CONFORMITY ASSESSMENT REPORT
(BY WAY OF VERIFICATION ON EVIDENCE OF CONFORMITY)

☐ Initial registration ☐ Re-registration *[State registration certificate number]*

Date of Verification: From *[State date]* to *[State date]*

Ref No.: CAB/MDV/CLIENT NO/PRODUCT NO

All sections A-J are mandatory, unless stated otherwise. Please tick ☒ at the appropriate box. For NA, a justification shall be provided.

SECTION A: CAB DETAILS	
Name of CAB	
CAB Registration No.	
Name of CAB Assessor	1. 2.
Medical Device Technical Areas (Code)	

SECTION B: ESTABLISHMENT DETAILS	
☐ Manufacturer ☐ Authorised Representative	
Establishment Name	
Establishment Address	
Establishment License No.	

SECTION C: CHANGE NOTIFICATION DETAILS *[only for re-registration application]*			
REQUIREMENTS	**INFORMATION TO BE FILLED BY THE ESTABLISHMENT/CAB** *[Please fill up all required information. Reference to CSDT or annexes is not acceptable]*	**COMPLY**	**VERIFICATION RESULT BY CAB**
Change notification approval letter issued by MDA *[Provide change notification approval letters]*	*Example* Category: *2* Summary of change: *[Addition of medical device (6 items)]* Category: *2* Summary of change: *[Change of labelling of medical device - addition warnings/ addition precautions]* Total number of approved changes: *2*	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ The details of approved change notification in the change notification approval letter are aligned with the technical documentation provided; or ☐ There are no change notification submissions in the last 5 years. ☐ Other remarks:

	REQUIREMENTS	INFORMATION TO BE FILLED BY THE ESTABLISHMENT/CAB *[Please fill up all required information. Reference to CSDT or annexes is not acceptable]*	COMPLY	VERIFICATION RESULT BY CAB
	SECTION D: MEDICAL DEVICE DETAILS			
1.	**Type of Device:** Choose an item. *[Choose relevant type of device]*			
2.	**Medical Device Name** *[The name of a medical device given by its manufacturer that identifies a manufacturer's medical device]*		☐ YES ☐ NO	☐ Reviewed and verified that the name of medical device is aligned with the information in the declaration of conformity, list of configurations, product label and CSDT; or Additional for re-registration: ☐ Reviewed and verified that the medical device name remains the same with existing registered medical device. ☐ Other remarks:
3.	**Brand** *[A unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name or brand name. The medical device proprietary name must appear on the label of each of the member medical devices]*		☐ YES ☐ NO	☐ Reviewed and verified that the medical device brand is aligned with the information in the declaration of conformity, product label and CSDT; or Additional for re-registration: ☐ Reviewed and verified that the brand name remains the same with existing registered medical device. ☐ Other remarks:

	REQUIREMENTS	INFORMATION TO BE FILLED BY THE ESTABLISHMENT/CAB *[Please fill up all required information. Reference to CSDT or annexes is not acceptable]*	COMPLY	VERIFICATION RESULT BY CAB
	SECTION D: MEDICAL DEVICE DETAILS			
4.	**Description of Medical Device** *[Explain how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging]*		☐ YES ☐ NO	The following information has been reviewed and verified: ☐ The description is aligned with the information in the CSDT. Additional for re-registration: ☐ The description of medical device remains the same with existing registered medical device. ☐ Other remarks:
5.	**Intended use of Medical Device** *[Intended use of the device according to the specifications of the product owner as stated on the product label, instruction of use or promotional materials]*		☐ YES ☐ NO	The following information has been reviewed and verified: ☐ The intended use is aligned with the information in the IFU, CSDT, and clinical evaluation report. ☐ The intended use is aligned with the approved intended use in the recognized foreign regulatory country. Additional for re-registration: ☐ The intended use of medical device remains the same with existing registered medical device. ☐ Other remarks:

