APPLICATION FORM FOR ADDITIONAL TECHNICAL PERSONNEL (REGISTERED CAB)

ATTENTION:

1. All information should be **completed** and written using **uppercase letters**.

MDA Office Use Only (Tick √ if completed)

☐ Received form	[Date:	][Signature&Name:	]
☐ CE Office	[Date:	][Signature&Name:	]
☐ Finance Unit	[Date:	][Signature&Name:	]
☐ Head of CAB Unit	[Date:	][Signature&Name:	]
☐ Evaluation officer	[Date:	][Signature&Name:	]
☐ TEKCAB Meeting	[Date:	][Signature&Name:	]
☐ Information to CAB	[Date:	][Signature&Name:	]
☐ Update Data	[Date:	][Signature&Name:	]

1.0 INFORMATION ON ORGANISATION				
1.1	Name of CAB			
1.2	Address			
1.3	Telephone No. (O)		Telephone No. (H)	
1.4	Fax No.		E-mail address	
1.5	Website			

2.0 INFORMATION ON PERSONNEL				
2.01	Title	Dato' / Datin / Prof. / Assoc. Prof / Dr. / Ir. / Mr. / Mrs. / Ms.		
2.02	Full Name			
2.03	IC/ Passport No.			
2.04	Telephone No. (O)		Telephone No. (H)	
2.05	Fax No.		E-mail address	
2.06	Employment Status	**PERMANENT / SUBCONTRACTOR**		
2.07	IRCA No.			
2.08	Qualification	**BACHELOR / DIPLOMA DEGREE of**		
2.09	Name of University			
2.10	Graduation Year			

I **(Name of personnel)** ..... hereby attest that the information provided on this application is accurate, correct and current to this date.

Signature:
Date:

3.0 INFORMATION ON SCOPE APPLIED (Please tick at the appropriate box)		
Conformity Assessment on Quality Management System (QMS)		
	ISO 13485	Quality Management System for Medical Devices-Requirements for Regulatory Purpose
	GDPMD	Good Distribution Practice for Medical Devices
Conformity Assessment by Way of Verification		
	Verification : Conformity Assessment by Way of Verification ***(No fee imposed)***	
Conformity Assessment of Medical Device Technical Areas		
☐	**MD 0100: General Non-Active, Non-Implantable Medical Devices**	
	MD 0101	Non-active devices for anaesthesia, emergency and intensive care
	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
	MD 0103	Non-active orthopaedic and rehabilitation devices
	MD 0104	Non-active medical devices with measuring function
	MD 0105	Non-active ophthalmologic devices
	MD 0106	Non-active instruments
	MD 0107	Contraceptive medical devices
	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
☐	**MD 0200: Non-Active Implants**	
	MD 0201	Non-active cardiovascular implants
	MD 0202	Non-active orthopaedic implants
	MD 0203	Non-active functional implants
	MD 0204	Non-active soft tissue implants
☐	**MD 0300: Devices For Wound Care**	
	MD 0301	Bandages and wound dressings
	MD 0302	Suture material and clamps
	MD 0303	Other medical devices for wound care
☐	**MD 0400: Non-Active Dental Devices And Accessories**	
	MD 0401	Non-active dental equipment and instruments
	MD 0402	Dental materials
	MD 0403	Dental implants
☐	**MD 1100: General Active Medical Devices**	
	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
	MD 1103	Devices for stimulation or inhibition
	MD 1104	Active surgical devices
	MD 1105	Active ophthalmologic devices
	MD 1106	Active dental devices
	MD 1107	Active devices for disinfection and sterilisation
	MD 1108	Active rehabilitation devices and active prostheses
	MD 1109	Active devices for patient positioning and transport
	MD 1110	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
	MD 1111	Software
☐	**MD 1200: Devices For Imaging**	
	MD 1201	Imaging devices utilising ionizing radiation
	MD 1202	Imaging devices utilising non-ionizing radiation
☐	**MD 1300: Monitoring Devices**	
	MD 1301	Monitoring devices of non-vital physiological parameters
	MD 1302	Monitoring devices of vital physiological parameters
☐	**MD 1400: Devices For Radiation Therapy And Thermo Therapy**	
	MD 1401	Devices utilising ionizing radiation
	MD 1402	Devices utilising non-ionizing radiation
	MD 1403	Devices for hyperthermia / hypothermia
	MD 1404	Devices for (extracorporal) shock-wave therapy (lithotripsy)
☐	**AIMD 0100: General Active Implantable Medical Devices**	

	AIMD 0101	Active implantable medical devices for stimulation/inhibition
	AIMD 0102	Active implantable medical devices delivering drugs or other substances
	AIMD 0103	Active implantable medical devices substituting or replacing organ functions
☐	**IVD 0100: List A Reagents And Reagent Products, Including Related Calibrators And Control Materials, For Determining The Following Blood Groups**	
	IVD 0101	AB0 system
	IVD 0102	Rhesus (C, c, D, E, e)
	IVD 0103	Anti-Kell
☐	**IVD 0200: List A Reagents And Reagent Products, Including Related Calibrators And Control Materials, For The Detection, Confirmation And Quantification In Human Specimens Of Markers Of**	
	IVD 0201	HIV infection (HIV 1 and 2)
	IVD 0202	HTLV I and II
	IVD 0203	Hepatitis B, C and D
☐	**IVD 0300: List B Reagents, Reagent Products And Devices For Self - Diagnosis, Including Related Calibrators And Control Materials, For Determining, Detection, Quantification, Diagnosing, Evaluating**	
	IVD 0301	Anti-Duffy and anti-Kidd
	IVD 0302	Irregular anti-erythrocytic antibodies
	IVD 0303	Congenital infections: rubella, toxoplasmosis
	IVD 0304	Hereditary disease: phenylketonuria
	IVD 0305	Human infections: cytomegalovirus, chlamydia
	IVD 0306	HLA tissue groups: DR, A, B
	IVD 0307	Tumoral marker: PSA
	IVD 0308	Risk of trisomy 21 (incl. software)
	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
☐	**IVD 0400: Devices For Self-Testing**	
	IVD 0401	Clinical chemistry
	IVD 0402	Haematology
	IVD 0403	Immunology
	IVD 0404	Molecular biology
	IVD 0405	Pregnancy and ovulation
	IVD 0406	Specimen receptacles
☐	**MDS 7000: MD / AiMD Specifics**	
	MDS 7001	Medical devices incorporating medicinal substances, according to Directive 2001/83/EC
	MDS 7002	Medical devices utilising tissues of animal origin, including Directive 2003/32/EC
	MDS 7003	Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC
	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment
☐	**MDS 7200: Ivd Specifics**	
	MDS 7206	IVDs in sterile condition
	MDS 7207	IVDs utilising micromechanics
	MDS 7208	IVDs utilising nanomaterials
	MDS 7209	IVDs utilising biological active coating and/or material
	MDS 7210	IVDs utilising material of human origin

4.0 APPLICATION FEE

(i) Number of scope applied at 3.0 **: [ ]**

(ii) Total of fee application ((i) x RM100) **: [ ]**

ATTESTATION BY APPLICANT FOR ADDITIONAL TECHNICAL PERSONNEL APPLICATION

[To be printed on CAB letterhead of applicant]

Medical Device Authority, MOH

Date: .....

Dear Sir,

ATTESTATION FOR ADDITIONAL TECHNICAL PERSONNEL APPLICATION

I .....(Person Responsible)..... , NRIC No:..... hereby attest that the information provided on this application with any attached documents and certificates are accurate, correct and current to this date.

I understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Yours Sincerely,

Signature : …….

Name : ……

Date : …….