Checklist for medical device conformity assessment by CAB

A.1 The checklist for Medical Device Conformity Assessment by CAB is as per the table below. This checklist is non exhaustive and as a minimum to be adopted by the CAB and included in their audit report.

NO.	INFORMATION		COMPLIANCE			EVIDENCE /FINDING
			YES	NO	N/A	
A. CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM						
1	Conformity assessment on Class B medical devices					
(a)	Establish and maintain a full QMS or may exclude design and development controls, process control and inspection and testing; and appoint CAB to review and conduct on-site audit if necessary, toverify evidence of conformity to QMSrequirements					
(i)	Validity and authenticity of thecertificate					
(ii)	Scope of certification is sufficient forthe medical device.					
(iii)	Audit report for ISO 13485					
2	Conformity assessment on Class B, C and D medical devices					
(a)	Establish, maintain and implement afull QMS and appoint CAB to reviewand conduct on-site audit to verify evidence of conformity to QMS requirements					
(i)	Validity and authenticity of thecertificate					
(ii)	Scope of certification is sufficient forthe medical device.					
(iii)	Audit report for ISO 13485					
	Note: For establishment that do notalready have ISO 13485 certificate,CAB may conduct the certification process and a separate ISO 13485checklist shall be used.					
B. CONFORMITY ASSESSMENT OF POST-MARKET SURVEILLANCE SYSTEM						
3	Conformity assessment on Class B, C & D medical devices					

(a)	Establish, maintain and implementPMS system					
(b)	Review record and evaluate reportsof adverse events.					
(c)	Establish, maintain and implement: i. complaint handling;					
	ii. distribution records;					
	iii. mandatory problem/adverseevent reporting;					
	iv. field corrective action; and					
	v. recall					
(d)	List of reported ongoing incidentsglobally (if applicable					
(e)	List of incidents that have been resolved for 5 years (if applicable)					
(f)	Date of last audit					
C. CONFORMITY ASSESSMENT OF TECHNICAL DOCUMENTATION						
C.1 Elements of Commission Submission Dossier Template for General Medical Device						
4	Executive summary					
(a)	Overview					
	i. medical device description					
	ii. Novel features					
	iii. Synopsis of the content of CSDT					
(b)	Commercial Marketing History					
	i. List of countries where the medical device is marketed, dateof introduction to those countries					
(c)	Intended use in its label					
(d)	Indication in its label					
(e)	List of regulatory approval or marketing clearance from othercountries with the following information/documents					
	i. registration status,					
	ii. intended use,					
	iii. indications					
	iv. copies of certificates/ approvals,					

	v. declaration on label, packaging and IFU					

(f)	Status of any pending application forregulatory approval or marketing clearance					
(g)	Important safety and performancerelated information:					
	i. summary of reportable adverse events and field corrective actions,					
	ii. Description of medical device if contain animal, human cells, tissues and /or derivatives, thereof, rendered non-viable cells, tissues and/or derivatives ofmicrobial or recombinant origin, irradiating components, ionising or non-ionising.					
(h)	Company stamp, signed by designated person by manufacturer,and dated					
5	Relevant Essential Principles and Method Used to Demonstrate Conformity					
(a)	Determine all the relevant EssentialPrinciple that are applicable to the medical device, taking into accountthe intended purpose of the device.					
(b)	The specific documents shall be referenced in the element of CSDT to support the rule used to demonstrateconformity to the essential principles					
	i. Compliance with standards according to 5.3.4. Are applicable standards applied in full? (Consider that if standards are referenced on the declarationof conformity, all applicable partsof the standards must be fulfilled)					
	ii. Internal industry methods					
	iii. Comparison to other similarmarketed device					

(c)	The essential principle conformity checklist is to be prepared based on the list of essential principle referred to MDR 2012 and MDA/GD/0007- Essential Principle of Safety and Performance of Medical Device					
6	Description of medical device;					
(a)	A complete description of the medicaldevice					