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	SECTION D: MEDICAL DEVICE DETAILS			
6.	**Risk Classification and Rule** *[in accordance with Medical Device Regulation 2012]*	Risk Class: Rule: Rationale for choosing the stated class and rule:	☐ YES ☐ NO	Rationale for verifying the stated risk class and rule:
7.	**Is the medical device a combination product?** *[The medical device incorporates medicinal substance in an ancillary role. Provide an endorsement letter (EL) issued by NPRA]*	Name of ancillary drug: Endorsement Letter reference letter number:	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ The NPRA Endorsement letter (EL) is provided; and ☐ The ancillary drug name is aligned with the information in Section D. ☐ Other remarks:
8.	**Is the medical device containing formulation, active ingredient, poison or drug?** *[Please indicate whether the medical device contains any formulation, active ingredient, poison or drug]*	State primary mode of action: Ingredient: Scientific Name: Ingredient Function: Quantity: Composition Percentage: If more than one, provide information in the **Attachment 2**	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ The primary mode of action does not have pharmacological, immunological or metabolic action; and ☐ The material datasheet / any related document is provided; and ☐ The information is aligned with the label and CSDT.

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	SECTION D: MEDICAL DEVICE DETAILS			
				☐ Other remarks:
9.	**Grouping** (Refer **Attachment 1-List of configurations**) *[Choose appropriate grouping]* Choose an item.	Rationale for choosing the stated grouping: Total number of devices in the list of configurations: List of configurations: **Attachment 1**	☐ YES ☐ NO	Rationale for verifying the stated grouping: Total number of verified devices in the list of configurations in **Attachment 1**: Additional for re-registration: ☐ The grouping of medical device remains the same with existing registered medical device.
10.	**Manufacturer name** *[The name of the legal manufacturer]*		☐ YES ☐ NO	☐ Reviewed and verified that the name of the manufacturer is aligned with the information in the Quality Management Certificate and all technical documentation. ☐ Other remarks:

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	SECTION D: MEDICAL DEVICE DETAILS			
11.	**Manufacturer address** *[The address of the legal manufacturer]*		☐ YES ☐ NO	☐ Reviewed and verified that the address of the manufacturer is aligned with the information in the Quality Management Certificate and all technical documentation. ☐ Other remarks:

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	SECTION E: RECOGNISED FOREIGN REGULATORY AUTHORITY OR NOTIFIED BODY			
1.	☐ Therapeutic Goods Administration (TGA), Australia *[Provide TGA License and TGA Declaration of Conformity]*	ARTG Number: Issuance Date: Risk classification in Australia:	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ Authenticity and validity of TGA license and evidence of approval against TGA database; and ☐ A TGA Declaration of Conformity is provided; and ☐ The name and intended use of medical device stated in the TGA license is aligned with the information in Section D and all technical documentation. ☐ Other remarks:
2.	☐ Health Canada, Canada *[Provide Health Canada Medical Device License]*	MDALL Number: Issuance Date: Risk classification in Canada:	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ Authenticity and validity of Health Canada license and evidence of approval against Health Canada database; and ☐ The name of medical device stated in the Health Canada license is aligned with the information in Section D and all technical documentation.

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	SECTION E: RECOGNISED FOREIGN REGULATORY AUTHORITY OR NOTIFIED BODY			
				☐ Other remarks:
3.	☐ Notified bodies listed in New Approach Notified and Designated Organisations (NANDO) database of European Union (EU) *[Provide EC Certificate and Declaration of Conformity]*	Country: Name of Notified Body: Certificate No: Annex: Issuance Date: Expiry Date: Scope of certification: *(highlight the applicable certification scope for the device to be registered)* Risk classification in EU:	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ Authenticity and validity of EC Certificate and evidence of approval against EUDAMED; and ☐ The Notified Body is listed in New Approach Notified and Designated Organizations (NANDO) database of European Union (EU); and ☐ The name and scope of medical device stated in the EC Certificate are aligned with the information in Section D and all technical documentation; and ☐ An EC Declaration of Conformity is provided. ☐ Other remarks:

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4.	☐ Ministry of Health, Labour and Welfare (MHLW) Japan - Choose an item. *[choose an approval type]* *[Provide the original and English translated certificate]*	Registration Certificate / Notified Body Name: Issuance Date: Risk classification in Japan:	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: Authenticity and validity of certificate and evidence of approval; and ☐ The translated certificate is provided. ☐ Other remarks:
5.	☐ Food and Drug Administration (FDA), United States of America (USA) - Choose an item. *[choose an approval type]* *[Provide 510(k) Pre-Market Notification or PMA Letter]*	510 (k) Pre-Market Notification Number/ Pre-Market Approval Number: Issuance Date: Risk classification in USFDA:	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ Authenticity and validity of certification and evidence of approval against USFDA database; and ☐ The name and intended use of medical device stated in the 510 (k)/PMA letter is aligned with the information in Section D and all technical documentation. ☐ Other remarks:

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6.	☐ Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom	☐ Public Access Database for Medical Device Registration; or ☐ UKCA Certification; or ☐ EC (CE Marking) and UKNI Certification Risk classification in UK MHRA:	☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ Authenticity and validity of certificate and / evidence of approval by UK MHRA; and ☐ The name of medical device stated in the certificate is aligned with the information in Section D and all technical documentation. ☐ Other remarks:

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	SECTION F: CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM (QMS)			
1.	The manufacturer's QMS certificate, issued by foreign recognised notified body (NB) or regulatory authority (RA) or MDA registered conformity assessment body (CAB) granting the certificate: ☐ ISO 13485; or ☐ US Quality System (QS) regulation (21 CFR Part 820); or ☐ Japan MHLW Ordinance 169 *[Provide QMS certificate and audit report (if applicable)]*	Name of CAB or RA or NB: Register No: Certificate no: Scope of certification: *(highlight the applicable certification scope for the device to be registered)* Issuance date: Expiry date:	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ Authenticity and validity of the manufacturer's QMS certificate, issued by foreign recognised NB or RA or MDA registered CAB; and ☐ The manufacturer's name and address are aligned with the information stated in the technical documentation including CSDT, declaration of conformity and product label; and ☐ The scope of certification is applicable to the medical device in Section D. ☐ Other remarks:

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	SECTION G: CONFORMITY ASSESSMENT ON POST MARKET SYSTEM (PMS)			
1.	List of reported on-going incident globally *[Provide list of reported on-going incident globally and if no PMS issue, provide a declaration letter from the manufacturer]*	List of reported ongoing incident:	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ List of reported ongoing incidents globally; or ☐ A PMS declaration letter is provided. ☐ Other remarks:
2.	List of incidents that have been resolved for the past 3 years *[Provide list of incidents that have been resolved for the past 3 years and if no PMS issue, provide a declaration letter from the manufacturer]*	List of incidents that have been resolved:	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ List of incidents that have been resolved for the past 3 years; or ☐ A PMS declaration letter is provided. ☐ Other remarks:
3.	Updated Post Market Surveillance & Vigilance Report for the past 3 to 5 years *[Provide PMSV report for the past 3 to 5 years]*	☒ Updated PMSV report is provided; and ☐ Date of report:	☐ YES ☐ NO	☐ Updated PMSV report has been reviewed and verified. ☐ Other remarks:
4.	Date of last ISO 13485 audit *[State date of the last audit]*	Date of last ISO 13485 audit:	☐ YES ☐ NO	☐ Date of last ISO 13485 audit has been reviewed and verified. ☐ Other remarks:

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	SECTION H: CONFORMITY ASSESSMENT ON TECHNICAL DOCUMENTATION			
1.	**Common Submission Dossier Template (CSDT)** *[CSDT elements must include executive summary, EPSP, description of medical device, summary of design verification and validation documents, summary of clinical evidence, labelling, risk analysis and manufacturer information. Where there are elements not applicable to the medical device dealt with, the justification for the no applicability should be provided]* *[Where such supporting documents are referenced within CSDT, every document must be submitted in full, i.e. all the pages of a document must be submitted. Those documents must be legible and within its validity period. All certificates or reports submitted must be and should be signed-off and dated by the person issuing the report]*	☐ CSDT includes all elements; and ☐ CSDT conforms to the template; and ☐ Manufacturer's name is stated; and ☐ Name of medical device is stated.	☐ YES ☐ NO	☐ All the CSDT elements have been reviewed and verified. ☐ Other remarks:
2.	**Essential Principle of Safety and Performance (EPSP)** *[The Essential Principles (EP) conformity checklist is to be prepared in the recommended format which includes applicability to the device (Yes/No), Method of conformity and identity of specific documents]*	☐ EPSP checklist is provided according to format; and ☐ Standards applicable is reflected in the DoC; and ☐ Name of medical device is stated; and ☐ Device identifier information is stated; and ☐ Brand/Model information is stated; and ☐ Manufacturer's name is stated; and ☐ The EPSP checklist is dated and signed by the person issuing the document.	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ The information in the EPSP checklist is aligned with the technical documentation; and ☐ The applicable standards particular to the medical device is included; and ☐ The EPSP checklist is dated and signed by the person issuing the document. ☐ Other remarks:

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3.	**Pre-Clinical Reports (GMD)** *[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]* ☐ Biocompatibility testing report *[State the name of report and standard applicable]* ☐ Engineering tests (mechanical or physical testing report, etc) *[State the name of report and standard applicable]* ☐ Electrical safety testing report *[State the name of report and standard applicable]* ☐ Electromagnetic test report *[State the name of report and standard applicable]* ☐ Sterilization testing report *[State the name of report and standard applicable]* ☒ Metrology tests *[State the name of report and standard applicable]* ☐ Radiation safety test/test report *[State the name of report and standard applicable]* ☐ Pre-clinical animal studies *[State the name of report and standard applicable]* ☐ Simulated use *[State the name of report and standard applicable]* ☐ Software validation studies *[State the name of report and standard applicable]* ☐ Stability test *[State the name of report and standard applicable]* ☐ Shelf life testing *[State the name of report and standard applicable]* ☐ Usability testing *[State the name of report and standard applicable]*	*[Summarize every pre-clinical report]* ☐ All the reports provided are dated and signed by the person issuing the documents.	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ The date and signature for each pre-clinical report is stated; and ☐ The summary of each pre-clinical report is provided; and ☐ The finding is sufficient to justify safety and performance of the device. ☐ Other remarks:

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	☐ Medical devices containing biological material *[State the name of report and standard applicable]* ☐ Other applicable test *[State the name of report and standard applicable]*			
4.	**Clinical Evaluation Report (CER) GMD** ☐ A systematic review of existing bibliography; and/or ☐ Clinical experience with the same or similar devices; and/or ☐ Clinical investigation in accordance with ISO14155; and/or ☐ Post Market Clinical Follow-Up (PMCF) *[The clinical evaluation shall be actively updated when the manufacturer receives new information from PMS that has the potential to change the current evaluation; if no such information is received, then* *at least annually if the device carries significant risks or is not yet well established or every 2 to 5 years if the device is not expected to carry significant risks and is well established, a justification should be provided]*	*[State intended use in the CER]* *[Summarize the CER]* ☐ CER Plan and Procedure is provided; and ☐ CER is signed by the person issuing the report; and ☒ Date of the CER: _____	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ CER is signed by the person issuing the report; and ☐ The manufacturer has clearly documented the objectives and the scope of the clinical evaluation; and ☐ The CER contains a short description of the medical device, its intended functions, description of the intended purpose and application of use. The information is aligned with the technical documentation; and ☐ The relevance of the author's background and expertise in relation to the particular device and/or medical procedure involved; and ☐ The manufacturer has adequately described and verified

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				the intended characteristics and performances related to clinical aspects; and ☐ The listing and characterisation of the clinical performance of the device intended by the manufacturer and the expected benefits for the patient. ☐ Other remarks:
5.	**Pre-Clinical Reports (IVD)** ☐ Analytical sensitivity; Limit of Detection/ Limit of Blank/ Limit of Quantitation *[State the name of report]* ☐ Analytical specificity; Cross reactivity *[State the name of report]* ☐ Interference; Endogenous, Exogenous *[State the name of report]* ☐ Linearity/ Assay's Measuring (Reportable) Range *[State the name of report]* ☐ Accuracy *[State the name of report]* ☐ Trueness *[State the name of report]* ☐ Shelf Life/ Projected useful life *[State the name of report]* ☐ Precision (Repeatability / Reproducibility) *[State the name of report]* ☐ Traceability and Expected Values *[State the name of report]* ☐ Cut-off Value *[State the name of report]*	*[Summarize every pre-clinical report]* The reports conform to template and includes: ☐ Study design ☐ Complete test/Study protocols ☐ Method of data analysis ☐ Data summaries ☐ Study conclusions ☐ Signature and date for each pre-clinical report	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ The date and signature for each pre-clinical report is stated; and ☐ The summary of each pre-clinical report is provided; and ☐ The finding is sufficient to justify safety and performance of the device; and ☐ The pre-clinical studies provided include information on study design, complete test or study protocols, methods of data analysis, data summaries and study conclusions; and

