Application for Recognition (or Change of Scope of Recognition)

Under the Conformity Assessment Body Recognition Scheme of the MDACS

(Note: Please use separate sheet if necessary)

Organization Profile				*
1	Name of Organization			
2	Address			
3	Telephone number			
4	Fax number			
5	Website			
6	E-mail address			
7	Certification Manager	Name		
		Position		
		Address		
		Telephone no.		
		Fax no.		
		E-mail address		
8	Local Representative	Name		
		Position		
		Address		
		Telephone no.		
		Fax no.		
		E-mail address		
9	Deputy Local Representative	Name		
		Position		
		Address		
		Telephone no.		
		Fax no.		

***** Please number all the documents submitted with this application form and enter the numbers in the respective cells in this column.

Organization Profile				*
		E-mail address		
10	Organization chart		*Please attach as Attachment (1)*	(1)
11	Business of Organization		☐ assessment and certification of quality systems ☐ product certification ☐ testing and calibration laboratories ☐ consultants ☐ others (please specify) _____	
12	Status of Organization (e.g. body corporate). Please also provide documentation that can identify its status.			
13	Number of employees			
14	Address(es) outside Hong Kong			
15	Has the Organization already been designated or accredited as a Conformity Assessment Body in the field of medical devices or one or more related fields (e.g. EMC) under regulatory systems of other countries (or any other systems, e.g., accreditation by a member of IAF for assessment of quality management system)? If yes, please provide details (including the scope of designation or accreditation) and supporting documents.			
16	If the Organization is part of a larger organization, please provide details about this larger organization and its structure, indicating in particular its relationship with the Organization.			

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Scope of Recognition Being Sought				*
17	A (revised) scope is being sought that is limited to: (Please indicate whether the scope includes type examination.)	Product ranges		

Resources of Organization			*
18	Test facilities. Please state their addresses and test capabilities and give details, including documentary proof, of any accreditation.		
19	In-house experts / specialists / assessors. Please list their names and their areas of competence and provide their CVs.		
20	Sub-contractors. Please specify their names, addresses, contact details, and their areas of competence. For individual sub-contract experts / specialists / assessors, please also provide their CVs. For sub-contract test laboratories, please state their testing capabilities and give details, including documentary proof, of any accreditation they have claimed.		
21	Liability insurance taken out by Organization (The insurance must cover its conformity assessment activities) *(Please provide a copy of the insurance certificate if possible)*	Sum Insured : _____ Insurer's name and address: _____ Renewal date: _____	

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Further Information for Assessment			*
22	Please submit a copy of the system documentation of the Organization's quality management system (QMS). Detailed work instructions may be excluded from this submission.	*Please attach. Softcopy is acceptable.*	
23	Procedures by which cases of conflicts of interest or potential conflicts of interest are identified and resolved.	*Please indicate where in the QMS documentation these procedures can be located:* _____	
24	Procedures by which the Organization ensures impartiality of its employees and sub-contractors	*Please indicate where in the QMS documentation these procedures can be located:* _____	
25	Procedures for sub-contracting including documented procedures for monitoring subcontractors' performance	*Please indicate where in the QMS documentation these procedures can be located:* _____	
26	Mechanisms that ensure confidentiality between the Organization and its clients	*Please indicate where in the QMS documentation these procedures can be located:* _____	
27	Procedures according to which conformity assessment within the scope of recognition will be carried out by the Organization (and its sub-contractors if any)	*Please indicate where in the QMS documentation these procedures can be located:* _____	
28	Sample agreements between the Organization and its subcontractors	*Please attach if available.*	

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Important Notes for Applicant

1. In these Notes and in the declaration below-

(i) "the MDACS" stands for "the Medical Device Administrative Control System";

(ii) "the MDD" stands for "the Medical Device Division";

(iii) "the CAB Recognition Scheme" or "the Scheme" means the Conformity Assessment Body Recognition Scheme of the MDACS; and

(iv) "the Government" means the Government of the Hong Kong Special Administrative Region.

2. The current requirements of the CAB Recognition Scheme can be ascertained from this form and other publicly accessible documents issued by the MDD, including but not limited to the Guidance Notes GN-04.

3. The CAB Recognition Appeal Board referred to in the Guidance Notes GN-04 is comprised of Government officials not directly involved in the administration of the CAB Recognition Scheme.

4. The information (which may include personal data) that the MDD obtains in confidence from the applicant or other persons in connection with its implementation or management of the MDACS, and in particular in connection with this application, will be retained, processed, and used by and within the Government for the purpose of implementing or managing the MDACS. The Government will also use the information for other purposes, or disclose the information to another party, only if this use or disclosure-

(i) has the consent of the persons who originally provided the information in confidence; or

(ii) is required by the laws of the Hong Kong Special Administrative Region; or

(iii) is in the interest of the public and is lawful.

5. The MDACS including the CAB Recognition Scheme is intended, not as a permanent arrangement, but as a predecessor to a longer term, statutory regulatory system. Where appropriate the planning of the latter system will take account of the experience gained from the implementation of the MDACS. There is, however, no representation or warranty on the part of the Government as regards the similarities or differences between the requirements of the MDACS and those of the longer term system. This longer term system is to be implemented only if the legislation on which it is based is enacted.

Declaration

(Please read the Important Notes above before signing this declaration.)

1. We _____

_____ (name and address of applicant) declare -

(i) that the information given on this application form and on any separate sheets that supplement this form is true and correct; and

(ii) that the documents that are submitted with this application form are either original documents or true copies of their respective originals.

2. We understand and agree that the requirements of the CAB Recognition Scheme are subject to revisions from time to time. We understand that the updated requirements will be either communicated to us in writing by the MDD or promulgated in publicly accessible documents issued by the MDD (e.g. a revised edition of the Guidance Notes GN-04), or both. We undertake that we will abide by the latest requirements of the Scheme and by any instructions that the Department of Heath or the MDD issues to us pursuant to any audits or investigations under the Scheme.

3. We agree that the Government may publish the following information to the public once this application is successful:

- **our name and contact details;**
- **our status as a recognized Conformity Assessment Body under the Scheme;**
- **our scope of recognition, as well as the date when this scope becomes effective.**

Signature (authorized representative):	
Name:	
Position:	
Telephone no:	
Organization:	
Date:	