(b)	Principles of operation or mode ofaction					
(c)	Risk class and applicable classification rule					
(d)	A description of the accessories					
(e)	A description or complete list of thevarious configurations (same with grouping)					
(f)	A complete description of the keyfunctional elements					
(g)	An explanation of any novel features					
(h)	Where appropriate, this will includelabelled pictorial representation					
(i)	Intended use					
(j)	Indications					
(k)	Instructions of use					
(l)	Contraindications					
(m)	Warnings					
(n)	Precautions					
(o)	Potential adverse effects					
(p)	Alternative therapy					
(q)	Materials					
(r)	Other relevant specifications anddescriptive information					
7	Summary of design verification andvalidation documents shall include:					
(a)	Declarations/certificates of conformityto the “recognized” standards listed as applied by the manufacturer; and/or					
(b)	Summaries or reports of tests and evaluations based on other standards, manufacturer rules and tests, or alternative ways of demonstrating compliance. The datamay cover:					
	i. A listing of and conclusions drawn from published reports thatconcern the safety and performance.					
	ii. engineering tests					

	iii. laboratory tests (e.g: sterility tests, metrology tests, etc)					

	iv. biocompatibility tests;					
	v. animal tests;					
	vi. simulated use;					
	vii. software validation					
8	Pre-clinical studies (if the device is invasive and/or in contact with patient)					
	Reports containing information on theobjectives, methodology, result, discussion and conclusion of the testing and/or certification and/or declaration of:					
(a)	Biocompatibility test conducted onmaterials used in a medical device					
(b)	Pre-clinical physical tests conducted on the medical device					
(c)	Pre-clinical animal studies to supportthe probability of effectiveness in humans.					
9	Software validation studies					
a)	Documentation on softwarevalidation studies. i. Objective evidence that validatesthe software design and development process ii. results of all verification, validation and testing performed in-house and in a user's environment prior to final release,for all of the different hardware configurations identified in the labelling, and representative datagenerated from both testing environments					
10	Medical devices containing biologicalmaterial					
(a)	A list of all materials of animal, human, microbial and/or recombinantorigin used in the medical device andin the manufacturing process of the medical device. This includes animal or human cells, tissues and/or derivatives, rendered non-viable and cells, tissues and/or derivatives of					

	microbial or recombinant origin;					
(b)	Detailed information concerning theselection of sources/donors;					
(c)	Detailed information on the harvesting, processing, preservation,					

	testing and handling of tissues, cells and substances;					
(d)	Process validation results to substantiate that manufacturing procedures are in place to minimisebiological risk in particular, with regard to viruses and other transmissible agents					
(e)	Full description of the system for record keeping allowing traceability from sources to the finished medicaldevice.					
(f)	Selection of relevant tests, justification available for not doing certain tests, results of testing, reference standard for testing and ifnot current, justification and gap analysis					
(g)	Test Report /certification from accredited Laboratory; e.g. OECD, ISO 17025					
	(i) Shelf life report					
11	Clinical Evidence *Note: This section should indicate how any applicable requirements ofthe Essential Principles for clinical evaluation of the device have beenmet. Where applicable, this evaluation may take the form of themedical device when used as intended by the manufacturer*					
(a)	A systematic review of existingbibliography					
(b)	Clinical experience with the same orsimilar devices, or					
(c)	Detailed checklists for clinical evaluation / investigation in separateforms – refer to ISO 14155					
12	Use of existing bibliography					
(a)	Copies of all literature studies, orexisting bibliography to support safety and effectiveness.					
(b)	Bibliography shall be derived from relevant publication in peer-reviewedscientific literature containing:					

	i. Objective					
	ii. methodology					
	iii. Result presented in context, clearly and meaningfully					

(c)	The conclusion on the outcome of clinical studies should be preceded by a discussion in context with published literature					
13	Medical device labelling					
(a)	Sample of labelling is provided *Note: Labelling complies with requirements as per MDA/GD/0026 –guidance Document on requirement for labelling of medical device.*					
14	Risk analysis/ Risk Management file					
(a)	Risk management report demonstrated conformance with ISO14971					
15	Manufacturing Information					
(a)	Documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and riskclass of the medical device. Manufacturing process shall includeresources and activities that transform input into the desired output.					
C.2 Elements of Commission Submission Dossier Template for IVD Medical Device						
16	Executive summary					
(a)	Overview					
	i. medical device description					
	ii. Novel features					
	iii. Synopsis of the content of CSDT					
(b)	Commercial Marketing History					
	i. List of countries where the medical device is marketed, dateof introduction to those countries					
(c)	Intended use in its label					
(d)	Indication in its label					
(e)	List of regulatory approval or marketing clearance from othercountries with the following information/documents					
	i. registration status,					

	ii. intended use,					
	iii. indications					
	iv. copies of certificates/ approvals,					