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	☐ Stability of reagent *[State the name of report]* ☐ Specimen stability *[State the name of report]* ☐ Carryover *[State the name of report]* ☐ Software Verification and Validation Studies *[State the name of report]* ☐ Usability testing (For Self-test use) *[State the name of report]* ☐ Electrical safety testing report *[State the name of report]* ☐ Other applicable test *[State the name of report]*			☐ The tests conducted met the set acceptance criteria which could reflect the safety and performance of the device. ☐ Other remarks:
6.	**Clinical Performance Report (CPR) IVD** ☐ Clinical (Diagnostic) Sensitivity *[State the name of report]* ☐ Clinical (Diagnostic) Specificity *[State the name of report]* ☐ Performance Evaluation *[State the name of report]* ☐ Comparison Studies Using Clinical Specimens; Matrix Comparison/Method Comparison *[State the name of report]* ☐ Clinical Cut-off *[State the name of report]* ☐ Reference Interval (Expected values) *[State the name of report]* ☐ Additional requirements for IVD medical device for self-testing and near patient testing *[State the name of report]* ☐ Method Comparison- Performance Validation (Cross table between layman user compare with professional user)-Infectious diseases test *[State the name of report]* ☐ Use of existing bibliography, Literature review *[State the name of report]*	*[Summarize the CPR]* The reports conform to template and includes: ☐ Study design ☐ Complete test/Study protocols ☐ Method of data analysis ☐ Data summaries ☐ Study conclusions ☐ CPR is signed by the person issuing the report	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ CPR is signed by the person issuing the report; and ☐ The manufacturer has clearly documented the objectives and the scope of the clinical evaluation and ☐ The intended use is the same as the device to be registered; and ☐ The clinical studies provided include information on study design, complete test or study protocols, methods of data analysis, data summaries and study conclusions; and ☐ The tests conducted met the set

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	[The clinical evaluation shall be actively updated when the manufacturer receives new information from PMS that has the potential to change the current evaluation; if no such information is received, then at least annually if the device carries significant risks or is not yet well established or every 2 to 5 years if the device is not expected to carry significant risks and is well established, a justification should be provided]			acceptance criteria which could reflect the safety and performance of the device. ☐ Other remarks:
7.	**Labelling** *[This section should summarize or reference or contain information on medical device labelling to the extent appropriate to the complexity and risk class of the device. Medical device labelling is a descriptive and informational product literature that accompanies the device any time while it is held for sale or shipped]* ☐ Home use / Self-test ☐ Professional use ☐ Home use and professional use ☐ Refurbished	☐ Labelling is provided in accordance with Sixth Schedule of the MDR 2012, Guidance Document on the Requirements of Labelling for Medical Devices and other relevant guidance documents specific for the device; and ☐ Medical device name and intended use on the label is aligned with the information stated in the CSDT; and ☐ Batch code/lot number (e.g. on single use disposable medical devices or reagents) or the serial number (e.g. on electrically-powered medical devices; and ☐ An indication of the date of manufacture; and ☐ The storage conditions and shelf life; and ☐ The use of internationally recognised symbols is encouraged; and	☐ YES ☐ NO	☐ Reviewed and verified the product label complied with Sixth Schedule of the MDR 2012 and Guidance Document on the Requirements of Labelling for Medical Devices. ☐ Other remarks:

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	☐ Name, address and contact details (optional) of the foreign manufacturer is provided; and ☐ Name, address and contact details of the local manufacturer or Authorized Representative (AR) is provided; and ☐ Bahasa Malaysia translation for home use/self-test medical device. ☐ Medical device registration number (For re-registration only). ☐ The medical device labelling includes the term "Refurbished" and carry a different catalogue number with a suffix of [R] (for refurbished medical device only). Others; Self testing kits (e.g.; Covid-19 self-test kit & HIVST) ☐ Disposal method ☐ IFU date and version ☐ Statement of "self-test use" in the IFU and product packaging ☐ English and translation in Bahasa Malaysia ☐ Infographic and video graphic explanation on how to conduct self-test ☐ QR code for TEST NOW platform (HIVST)		

