Please read this section carefully before completing the form

1. ***Please check the corresponding boxes in the "Encl." column if any document is enclosed and indicate the respective indexes in the submission folder***
2. ***Please check the boxes as appropriate***

Note	Part A: Particulars of Applicant		Encl.
A1	Applicant's name		
	Post Code:	Country:	
	Contact Person:	Telephone:	
	Fax:	E-mail:	
	Website:		
	Part B: Particulars of the Manufacturing site		
B1	Name		
	Physical address of the site		
	Post Code:	Country:	
	Contact Person:	Telephone:	
	Fax:	E-mail:	
	Website:		
B2	Quality Management System Established by the Manufacturer Standards with which the system complies: ☐ ISO 9001 (current version) ☐ ISO13485 (current version) ☐ Manufacturing site Quality Audit ☐ Others _____ ***(please specify)*** ☐ System certified by _____, and a certified copy of the certificate is enclosed. Indicate areas covered by Quality Management System ☐ Device design,		☐ _____

	☐ Production ☐ Post-production processes ☐ Others **(*please specify*)** _____ _____		
	Part C: Particulars of Local Responsible Person (LRP)		
C1	LRP's name		☐ _____
	Address (*Please give the registered place of business, if any*)		
	Contact person:	Telephone:	
	Fax:	E-mail:	
	Contact telephone for public enquiries ***(if different from the number given above)*:**		
	☐ Certified copy of business registration certificate with business registration number: _____ is enclosed		
C2	☐ Power of attorney authorizing the LRP is enclosed		☐ _____
C3	☐ The LRP is also an importer of the device named in Part D		
	Part D: Particulars of the IVDD		
D1	Generic name of the IVDD		
D2	Brand name of the IVDD		
D3	Model /Series/System ***(if applicable)***		
D4	Reagents/ Controls **(*if applicable*)**		

D5	Country of origin		
D6	Description of the IVDD ***(Please enter appropriate GMDN description. If none of the descriptions in GMDN appear appropriate, enter a short description of the device)*** _____ _____		
D7	GMDN Code: _____ **(*Please enter if known*)**		
D8	Other common descriptions of the IVDD: _____ _____ _____		
D9	Intended use of the IVDD:		
D10	Class of the IVDD: ☐ Class A ☐ Class B ☐ Class C ☐ Class D		
D11	Reasons for classifying the IVDD as Class A, B, C or D device: _____ _____		

D12	History ☐ No previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ☐ Yes ***(Please tick the appropriate boxes and provide details):*** ☐ Recalls completed or in progress ☐ Any reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☐ Pro-active post-market surveillance studies	☐ _____
D13	Performance and Safety International or national standards with which the IVDD complies _____ (Please enclose copy of the standard)	☐ _____
	Part E: Marketing Approvals in Foreign countries	
E1	Mention the countries where the IVDD has obtained marketing approvals _____ _____ (Please enclose certified copy of valid marketing authorization)	☐ _____
E2	Mention the countries where the IVDD approval is still pending _____	
	Part F: Declaration of conformity (DoC)	
F1	Submit a written declaration of conformity. The DoC should contain the following:- (i) An attestation that a device complies with the applicable EPSP, has been classified accordingly and has met applicable conformity assessment elements. (ii) Information sufficient to identify the device including	☐

	its nomenclature. (iii) The risk class allocated to the IVDD. (iv) Which of the conformity assessment elements have been applied. (v) The date from which the DoC is valid. (vi) The name and address of the IVDD manufacturer. (vii) The name, position and signature of the responsible person who has been authorized to complete the DoC. Note: The Essential Principles of Safety and Performance which apply to the IVDD are appended.	_____

Declaration by applicant

I, the undersigned certify that all the information in this form and accompanying documentation is correct and true to the best of my knowledge.

Name: _____

Position: _____

Signature: _____

Official stamp:

Date: _____