	v. declaration on label, packaging and IFU					
(f)	Status of any pending application forregulatory approval or marketing clearance					
(g)	Important safety and performancerelated information:					
	iii. summary of reportable adverseevents and field corrective actions, If there have not been adverseevents of FSCAs to date, an attestation that this is the caserequired					
(h)	Company stamp, signed by designated person by manufacturer,and dated					
17	Relevant Essential Principles and Method Used to Demonstrate Conformity					
(a)	Determine all the relevant EssentialPrinciple that are applicable to the medical device, taking into accountthe intended purpose of the device.					
(b)	The specific documents shall be referenced in the element of CSDT to support the rule used to demonstrateconformity to the essential principles					
	i. Compliance with standards according to 5.3.4. Are applicable standards applied in full? (Consider that if standards are referenced on the declarationof conformity, all applicable partsof the standards must be fulfilled)					
	ii. Internal industry methods					
	iii. Comparison to other similar marketed device					
18	Description of medical device;					
(a)	A general description of the principleof assay method or instrument principles of operation.					

(b)	A description of all components of the IVD medical device, including butnot limited to:					
	i. antibodies, antigens, nucleic acid primers;					
	ii. buffers, assay controls and calibrators;					

	iii. substrates used to detect antigen-antibody complexes; and					
	iv. reagents provided with the IVD medical device or recommendedfor use					
(c)	A description of the specimen collection and transport materials provided with the IVD medical deviceor recommended for use.					
(d)	A description or complete list of various configurations of the IVD medical device to be registered as a family/ system, if applicable. For example, a family of pregnancy rapid test can consist of device available in different configurations, such as a test strip or in a cassette.					
(e)	A description of the accessories, other IVD medical devices and other products that are not IVD medical devices, which are intended to be used in combination with the IVD medical device. For example, a lancet, which is a medical device and not an IVD medical device that is provided in the package to the user to perform a test. Note: Supporting documents, in CSDT format, must be provided for the medical device accompanying the IVD medical device.					
19	Intended Use					
	i. Type of analyte or measure and of the assay.					
	ii. Whether the test is quantitative or qualitative.					
	iii. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic,monitoring.					
	iv. Disease or condition that the test is intended for					
	v. Type of specimen to be used e.g. serum, plasma etc.					

	vi. The intended users (e.g. self-testing by lay person, near-patient by trained personnel orprofessionals					

	vii. Assay type e.g. immunoassay, chemistry, cytochemistry, imageanalysis, immunohistochemistry					
	viii. The specific name of the instrument required for theassay, if any.					
	ix. For instruments, the intended use shall also include the modes of operation for instruments e.g., random access, batch, stat, open tube, closed tube, automatic, manual.					
20	Instruction of use					
21	Warnings					
22	Precautions					
23	Materials					
(a)	All components of the IVD medical device shall be listed and chemically and biologically characterised, including antibodies, antigens, assay controls, substrates used to detect antigen-antibody complexes, and testreagents. Appropriate references shall be cited.					
(b)	If synthetic peptides are used, the peptide sequence shall be provided					
(c)	If components are of biological origin or recombinant, the source must be indicated and details on production must be provided. These details would include the strain of the virus, the cell line for cultivation of the virus,sequences of relevant nucleic acids and amino acids, etc., used in the manufacturing process of viral lysate,purified proteins, recombinant and synthetic proteins.					
(d)	If applicable, process validation results to be provided to substantiatethat manufacturing procedures are inplace to minimise biological risks, in particular, with regard to viruses andother transmissible agents. This also includes inactivation of infectious					

	organisms in reagents and the production of reagents.					
(e)	if applicable, information to be provided on irradiating components,nonionising or ionising (e.g. Iodide- 131 in the Radioimmunoassay kit,					

	radio-labelled Phosphorus-32 DNA probes in Southern blots)					
(f)	if applicable, information to be provided on the poison or controlledsubstance (e.g. Buprenorphine in drug assay kit).					
24	Other relevant Specifications					
(a)	The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant EssentialPrinciples.					
25	Other descriptive Information					
(a)	The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant EssentialPrinciples					
26	Product verification and Validation					
(a)	Pre-clinical Studies The pre-clinical studies provided should include information on study design, complete test or study protocols, methods of data analysis, data summaries and study conclusions. The most common characteristics that must be validatedshould include but are not limited to:					

