Medical Device AUTHORITY MALAYSIA	**PERMOHONAN BAGI PERTAMBAHAN KAKITANGAN TEKNIKAL CAB** ***APPLICATION FORM FOR ADDITIONAL TECHNICAL PERSONNEL (REGISTERED CAB)***	**BK-BPPP-070** **Versi 00** **Tarikh Kuatkuasa** *Effective date* **27 OGOS 2018**

Kegunaan Pejabat MDA sahaja (Sila tandakan √ jika selesai)

☐ Received form	[Signature&Name:	] [Date:]
☐ CE Office	[Signature&Name:	] [Date:]
☐ Finance Unit	[Signature&Name:	] [Date:]
☐ Head of CAB Unit	[Signature&Name:	] [Date:]
☐ Evaluation officer	[Signature&Name:	] [Date:]

A. MAKLUMAT ORGANISASI *INFORMATION ON ORGANISATION*

NAMA CAB *Name of CAB*			
ALAMAT CAB *CAB Address*			
LAMAN SESAWANG *Website Address*		**ALAMAT EMEL** *Email Address*	
NO. TELEFON (PEJABAT) *Telephone No (Office)*		**NOMBOR FAKS** *Fax Number*	

B. MAKLUMAT PERSONEL *INFORMATION ON PERSONNEL*

NAMA (Seperti di dalam IC) *Name (Same as IC)*			
NO. IC/ PASSPORT *IC/ Passport No.*			
NO. TELEFON (PEJABAT) *Contact Number (O)*		**JANTINA** *Gender*	**LELAKI/ PEREMPUAN** *Male / Female*
NO. TELEFON (HP) *Contact Number (HP)*		**JAWATAN** *Designation*	
ALAMAT EMEL *Email Address*		**WARGANEGARA** *Nationality*	
STATUS PEKERJAAN *Employment Status*	**TETAP *Permanent* / SUBKONTRAKTOR *Subcontractor***		
NO. IRCA *IRCA No.*			
KELAYAKAN *Qualification*	**IJAZAH** *Bachelor* **/ DIPLOMA IJAZAH** *Diploma Degree:*		
NAMA UNIVERSITI *Name of University*		**TAHUN GRADUASI** *Graduation Year*	

Saya (Nama personel) dengan ini mengesahkan bahawa segala maklumat yang diberikan terhadap permohonan ini adalah tepat, benar dan terkini sehingga tarikh ini.

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

Tandatangan *Signature:*
Tarikh Date:

*Sila lengkapkan Jadual Matrik Kompetensi di Lampiran 1
Please complete the Competency Matrix Template at Annex 1.

C. MAKLUMAT SKOP YANG DIMOHON *INFORMATION ON SCOPE APPLIED* (**Sila tanda di petak yang berkaitan** *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

D. FI PERMOHONAN *APPLICATION FEE*

(i) Bilangan skop yang dimohon di 3.0
Number of scope applied at 3.0 **: [ ]**

(ii) Jumlah bayaran fi permohonan (i) x RM100
Total of fee application (i) x RM100 **: [RM]**

E. Dokumen Sokongan (Sila Rujuk Lampiran 2)
Supporting documents (Please refer to Annex 2)

PERAKUAN ORANG YANG BERTANGGUNGJAWAB BAGI PERMOHONAN PENDAFTARAN CAB

ATTESTATION BY PERSON RESPONSIBLE FOR ADDITIONAL TECHNICAL PERSONNEL APPLICATION

[Untuk dicetak pada kepala surat syarikat syarikat]
[To be printed on CAB letterhead of applicant]

KEPADA : PIHAK BERKUASA PERANTI PERUBATAN
TO : MEDICAL DEVICE AUTHORITY

Tarikh *Date: ……..*

Tuan, *Dear Sir,*

PERAKUAN PERMOHONAN PERTAMBAHAN KAKAITANGAN TEKNIKAL
ATTESTATION FOR ADDITIONAL TECHNICAL PERSONNEL APPLICATION

Saya (nama Orang yang Bertanggungjawab) , (nombor kad pengenalan) dengan ini membuktikan bahawa maklumat yang diberikan untuk permohonan ini dan mana-mana dokumen yang dilampirkan, sijil yang telah disahkan benar adalah salinan yang tepat, benar dan terkini sehingga ke tarikh ini.
I (Person Responsible name) , (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.

Saya faham dan mengakui bahawa ia adalah menjadi kesalahan di bawah Seksyen 76 Akta Peranti Perubatan 2012 (Akta 737) dengan membuat penandaan atau memberi apa-apa perisytiharan, perakuan atau dokumen lain yang tidak benar, tidak tepat atau mengelirukan.
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.

