

# GUIDELINES AND PROCEDURES FOR APPLICATION OF TAX INCENTIVES UNDER THE PROMOTION OF INVESTMENTS ACT, 1986 AND/OR EXPATRIATE POSTS FOR MEDICAL DEVICE TESTING LABORATORIES

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## 1. TAX INCENTIVES

- A. Companies investing in **new laboratories** of recognised international standard for testing of medical devices can be considered for the following tax incentives:
- (a) Pioneer Status of 100% tax exemption on statutory income for 5 years; or
  - (b) Investment Tax Allowance (ITA) of 60% on qualifying capital expenditure incurred within a period of 5 years to be offset against 100% of statutory income.
- B. Companies **upgrading existing testing laboratories** to meet international standards for testing of medical devices can be considered for ITA of 60% on qualifying capital expenditure incurred within a period of 5 years to be offset against 100% of statutory income.

These incentives are applicable for applications received by MIDA from 8 September 2007 to 31 December 2012.

## 2. ELIGIBLE APPLICANTS

- A company which invests in new laboratories to test medical devices for compliance with recognised international standards.
- A company which upgrades existing testing laboratories by investing in additional equipment/machinery for testing of medical devices to meet recognised international standards.

## 3. QUALIFYING CRITERIA

- The company must be incorporated under the Companies Act 1965.
- The company must obtain accreditation for the testing laboratory in compliance with recognised international standards, for purposes of testing medical devices, from recognised international bodies such as International Standards Organisation (ISO) and International Electrotechnical Commission (IEC).
- The minimum certification required should be at least ISO 15189 or its equivalent. The company is required to submit certified true copies of the certificate(s) of accreditation/certification in compliance with recognised international standards within 2 years from the date of approval of the incentive.

- At least 70% of the income of the company should be derived from medical device testing activities.
- At least 50% of the workforce of the company must be appropriately qualified personnel performing medical device testing activities.

#### **4. QUALIFYING CAPITAL EXPENDITURE**

For ITA, qualifying capital expenditure means expenditure incurred on building, machinery and/or equipment used for purposes of testing medical devices.

#### **5. DEFINITION OF MEDICAL DEVICES**

Medical devices are defined as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
  - investigation, replacement, modification, or support of the anatomy or of a physiological process,
  - supporting or sustaining life,
  - control of conception,
  - disinfection of medical devices,
  - providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

- b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

## 6. EXPATRIATE POSTS

Companies which invest in new laboratories or upgrade existing laboratories for testing of medical devices may also apply for expatriate posts subject to current policy on employment of expatriates.

## 7. APPLICATION PROCEDURES

- (a) Applications should be made using the **TL / JA** application form.
- (b) Applicants are also required to submit a copy each of the certified true copies of the following documents:-
- Form 9 or 13
  - Form 24
  - Form 44
  - Form 49
  - Memorandum and Articles of Association
- (c) Applications should be submitted in **three (3)** copies to:-

**Director-General  
Malaysian Industrial Development Authority (MIDA)  
2<sup>nd</sup> Floor, Plaza Sentral  
Jalan Stesen Sentral 5,  
50470 Kuala Lumpur  
P.O. Box 10618  
50720 Kuala Lumpur  
Malaysia  
(Attn: Director, Business & Other Services Division)**

For projects in Sabah and Sarawak, **three (3) copies** of the forms should also be submitted to the relevant MIDA offices as follows:-

### Sabah

**Director  
MIDA Sabah Office  
Lot D9.4 & D9.5  
9th Floor, Block D  
Bangunan KWSP  
Karamuning  
88100 Kota Kinabalu  
Sabah, Malaysia**

### Sarawak

**Director  
MIDA Sarawak State Office  
Room 404, 4th Floor  
Bangunan Bank Negara Malaysia  
No. 147 Jalan Satok  
PO Box 716  
93714 Kuching  
Sarawak, Malaysia**

For enquiries and clarifications, please refer to:-

MIDA's website : [www.mida.gov.my](http://www.mida.gov.my)  
Tel : 603-2267 3633  
Fax : 603-2274 7970 / 2267 6655  
E-mail : [investmalaysia@mida.gov.my](mailto:investmalaysia@mida.gov.my)

**APPLICATION FOR TAX INCENTIVES AND/OR EXPATRIATE POSTS FOR MEDICAL  
DEVICE TESTING LABORATORIES**

(I) Type of application (Please tick (✓) where relevant):

**Incentive**

(i) Pioneer Status

(ii) Investment Tax Allowance

**Laboratory**

(i) New Laboratory

(ii) Upgrading of Existing Laboratory

**Expatriate Posts**

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**A. PARTICULARS OF COMPANY**

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1. (a) Name of company:

\_\_\_\_\_

Type of company registration (Please tick (✓) where relevant):

(i) Registrar of Business

(ii) Registrar of Companies

(iii) Others (Please specify):

\_\_\_\_\_

Date of incorporation:

Company registration no.:

\_\_\_\_\_

\_\_\_\_\_

(b) Correspondence address:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Contact person:

Designation:

\_\_\_\_\_

\_\_\_\_\_

Telephone no.:

Fax no.:

\_\_\_\_\_

\_\_\_\_\_

E-mail:

Website:

\_\_\_\_\_

\_\_\_\_\_

(c) Registered address:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Contact person:

Designation:

\_\_\_\_\_

\_\_\_\_\_

Telephone no.:

Fax no.:

\_\_\_\_\_

\_\_\_\_\_

E-mail:

Website:

\_\_\_\_\_

\_\_\_\_\_

2. Particulars of Board of Directors\*

Name and residential address	Nationality	% shares held in the company

Note:\* If the space provided is insufficient, please provide the information on a separate sheet of paper