	i. Analytical Sensitivity					
	ii. Analytical Specificity and Interference					

	iii. Precision (Repeatability /Reproducibility)					
	iv. Linearity/Assay's Measuring(Reportable) Range					
	v. Traceability, & Expected Values					
	vi. Cut-off Value					
	vii. Trueness					
	viii. Stability of reagent					
	ix. Specimen stability					
	x. Performance Characteristics for Instrument (if applicable):					
	xi. Accuracy					
	xii. Precision/Reproducibility					
	xiii. Linearity					
	xiv. Carryover					
	xv. Interfering Substances					
	xvi. Projected useful life					
	xvii. Software Verification andValidation Studies					
(b)	Clinical Evidence The clinical evidence to be provided shall include the information mentioned in this section. For any IVD medical device, if discrepant testresults are identified as part of an evaluation, these results shall be resolved as far as possible, using one or more of the following approaches:-					
	i. evaluation of the discrepant sample in further test systems,					
	ii. use of an alternative method ormarker,					
	iii. a review of the clinical statusand diagnosis of the patient,					
	iv. the testing of follow-up-samples.					
	v. Clinical (Diagnostic) Sensitivity					

	vi. Clinical (Diagnostic) Specificity					
	vii. Comparison Studies Using Clinical Specimens (Method comparison: All performance evaluations shall be carried out					

	in direct comparison with an established state of the art IVD medical device. The established product for comparison must have obtained marketing clearance from the reference agencies, namely Australia TGA, Canada TPP, Europe, Japan MHLW, and US FDA.					
(c)	Result shall include:-					
	i. Description on the overall results and/or results fromspecific sites and patient groups, as appropriate					
	ii. For quantitative tests, information such as slope and intercept (with confidence intervals), correlation coefficient,measure of scatter around the regression line, measure of biasat medical decision levels					
	iii. In some cases, a graph (x-y graph or bias plot) can be included, and					
	iv. For qualitative or semi-quantitative tests, per cent agreement with comparator forpositive/negative samples, confidence intervals.					
(d)	Matrix comparison:					
	i. for each matrix in the intended use, the method for comparisonor determination of accuracy, and					
	ii. sample types tested, number of samples, sample range or target concentrations tested and calculations/statistical methods					
	iii. Results/Acceptance criteria shall include: the accuracy of the new matrix or results of thematrix comparison					
(e)	Clinical Cut-off					
	i. The established cut-off and itsvalidation for the new IVD medical device; and					

	ii. If applicable, the “equivocalzone” is to be defined, and include a description of howresults within this zone are reportable to the user					

(f)	Reference Interval (Expected Values)					
	i. The reference interval for this measured and the method usedto determine it;					
	ii. Additional requirements for IVDmedical device for self-testing and near patient testing (if applicable)					
(g)	USE of Existing Bibliography					
27	Device labelling					
(a)	Sample of labelling is provided Note: Labelling complies with requirements as per MDA/GD/0026 – guidance Document on requirementfor labelling of medical device.					
	i. Labels on the device and its packaging;					
	ii. Instructions for use;					
28	Risk analysis/ Risk Management file					
(a)	Risk management report demonstrated conformance with ISO14971					
29	Manufacturing Information					
(a)	Documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and riskclass of the medical device. Manufacturing process shall includeresources and activities that transform input into the desired output.					
D. DECLARATION OF CONFORMITY						
16	Prepare declaration of conformity asper specified in MDA/GD/0025.					
(a)	Name and address of manufacturerand printed on company letterhead					
(b)	Name of Person Responsible/ Manufacturer					
(c)	Particular of medical device:					
	i. Generic Name					
	ii. Specified Name					

	iii. Brand / Model					
	iv. Manufacturer					

	v. Country of Origin					
	vi. Manufacturing Site					
	vii. Risk-based classification					
	viii. Classification rule					
	ix. GMDN Code					
	x. Medical Device Registration Code/ Approval number (e.g:CE marking code, USFDA approval number, etc)					
(d)	QMS certificate					
	i. Conformity Assessment Body issuing the certificate					
	ii. Certificate Number					
	iii. Issuance Date					
	iv. Expiry Date					
(e)	List of all standards (vertical and horizontal standard) applicable forthe medical device.					
(f)	Name & Position i. The name and position of topmanagement ii. Company Stamp					
(g)	Signature and date of Signatory					