Terima kasih
Thank you.

Yang Benar,
Yours Sincerely,

Tandatangan
Signature *: ……*

Nama
Name *: ……*

Tarikh
Date *: ……*

Cop rasmi
Official stamp *: ……....*

RINGKASAN JADUAL MATRIK KOMPETENSI
SUMMARY OF TECHNICAL COMPETENCY MATRIX TEMPLATE

No.	Applicant Detail	Work Experience	Training Course	Remark
1	Salutation: *(Note: Please select)* **MR. / MRS. / MS.** Name: *(Note: As in Identity Card / Passport)* **FULL NAME** Identity Card / Passport Number: **XXXXXX-XX-XXXX** Nationality: **XXXXX** Applied for: *(Note: Please select or add)* **ISO 13485** **GDPMD** **MD XXXX** **VERIFICATION** Employment status: *(Note: Please select)* **PERMANENT / SUBCONTRACTOR** Bachelor Of: *(Note: As in Education Certificate)* **COURSE NAME** University: **UNIVERSITY NAME, COUNTRY NAME** Graduation year: **XXXX – XXXX**	Total experience-years in certification industry: **XX YEARS** Total experience-years in medical device industry: **XX YEARS** Total experience-years in related technology: **XX YEARS** **[NAME OF CURRENT COMPANY]** Business nature: **XXXXX** Total years: **XX YEARS** Position: **XXXXX** Job description: **XXXXX** **[NAME OF PREVIOUS COMPANY]** Business nature: **XXXXX** Total years: **XX YEARS** Position: **XXXXX** Job description: **XXXXX** **[NAME OF PREVIOUS COMPANY]** Business nature: **XXXXX** Total years: **XX YEARS** Position: **XXXXX** Job description: **XXXXX** *(Note: Please delete where necessary)*	Training sanctioned by the Authority: *(Note: Pre-requisite requirement for GDPMD, ISO 13485 & MD Technical Areas applications)* **TRAINING ON CONFORMITY ASSESSMENT BODY REGISTRATION UNDER THE ACT 737** Type of certificate: CERTIFICATE OF PROFICIENCY Training date: XX/XX/XXXX (1 DAY) Venue: XXXXX, XXXXX Examination Mark: XX.XX% Training sanctioned by the Authority: *(Note: Pre-requisite requirement for Verification application only)* **TRAINING ON CONFORMITY ASSESSMENT PROCEDURES ON QMS & PMSS** Type of certificate: CERTIFICATE OF PROFICIENCY Training date: XX/XX/XXXX (1 DAY) Venue: XXXXX, XXXXX Examination Mark: XX.XX% Training sanctioned by the Authority: *(Note: Pre-requisite requirement for Verification application only)* **TRAINING ON CONFORMITY ASSESSMENT PROCEDURES ON TECHNICAL DOCUMETATION & VERIFICATION** Type of certificate: CERTIFICATE OF PROFICIENCY Training date: XX – XX/XX/XXXX (2 DAYS) Venue: XXXXX, XXXXX Examination Mark: XX.XX% *(Note: Pre-requisite requirement for GDPMD and/or ISO 13485 applications only)* **ISO 9001 QUALITY MANAGEMENT SYSTEM LEAD AUDITOR TRAINING COURSE** Type of certificate: CERTIFICATE OF XXXXX Training date: XX – XX/XX/XXXX (5 DAYS) Venue: XXXXX, XXXXX And *(Note: For ISO 13485 application only)* **ISO 13485 MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM AUDITOR TRAINING COURSE (MINIMUM 2-DAYS)**	Registered for: *(Note: If available)* **INTERNATIONAL REGISTER OF CERTIFICATED AUDITOR (IRCA)** Registered since: **XX/XX/XXXX** Certification No. : **XXXXX** *(Note: For GDPMD application)* Total audit-days for ISO 9001 certification: **XX DAYS** *(Note: For ISO 13485 application)* Total audit-days for ISO 13485 certification: **XX DAYS** *(Note: For MD Technical Areas application)* Total audit-days for Technical Documentation certification: **XX DAYS** *(Note: For Verification application)* Total audit-days for Verification certification: **XX DAYS**