**B. PROJECT COST\***

	New/Existing <u>RM</u>	Additional <u>RM</u>	Total <u>RM</u>
<b>1. Fixed assets**</b>			
(i) Land (Specify area in hectares)			
(ii) Building and other built-up facilities (Specify built-up area in m <sup>2</sup> )			
(iii) Equipment/Machinery			
(iv) Others			
<b>Total fixed assets</b>			
<b>2. Pre-operational expenditure</b>			
<b>3. Working capital</b>			
<b>Total project cost</b>			
<i>**If assets are rented/leased, please indicate the annual cost of rental/lease below:</i>			
(i) Land (Specify area in hectares)			
(ii) Building and other built-up facilities (Specify built-up area in m <sup>2</sup> )			
(iii) Equipment/Machinery			
(iv) Others			
<b>Total rental/lease</b>			

\* If there is more than one laboratory location, please provide the same information on a separate sheet of paper

**C. FINANCING**

	New/Existing <u>RM</u>	Additional <u>RM</u>	Total <u>RM</u>	<u>%</u>
1. Authorised capital	_____	_____	_____	
2. Shareholders' funds				
(a) Paid-up capital				
(i) Malaysian individuals				
Bumiputera	_____	_____	_____	_____
Non-Bumiputera	_____	_____	_____	_____
(ii) Companies incorporated in Malaysia*	_____	_____	_____	_____
_____	_____	_____	_____	_____
(iii) Foreign nationals/ companies (Specify name and nationality/country of origin)	_____	_____	_____	_____
_____	_____	_____	_____	_____
<b>Total of (i), (ii) and (iii)</b>	_____	_____	_____	<b>100%</b>
(b) Reserves (excluding capital appreciation)	_____	_____	_____	
<b>Total of (a) and (b)</b>	_____	_____	_____	

\* For 2(a)(ii), please provide equity structure as follows:

Name of company:

Name of company:

\_\_\_\_\_ %

\_\_\_\_\_ %

Bumiputera \_\_\_\_\_

Bumiputera \_\_\_\_\_

Non-Bumiputera \_\_\_\_\_

Non-Bumiputera \_\_\_\_\_

Foreign nationals/companies  
(Specify name and  
nationality/country of origin)  
\_\_\_\_\_

Foreign nationals/companies  
(Specify name and  
nationality/country of origin)  
\_\_\_\_\_

**Total** 100%

**Total** 100%

	New/Existing <u>RM</u>	Additional <u>RM</u>	<b>Total <u>RM</u></b>
3. Loan:			
Domestic	_____	_____	_____
Foreign (Specify country of origin)	_____	_____	_____
_____			
<b>Total</b>	_____	_____	_____
4. Other sources (Please specify)			
_____	_____	_____	_____
_____	_____	_____	_____
<b>Total</b>	_____	_____	_____
<b>Total of 2, 3 and 4</b>	_____	_____	_____

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**D. PARTICULARS OF TESTING LABORATORY**

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1. Name of Laboratory: \_\_\_\_\_

Address of Laboratory:

\_\_\_\_\_

\_\_\_\_\_

Contact person: \_\_\_\_\_

Designation: \_\_\_\_\_

Telephone no.: \_\_\_\_\_

Fax no.: \_\_\_\_\_

E-mail: \_\_\_\_\_

2. Describe in detail the Main Scope of Testing carried out by Laboratory (such as chemical, mechanical, biological, electrical/electronic).

\_\_\_\_\_

\_\_\_\_\_



3. Laboratory Accreditation

3.1 Please indicate areas of testing to be undertaken (Append Certificate where applicable)

No.	Type of Accreditation	Scheme	Areas Accredited	Year (where applicable)

4. List of Testing Equipment/Machinery

No.	Equipment	Cost	Function	Country of Origin
	Testing Equipment/Machinery			
	Others (Please specify)			

**D. INCOME SCHEDULE**

1. Annual income: RM \_\_\_\_\_

2. Income derived from testing services

Services	Value (RM)		
	Year 1	Year 2	Year 3

**E. MANPOWER**

Category	Full-time employment		
	Malaysian	Foreign national	Total
1. Managerial staff with:			
(a) Technical/ science qualification/experience			
(b) Other qualifications/experience			
2. Technical and supervisory staff with:			
(a) Technical/science qualification/experience			
(b) Other qualifications/experience			
4. Others			
Please specify			
<b>Total</b>			

## F. EXPATRIATE POSTS

Please complete this section if the applicant is applying for expatriate posts.

### 1. Details of expatriate posts applied for\*

Designation	Type of post (key/term post)	Number	Duration (years)

Note:\* For each expatriate post applied for, please provide details as in Appendix I

### 2. Details of existing posts approved (if any)

Designation	Name and nationality	Duration approved	Date post filled	Expiry date of post

3. Please attach the organisation chart of the company indicating the positions of the expatriate posts.

**G. DECLARATION**

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I, \_\_\_\_\_, the Managing Director of

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(i) hereby declare that to the best of my knowledge, the particulars furnished in this application are true.

(ii)\* have engaged/is planning to engage the services of the following consultant for my application :

Company Name : \_\_\_\_\_

Address : \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Contact Person : \_\_\_\_\_

Designation : \_\_\_\_\_

Telephone no. : \_\_\_\_\_

Fax no. : \_\_\_\_\_

E-mail : \_\_\_\_\_

\_\_\_\_\_

I take full responsibility for all information submitted by the consultant(s).

\_\_\_\_\_

Date

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(Signature)

\*Please complete this section if the company has engaged/is planning to engage the services of consultant(s) to act on behalf of the company. Please provide information on a separate sheet of paper if space is insufficient