

**ANNEX A**  
(normative)

**Request for confirmation on change notification category for registered medical device**

*[To be printed on Establishment Letterhead of the registration holder]*

*[Your reference number]*

Chief Executive  
Medical Device Authority  
Level 6, Prima 9, Prima Avenue II,  
Block 3547, Persiaran APEC,  
63000 Cyberjaya Selangor,  
Malaysia

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Establishment address

*[Date]*

Dear Sir/Madam,

**Request for confirmation on change notification category for registered medical device**

The registration holder of the medical device(s) stated below, hereby request for confirmation on change notification category for registered medical device(s) as per description stated below:

<b>Establishment Licence No.</b>	:	
<b>Medical Device Registration Certificate No.</b>	:	
<b>MEDCAST Registration Submission ID</b>	:	
<b>Medical Device Name and include medical device identifier</b>	:	
<b>Proposed Change Category</b>	:	<input type="checkbox"/> Category 2 <input type="checkbox"/> Category 3
<b>Description of change</b>	:	
<b>Relevant Document (attached)</b>	:	

I am aware that a false declaration is an offence under Section 76 of Act 737 and may result in the cancellation of registration of the above medical devices under Section 5 of Act 737.

I hereby submit a processing fee of RM150.

Yours Faithfully,

*[Signature]*

*[Responsible person of Authority establishment]*

*[Company stamp]*

NOTES:

1. This request may be submitted by hand or mail to the above address together with the payment.
2. Processing fee shall be paid through bank draft. CASH WILL NOT BE accepted. We will not be responsible for the cash sent or brought to MDA.
3. Kindly inform that payment can be combined for a maximum of 5 submissions only.

4. The bank draft shall be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Information on reference number and telephone number of the applicant shall be written at the back of the bank draft but not in the table section.
5. Complete submission for request for confirmation on change notification category will be processed within 30 working days.