CYBERSECURITY LABELLING SCHEME FOR MEDICAL DEVICES DECLARATION OF CONFORMITY

Instructions for Use

Applicants shall declare against **ALL** clauses even if the clauses may not be mandatory for the level the developer is applying. "**M**" refers to Mandatory, whereas "**R**" refers to "Recommended". "**C**" refers to "Conditional" should a dependent provision is being implemented. The mandatory clauses for each CLS(MD) Levels are marked in green.

Applicants shall ensure that the information given in this declaration is true and return a signed copy to the CCC.

Applicants shall provide supporting evidence via the use of the CLS(MD) - Company - Supporting Evidence template.

Applicants may refer to the CLS(MD) Publication #4 – Assessment Methodology for the minimum requirements and expected supporting evidence for the clauses and provisions.

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				Developer's Conformity (Yes/No/Not Applicable)
		L1	L2	L3	L4	
Vulnerability Disclosure Policy (VDP)	VDP.1	M	M	M	M	
	VDP.2	R	M	M	M	
Management of Sensitive Data (MSD)	MDS.1	R	M	M	M	
Audit Controls (AUDT)	AUDT.1	R	M	M	M	
	AUDT.2	R C (1)	M C (1)	M C (1)	M C (1)	
Authorization (AUTH)	AUTH.1	R	M	M	M	
	AUTH.2	R C (1)	M C (1)	M C (1)	M C (1)	
Cyber Security Product Upgrades (CSUP)	CSUP.1	M	M	M	M	
	CSUP.2	R	M	M	M	
	CSUP.3	R	M	M	M	
	CSUP.4	M	M	M	M	
Data Backup and Disaster Recovery (DTBK)	DTBK.1	R C (2)	M C (2)	M C (2)	M C (2)	
	DTBK.2	R C (1)	M C (1)	M C (1)	M C (1)	
Malware Detection/Protection (MLDP)	MLDP.1	R C (3)	M C (3)	M C (3)	M C (3)	
Node Authentication (NAUT)	NAUT.1	R C (4)	M C (4)	M C (4)	M C (4)	
Connectivity Capabilities (CONN)	CONN.1	R C (4)	M C (4)	M C (4)	M C (4)	
Person Authentication (PAUT)	PAUT.1	R	M	M	M	
	PAUT.2	R C (5)	M C (5)	M C (5)	M C (5)	
	PAUT.3	M C (6)	M C (6)	M C (6)	M C (6)	
	PAUT.4	M C (5)	M C (5)	M C (5)	M C (5)	

Clause	Provision	CLS(MD) Requirements				Developer's Conformity (Yes/No/Not Applicable)
		L1	L2	L3	L4	
Roadmap for Medical Device Lifecycle (RDMP)	RDMP.1	M	M	M	M	
	RDMP.2	R	M	M	M	
	RDMP.3	R	M	M	M	
	RDMP.4	R	M	M	M	
Software Bill of Materials (SBOM)	SBOM.1	R	M	M	M	
System and Application Hardening (SAHD)	SAHD.1	R	M	M	M	
	SAHD.2	R	M	M	M	
	SAHD.3	R	M	M	M	
	SAHD.4	R	M	M	M	
Security Guidance (SGUD)	SGUD.1	R	M	M	M	
	SGUD.2	R	M	M	M	
	SGUD.3	R	M	M	M	
Health Data Storage Confidentiality (STCF)	STCF.1	R C (1)	M C (1)	M C (1)	M C (1)	
Transmission Confidentiality (TXCF)	TXCF.1	R C (4)	M C (4)	M C (4)	M C (4)	
Transmission Integrity (TXIG)	TXIG.1	R C (4)	M C (4)	M C (4)	M C (4)	
Remote Service (RMOT)	RMOT.1	R C (7)	M C (7)	M C (7)	M C (7)	
Other Security Considerations (OTHR)	OTHR.1	R C (7)	M C (7)	M C (7)	M C (7)	
	OTHR.2	R C (8)	M C (8)	M C (8)	M C (8)	
	OTHR.3	R	M	M	M	

Clause	Provision	CLS(MD) Requirements				Developer's Conformity (Yes/No/Not Applicable)
		L1	L2	L3	L4	
Note: Where the conditional notation is used, this is conditional on the text of the provision. The conditions are provided below with references provided for the relevant provisions to help with clarity.						

Conditions:

1) the device is unconstrained,

2) the device handles non-transient data or data which is needed for further processing/storing,

3) the device is unconstrained and makes use of operating systems,

4) the device communicates with other devices,

5) the device supports authentication,

6) the device supports password or PIN-based authentication,

7) the device supports remote sessions,

8) the device supports Wi-Fi communications.

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