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8.	**Risk Analysis** *[The accompanying documents referenced in the risk management report, including the risk management plan and results of risk assessment and risk control is to be provided. The risks and benefits associated with the use of the medical device should be described. Information required in this section is to be provided in the form of a risk management report. It is recommended that the risk management activities be conducted according to ISO 14971]*	A risk management report contains the following: ☐ A list of possible hazards for these devices. This should include indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from user related hazards, such as ionizing radiation from an X-ray machine; and ☐ The technique used to analyse risk to ensure that it is appropriate for the device and the risk involved. State technique use: _____; and ☐ The evaluation of these risks against the claimed benefits of the device; and ☐ The description on the method(s) used to control or reduce risk to acceptable levels; and ☐ The identification of individual or organization that carries out the risk analysis; and ☐ The report is signed and dated by the person issuing the report.	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ The risk management plan and results of risk assessment and risk control are provided; and ☐ The risk analysis is performed and the undesirable side effects is estimated; and ☐ Concluded on the basis of documented justification that the risks are acceptable when weighed against the intended benefits. ☐ Other remarks:

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9.	**Manufacturer Information** *[Manufacturing process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output. The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labelling, storage of the device]*	☐ The manufacturing process flowchart is provided; and ☐ Manufacturing processes including quality assurance measures is provided; and ☐ Batch release plan as required in the MDA/GD//0004 Guidance Document of CSDT of IVD (Class D IVD devices only).	☐ YES ☐ NO	☐ Reviewed and verified the manufacturing process for the device is provided in the form of a list of resources and activities that transform inputs into the desired output. ☐ Other remarks:
10.	**Manufacturing site information** The manufacturing site's QMS certificate, issued by foreign recognised notified body (NB) or regulatory authority (RA) or MDA registered conformity assessment body (CAB) granting the certificate: ☐ ISO 13485; or ☐ US Quality System (QS) regulation (21 CFR Part 820); or ☐ Japan MHLW Ordinance 169 *[The sites including contract manufacturers where design and manufacturing activities are performed shall be identified. Quality Management System certificates are to be provided for the design and manufacturing sites including contract manufacturers]*	Manufacturing site name: Address: Name of CAB or RA or NB: Register No: Certificate no: Scope of certification: *(highlight on the applicable device to be registered)* Issuance date: Expiry date:	☐ Same as above ☐ YES ☐ NO ☐ NA	The following information has been reviewed and verified: ☐ Authenticity and validity of the manufacturer's QMS certificate, issued by foreign recognised NB or RA or MDA registered CAB; and ☐ The manufacturing site's name and address are aligned with the information stated in the technical documentation including CSDT, declaration of conformity and product label; and ☐ The scope of certification is applicable to the medical device in Section D. ☐ Other remarks:

	REQUIREMENTS	INFORMATION TO BE FILLED BY THE ESTABLISHMENT/CAB *[Please fill up all required information. Reference to CSDT or annexes is not acceptable]*	COMPLY	VERIFICATION RESULT BY CAB
	SECTION I: CONFORMITY ASSESSMENT ON DECLARATION OF CONFORMITY (DOC)			
1.	**Declaration of conformity (DoC)** *[Provide a declaration of conformity document in accordance with the Malaysian DoC in the Appendix 3 Third Schedule Medical Device Regulation 2012. The information shall be consistent with the technical documentation including label, IFU, CSDT, QMS and EPSP. The QMS information shall be valid. The vertical and horizontal standards shall be stated.]*	☐ The information in the DoC is aligned with the technical documentation including label, IFU, CSDT, QMS and EPSP; and ☐ The DoC is prepared in accordance with the Malaysian DoC in the Appendix 3 Third Schedule Medical Device Regulation 2012; and ☐ The DoC is prepared with the manufacturer's letterhead and signed by the manufacturer's top management (including name, position and date); and ☐ The QMS information is aligned with section 4.0; and ☐ The vertical and horizontal standards are stated.	☐ YES ☐ NO	The following information has been reviewed and verified: ☐ The information in the DoC is aligned with the technical documentation including label, IFU, CSDT, QMS and EPSP; and ☐ The DoC is prepared in accordance with the Malaysian DoC in the Appendix 3 Third Schedule Medical Device Regulation 2012; and ☐ The DoC is prepared with the manufacturer's letterhead and signed by the manufacturer's top management (including name, position and date); and ☐ The QMS information is aligned with Section F; and ☐ The vertical and horizontal standards are stated. ☐ Other remarks:

	SECTION J: CONCLUSION OF VERIFICATION	
1.	Satisfactory	☐ YES ☐ NO
2.	Recommendation of issuance of certificate	☐ YES ☐ NO
3.	Pending for outstanding documents within time frame	☐ YES ☐ NO ☐ NA
4.	Outstanding documents are rectified within time frame	☐ YES ☐ NO ☐ NA
5.	CAB Overall Verification Findings and Conclusions	

Prepared and verified by:
[State signature, name and position]
[State date]

Verified and Approved by:
[State signature, name and position]
[State date]

Confidentiality
The contents of this report and all information received in association with the verification of the subject company will be maintained in the strictest confidence by the members of the audit team and by CAB, in accordance with prior agreements.
Additional Document
The Authority and CAB may request for information or specify conditions not described in this document that is deemed necessary to ensure the safety, quality, efficacy and performance of the medical device.
Report Template Revision
The Authority reserves the right to amend or revise any part of this report template whenever it deems fit.

ATTACHMENT 1 LIST OF CONFIGURATIONS

MEDICAL DEVICE LIST – SINGLE

No	Name as per Device Label	Device Identifier	Brief Description of Item	Unique Device Identifier

MEDICAL DEVICE LIST – SYSTEM

No	Name as per Device Label	Device Identifier	Brief Description of Item	Unique Device Identifier

MEDICAL DEVICE LIST – FAMILY

No	Name as per Device Label	Permissible Variant	Details on Permissible Variant	Device Identifier	Brief Description of Item	Unique Device Identifier

MEDICAL DEVICE LIST – FAMILY OF SYSTEM

No	Name as per Device Label	Permissible Variant	Details on Permissible Variant	Device Identifier	Brief Description of Item	Unique Device Identifier

MEDICAL DEVICE LIST – SET

No	Name as per Device Label	Device Identifier	Brief Description of Item	Unique Device Identifier

MEDICAL DEVICE LIST – IVD TEST KIT

No	Name of device, Accessories, Constituent components, Reagent or Articles as per product label	Model	Product Identifier/ Product Code	Brief Description of Item	Unique Device Identifier

MEDICAL DEVICE LIST – IVD CLUSTER

Components of Medical Device IVD Cluster										
No	**Subgroup of Cluster**	**Subgroup Name as per label**	**Permissible Variant**	**Details of Permissible Variant**	**Identifier of Subgroup**	**Brief Description of Item**	**Category as per MDA Guidance document**	**Test Principle**	**Methodology as per MDA guidance document**	**Unique Device Identifier**
1	**Family**	*Amylase 1*	*Package Size*	*10 x 3 mL*		**Description based on IFU**		**Test Principle based on IFU**		
		Amylase 2	*Package Size*	*10 x 3 mL*						
2	**IVD Test Kit**	*Alanine Aminotransferase (ALT)*	*Package Size*	*10 x 3 mL*		**Description based on IFU**		**Test Principle based on IFU**		
3	**System**	*Analyzer*	*NA*	*NA*		**Description based on IFU**		**Test Principle based on IFU**		
		Reagent								
		Control								
4	**Single**	*Calibrator*	*Package Size*	*5 x 2 mL*		**Description based on IFU**		**Test principle**		

								based on IFU		

ATTACHMENT 2 FORMULATION, ACTIVE INGREDIENT, POISON OR DRUG

No.	Ingredient	Scientific Name	Ingredient Function	Quantity	Composition Percentage

ATTACHMENT 3 LIST OF DOCUMENTS/ANNEXES

No.	Name of Document	File Name

ATTACHMENT 4 FINDINGS AND ACTIONS

No.	Verification findings (Action request with further submission)	Correction by establishment with reply date	Date and Review status by auditor (e.g.: reviewed and accepted or reviewed and not accepted with comment)

Conformity Assessment Report Revision History

Date	Revision Details
19 March 2024	Initial version
07 May 2024	Add CAB word in the column - Information to be filled by the Establishment/CAB