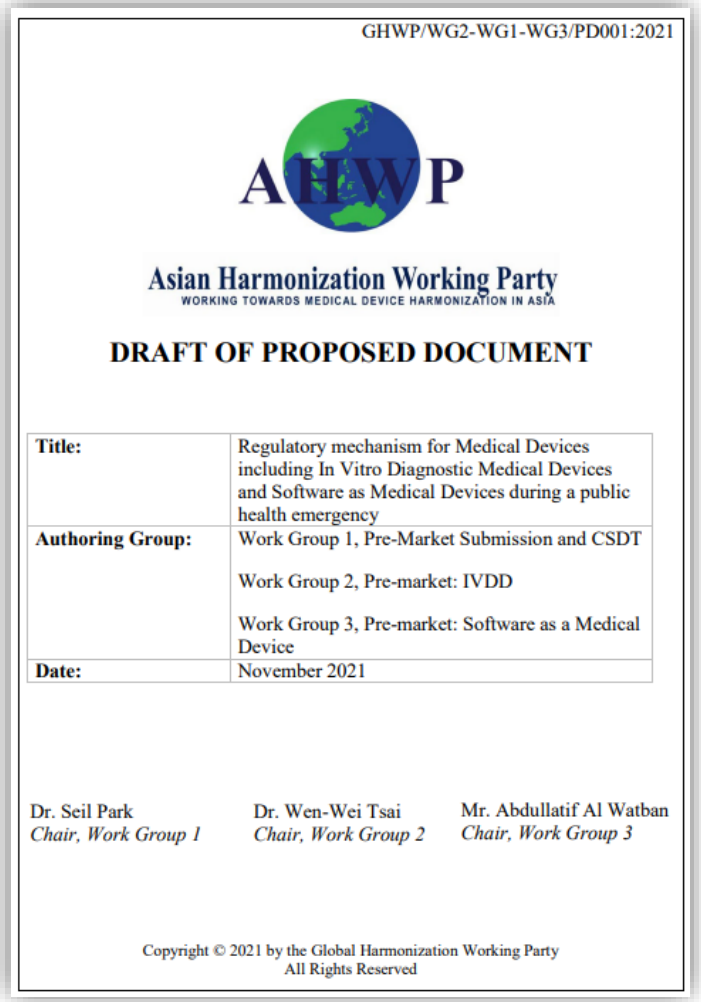
WG 1 to WG 9

WG 1	Pre Market Submission and CSDT
WG 2	Pre-Market: IVDD
WG 3	Pre-Market: Software as a Medical Device (SaMD)
WG 4	Post Market
WG 5	Clinical Evidence for Performance and Safety
WG 6	QMS: Audit and Assessment
WG 7	QMS: Operation and Implementation
WG 8	Standards
WG 9	Unique Device Identifier (UDI) and Nomenclature

WG	WORK ITEMS (2020 onwards) Complete List: http://www.ahwp.info/index.php/node/263
Joint Work by WG 1, 2 & 3	New guidance on artificial intelligence Change management for medical device registration guideline E labeling/e IFU guideline
WG1	Final Documents: Handbook for Approval of Patient-matched Medical Devices Using 3D Printers Final Document: Guidance for Minor Change Reporting
WG 2	Draft Guidance for Comments: Clinical Evidence for IVD Clinical Performance studies for IVD Contribution to WHO Technical Specification Documents Draft Guidance for Comments: Replacement Reagent and Instrument Family Policy

Joint Work by WG 1, 2 & 3

EUA Draft Guidance for Comments: 'Regulatory mechanism for Medical Devices including In Vitro Diagnostic Medical Devices and Software as Medical Devices during a public health emergency



GHWP/WG2-WG1-WG3/PD001:2021

AHWP

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

DRAFT OF PROPOSED DOCUMENT

Title:	Regulatory mechanism for Medical Devices including In Vitro Diagnostic Medical Devices and Software as Medical Devices during a public health emergency
Authoring Group:	Work Group 1, Pre-Market Submission and CSDT Work Group 2, Pre-market: IVDD Work Group 3, Pre-market: Software as a Medical Device
Date:	November 2021

