CYBERSECURITY LABELLING SCHEME FOR MEDICAL DEVICES
CCC SP-153-6B
DECLARATION OF CONFORMITY

Instructions for Use

This document is the **Declaration of Conformity for CLS(MD) Level 2, 3, and 4 applications.**

Applicants shall declare against **ALL** clauses specified in this document.

- "**M**" refers to Mandatory

Mandatory clauses for each CLS(MD) level are marked in green. Additionally, applicants shall ensure that the information provided in this declaration is accurate and return a signed copy to the Cybersecurity Certification Centre (CCC).

Moreover, applicants shall provide the necessary supporting evidence via the use of the CLS(MD) – Company – Supporting Evidence template.

Applicants shall refer to the CCC SP-153-4 CLS(MD) Pub 4 – Assessment Methodology for clarification on the minimum requirements and expected supporting for each clause. For clauses that the applicant declares as "Not Applicable", the applicant shall refer to CCC SP-153-4 CLS(MD) Pub 4 – Assessment Methodology for guidance on providing justification.

General Information

Company Name	
Device Proprietary / Brand Name	
Medical Device Model and Version	
Medical Device Class	
Singapore Medical Device Register (SMDR) Registration Number	

Clause	Provision	CLS(MD) Requirements Level 2, 3, 4	Conformity (Yes/No/NA)
Vulnerability Disclosure Policy (VDP)	VDP.1	M	
Management of Sensitive Data (MSD)	MDS.1	M	
Audit Controls (AUDT)	AUDT.1	M	
	AUDT.2	M	
Authorization (AUTH)	AUTH.1	M	
	AUTH.2	M	
Cyber Security Product Upgrades (CSUP)	CSUP.1	M	
	CSUP.2	M	
	CSUP.3	M	
	CSUP.4	M	
Data Backup and Disaster Recovery (DTBK)	DTBK.1	M	
	DTBK.2	M	
Malware Detection/ Protection (MLDP)	MLDP.1	M	
Node Authentication (NAUT)	NAUT.1	M	
Connectivity Capabilities (CONN)	CONN.1	M	
Person Authentication (PAUT)	PAUT.1	M	
	PAUT.2	M	
	PAUT.3	M	
	PAUT.4	M	
Roadmap for Medical Device Lifecycle (RDMP)	RDMP.1	M	
	RDMP.2	M	
	RDMP.3	M	
	RDMP.4	M	
Software Bill of Materials (SBOM)	SBOM.1	M	

Clause	Provision	CLS(MD) Requirements	Conformity (Yes/No/NA)
		Level 2, 3, 4	
System and Application Hardening (SAHD)	SAHD.1	M	
	SAHD.2	M	
	SAHD.3	M	
	SAHD.4	M	
Security Guidance (SGUD)	SGUD.1	M	
	SGUD.2	M	
	SGUD.3	M	
Health Data Storage Confidentiality (STCF)	STCF.1	M	
Transmission Confidentiality (TXCF)	TXCF.1	M	
Transmission Integrity (TXIG)	TXIG.1	M	
Remote Service (RMOT)	RMOT.1	M	
Other Security Considerations (OTHR)	OTHR.1	M	
	OTHR.2	M	
	OTHR.3	M	

Declaration of Conformity

We declare that all information given in this document is true and correct and that we have not and will not wilfully omit or suppress any material facts.

Authorised Signature & Date	Name & Designation	Company's Stamp