			Type of certificate: CERTIFICATE OF XXXXX Training date: XX – XX/XX/XXXX (2 DAYS) Venue: XXXXX, XXXXX Or *(Note: For ISO 13485 application only)* **ISO 13485 MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM LEAD AUDITOR TRAINING COURSE** Type of certificate: CERTIFICATE OF XXXXX Training date: XX – XX/XX/XXXX (5 DAYS) Venue: XXXXX, XXXXX *(Note: Pre-requisite requirement for all applications)* **ISO 14971 RISK MANAGEMENT FOR MEDICAL DEVICE TRAINING COURSE** Type of certificate: CERTIFICATE OF XXXXX Training date: XX/XX/XXXX (1 DAY) Venue: XXXXX, XXXXX *(Note: For MD Technical Personnel application only)* **MD XXXX TRAINING COURSE** Type of certificate: CERTIFICATE OF XXXXX Training date: XX – XX/XX/XXXX (X DAYS) Venue: XXXXX, XXXXX	

***Sila patuhi jadual yang diberikan dengan tepat. Jangan tinggal sebarang maklumat yang diperlukan. Terima kasih**
**Please follow exactly the template given. Do not skip any required information from the table. Thank you.*

LAMPIRAN 2
ANNEX 2

DOKUMEN YANG DIPERLUKAN UNTUK PENDAFTARAN JURUAUDIT/ KAKITANGAN PERSONNEL
REQUIRED DOCUMENTS FOR REGISTERING AUDITORS/ TECHNICAL PERSONNEL

Nota: Sila letakkan nombor pada setiap dokumen yang dihantar mengikut seperti yang dinyatakan di ruangan *DOCUMENT NUMBERING*'.
Note: Please indicate the numbering for all submitted documents as declared at the column of 'DOCUMENT NUMBERING'.

	GDPMD AUDITOR	***DOCUMENT NUMBERING***
(1)	*Competency Matrix;*	
(2)	*Copy of Curriculum Vitae;*	
(3)	*Copy of Identity Card or Passport or Work Permit;*	
(4)	*Copy of Employment Letter or Subcontractor Agreement;*	
(5)	*Copy of Education Certificate (Bachelor's Degree);*	
(6)	*Copy of Proficiency Certificate of MDA's Sanctioned Training Courses (Legislation);*	
(7)	*Copy of Proficiency Certificate of MDA's Sanctioned Training Courses (QMS);*	
(8)	*Copy of Attendance Certificate of ISO 9001:2015 Lead Auditor Training Course; or*	
(9)	*Copy of Attendance Certificate of ISO 13485:2016 Lead Auditor Training Course;*	
(10)	*Copy of Attendance Certificate of ISO 14971:2012 Training Course;*	
(11)	*Copies of Attendance Certificates of Related Medical Device Areas Training Courses;*	
(12)	*Copy of Audit Log (in man-day or man-hour) of ISO 9001 audits (minimum 40 hours).*	

	ISO 13485 AUDITOR	***DOCUMENT NUMBERING***
(1)	*Competency Matrix;*	
(2)	*Copy of Curriculum Vitae;*	
(3)	*Copy of Identity Card or Passport or Work Permit;*	
(4)	*Copy of Employment Letter or Subcontractor Agreement;*	
(5)	*Copy of Education Certificate (Bachelor's Degree);*	
(6)	*Copy of Proficiency Certificate of MDA's Sanctioned Training Courses (Legislation);*	
(7)	*Copy of Proficiency Certificate of MDA's Sanctioned Training Courses (QMS);*	
(8)	*Copy of Attendance Certificate of ISO 13485:2016 Lead Auditor Training Course;*	
(9)	*Copy of Attendance Certificate of ISO 14971:2012 Training Course;*	
(10)	*Copies of Attendance Certificates of Related Medical Device Areas Training Courses;*	
(11)	*Copy of Audit Log (in man-day or man-hour) of ISO 9001 and/ or ISO 13485 audits (minimum 40 hours).*	

	MEDICAL DEVICE TECHNICAL PERSONNEL	***DOCUMENT NUMBERING***
(1)	*Competency Matrix;*	
(2)	*Copy of Curriculum Vitae;*	
(3)	*Copy of Identity Card or Passport or Work Permit;*	
(4)	*Copy of Employment Letter or Subcontractor Agreement;*	
(5)	*Copy of Education Certificate (Bachelor's Degree);*	
(6)	*Copy of Proficiency Certificate of MDA's Sanctioned Training Courses (Legislation);*	
(7)	*Copy of Proficiency Certificate of MDA's Sanctioned Training Courses (Technical Documentation & Verification);*	
(8)	*Copy of Attendance Certificate of ISO 14971:2012 Training Course;*	
(9)	*Copies of Attendance Certificates of Related Medical Device Areas Training Courses;*	
(10)	*Copy of Audit Log (in man-day or man-hour) of technical file/ verification reviews (minimum 40 hours).*	

<Senarai Tamat *End List*>