Dr. Seil Park
Chair, Work Group 1

Dr. Wen-Wei Tsai
Chair, Work Group 2

Mr. Abdullatif Al Watban
Chair, Work Group 3

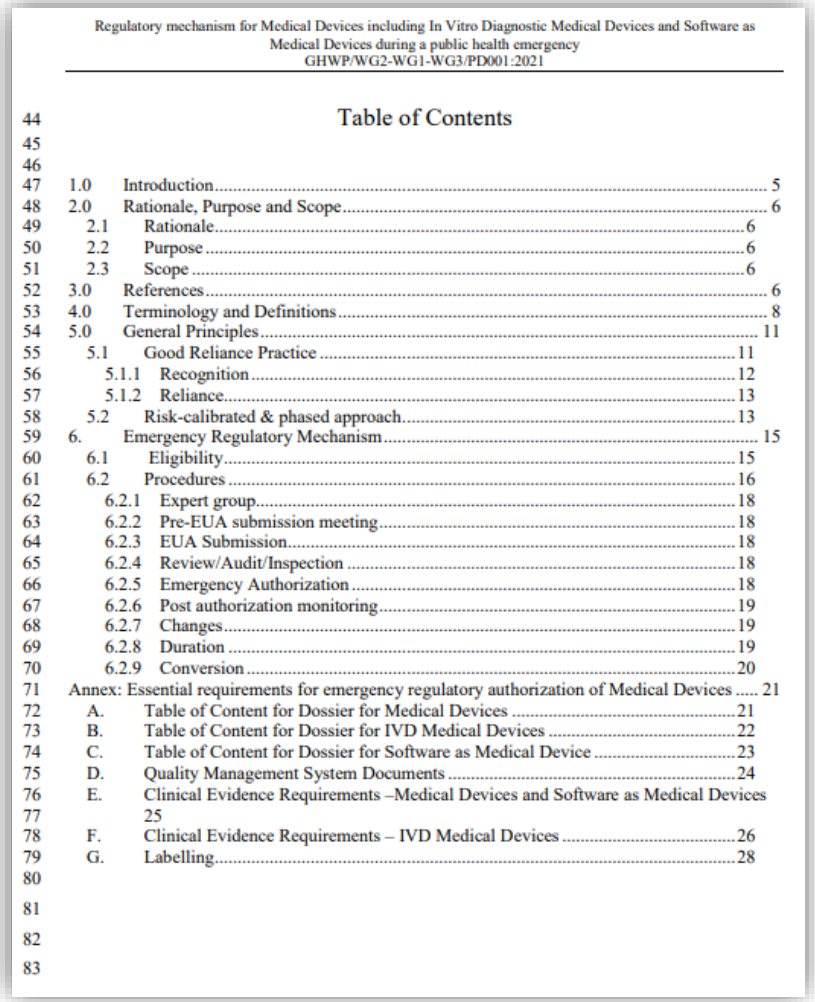


Table of Contents

WG3	White paper on pre market initial submission format for SaMD
	White paper on cybersecurity for SaMD
	Guidance document on Cyber Security for SaMD
	Guidance document for premarket submission format for SaMD (draft)
WG4	Post-Market Resource Centre (Feb 2021)
	Gap analysis on the implementation of AHWP guidance among AHWP members
	Participation in the development works of ISO TC210/ WG6
	Report on post-market support in relation to COVID 19
	Study on post-market trend in medical devices with AL and cybersecurity
WG5	Annual review SWOT analysis of WG5 framework
	Guidance document on general principles of clinical investigation audit & inspection for medical devices
	Training: WG5 & AHWP members
	Survey: country regulations/guidelines and implementation

WG 6	A guide to understanding best practices in audit life cycle management. A guide to understanding presently available audit duration determination systems. A guidance for NB auditing suppliers to medical device manufacturers. Online training session: Co-Chair Vincent Lam conducted remote audit technique (4 Feb 2021)
WG7	Comparison study of new ISO13485 vs QMS requirements in each country QMS consideration for manufacturers and importers for localization

WG8	Document on Code of practice for good engineering maintenance management of medical devices: endorsed, to be proposed to ISO /TC210 for development as ISO standard. Current status: New Proposal (NP 5137) on COP Good maintenance management of active medical devices has been approved and registered as new ISO project on 29 July 2020. A new WG, ISO/TC 210 WG 7 has been established on 17 Sept 2020 and Ms Salbiah Yaakop was appointed as Convenor. Member countries are encouraged to participate in the works of WG 7 through registration by their National Standards Body. Collecting a list of standards used for medical device regulatory purposes that are recognized by AHWP member countries Continue working relationship with ISO TC 210, etc - WG8/AHWP TC Chair participated in ISO/TC 210 meetings in May 2021 and Nov 2021. Adoption of ISO 16142-2:2017 and ISO 16142-1:2016, to harmonize list of standards in demonstrating compliance with EPSP where member countries could recognize the same standards during IVD medical device evaluation by NB/CAB and regulators Proposal on development of guidance on regulatory control of medical gas • Medical Gas System – Recognized Essential Principles of Safety and Performance – Standards for Demonstrating Compliance Proposal on development of guidance on the guideline 'Validation of Process for Manufacturing of medical devices'. Virtual Training: Medical Device Process Validation: The Need for a State of Art and Holistic Risk-Based Approach (22 April 2021)

WG9	Seminar: UDI Regulation and Implementation Seminar (28th July 2021)
	AHWP UDI report
	AHWP UDI rule White Paper

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Thank You
Keep Safe