

ANNEX A (NORMATIVE)



APPLICATION FORM FOR MEDICAL DEVICE ADVERTISING
In accordance with Medical Device (Advertising) Regulations 2019

FOR OFFICE USE ONLY : Application Reference Number

Acknowledged by:	Designated Evaluation Officer:
Officer's Name: _____	_____
Designation: _____	Assigned by: _____
Date: _____	Date: _____

1. APPLICANT'S DETAILS

Name of Applicant:
Note: Applicant will be the person responsible for the advertisement.

Identification Card/ Passport Number:

Designation:

Phone No.:	Email Address:
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Company name & registration number (if applicable):

Address:

Postcode:	City:	State:
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Company's Phone No.:	Company Email Address:
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Role of Applicant: Please tick one only.

- Establishment (Please state the Establishment License Number:)
- Manufacturer
- Authorized Representative (AR)
- Distributor
- Importer
- Advertising agency/ service provider
- Other (Please specify:)
- e.g.: Retailer, Healthcare Service Provider, Online Selling Platform Provider, etc.

2. MEDICAL DEVICE DETAILS

Name of Medical Device	Brand	Registration Number	Establishment License Number

3. ADVERTISEMENT DETAILS

Has this advertisement been approved before?

- Yes; **Please provide approval number:**
- No

4. CONTENT TYPE (TICK 1 ONLY)

- Text/ Infographic/ Pictorial presentation (without video/ audio recording)
- Visual recording/ Audio visual recording
- Audio recording

5. PROPOSED MEDIA FOR ADVERTISEMENT

Broadcast Media

- TV
- Radio
- Others (please state)
- Name of program/ slot:
-

External Media

- Billboard
- Signage
- Moving signage (Bus/ Taxi/ Car/ etc.)
- Others (please state):
-

Printed Media

- Newspaper
- Magazine
- Book
- Catalogue
- Brochure
- Poster/Flyer
- Others (please state)
- Name of publication:
-

Internet/ Social Media

- Company Webpage/portal
- YouTube
- Facebook
- Instagram
- Other Online selling platform (please state)
- URL:
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6. PROPOSED LANGUAGE(S) FOR ADVERTISEMENT

- Malay
- English
- Mandarin
- Tamil
- Other language (Please specify:

**Note: Kindly provide the translated format of the advertisement in a language other than Malay or English.*

7. ADVERTISEMENT CONSIST OF:

- Information on tests, trials, scientific reference
- Testimony
- Celebrity endorsement

Note: Please provide supporting documents for the above, e.g.: consent/ endorsement/ approval letter from the relevant individual/ organization and data/ report/ evidences.

8. ATTESTATION & DECLARATION

I, (name of person responsible), Identification Card/ Passport Number....., as the applicant of this advertisement, hereby declare that:

- i. This advertisement complies with Medical Device (Advertising) Regulations 2019; and
- ii. Medical device(s) in this advertisement has/ have been registered under Section 5 of Act 737.

I, the undersigned, hereby attest that the information and documents provided in this application are true, accurate, correct, complete and current to this date. I understand that any declaration made by me in this application that is untrue, inaccurate or misleading is an offence under section 76(1) Act 737 and shall, upon conviction be liable to a fine not exceeding RM100,000.00 or to imprisonment for a term not exceeding 2 years or to both.

Signature:
Applicant's Name:
Date:

Company stamp:

ANNEX B
(NORMATIVE)

CHECKLIST FOR MEDICAL DEVICE ADVERTISING
In accordance with Medical Device (Advertising) Regulations 2019

Please tick (√) in the box if the document(s) is/are available.

- | | |
|--|--------------------------|
| 1. Complete application form | <input type="checkbox"/> |
| 2. Copy of proposed advertisement for the registered medical device (such as story board, script or art work) | <input type="checkbox"/> |
| 3. Appointment/ Authorisation Letter from the manufacturer or AR | <input type="checkbox"/> |
| 4. Copy of translated advertisement (if the advertisement is in other language apart from Bahasa Malaysia and English) | <input type="checkbox"/> |
| 5. Supporting documents (where applicable): | |

For contents with: Supporting document

- | | | |
|---|---|--------------------------|
| i) Testimonials | Consent letter from the user using the medical device to be advertised | <input type="checkbox"/> |
| ii) Celebrity Endorsement | Endorsement/Consent letter form the celebrity | <input type="checkbox"/> |
| iii) Test, trials or scientific reference | Approval or permission letter from the sponsor/ investigator (hospital) and data/ reports/ evidence of claims | <input type="checkbox"/> |
| 6. Attestation & Declaration | | <input type="checkbox"/> |