



# Application Form

## MDA/BKPP/DCR/01

### Dispute Classification Risk

Application date received :  
(Fill in by MDA officer) \_\_\_\_\_

\*This application form is used as to provide information to MDA in order to solve the dispute of classification risk between Establishment and Conformity Assessment Body (CAB).

<b>Section 1: Applicant information</b>	
Name of person responsible:	
IC No. / Passport No.:	Position:
Telephone no:	Email:
Establishment:	
Establishment address:	
Establishment role: <ul style="list-style-type: none"> <li><input type="checkbox"/> Authorized representative</li> <li><input type="checkbox"/> Manufacturer</li> <li><input type="checkbox"/> Others</li> </ul>	License No. : License No. : Please state :
<b>Section 2: Dispute information</b>	
<b>Establishment</b>	<b>CAB</b>
Name:	Name:
Classification risk & rule:	Classification risk & rule:
Justification:	Justification:



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## Section 3: Medical Device information

Name:

Description:

Intended use:

List of configurations: *\*you can list here or provide in a form of excel as supporting document*

No.	Name of device	Identifier	Description	Intended use	Class risk

## Status of Medical Device from recognised countries (Pre-market Approval)

*\*The information given can be based on the SAME device or SIMILAR type devices*

Recognised countries	Class risk & rule	Registration No.
1) USFDA		
2) Canada		
3) Australia (ARTG)		
4) EU		
5) Japan		
6) UK (MHRA)		



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**Section 4: Supporting document**

Type of Document	Document Name
1) Product leaflet / brochure / catalogue / IFU (contain description, intended use)	
2) Pre-market approval registration information (certificate/DoC)	
3) Clinical report (if applicable)	
4) Others: ..... (please state)	

**Declaration**

I confirm that:

- i) All the information and supporting document provided is true and complete.
- ii) I will submit relevant documents pertaining to this application whenever requested by MDA.
- iii) I am aware on the consequences of pending of this application if I failed / refused to submit satisfactory document(s)/information as requested.
- iv) I will obey to the decision made by MDA. All decision is final.

Signature:

Name:

Stamp:

Date:

\*Complete application form shall be sent to email, [registration@mda.gov.my](mailto:registration@mda.gov.my) / [ivd.registration@mda.gov.my](mailto:ivd.registration@mda.gov.my)