APPLICATION FORM

A. PRIMIRAY CLIENT INFORMATION:

Name of Company:								
Audit Location (Address)								
Scope of Certification								
Contact No.								
Email:								
Legal Registration								
Services required	14065	☐	17029	☐	Q/E/ OHS	☐	FSMS	☐
	13485 MD QMS	☐	FSSSC 22000	Others ☐		Others ☐	Others	☐
Accreditation Required	NABCB	☐			PBPL	☐		
Mode of Audit	Physical / Onsite	☐			Remote/Hybrid	☐		
Type of Certification	Initial (Stage 1 and stage 2)	☐	Transfer	☐	Recertification	☐		
State of implementation of standards	Implemented	☐	Not yet	☐				

B. Staff and organization details

	Main office/Site	**Additional Site (if any)**	**Temporary Site / Virtual site**
Address			
Activities			
Critical Process			
Other Process			
Sub Scope			
Total No. of Employee: **(For multi-site, indicate all sites to be covered under certification)** (If there are any employees on site which you are claiming are out of Scope, please explain rationale for justification here)			
	Main Site	Additional Site	Temporary/Virtual site
Full time			
Part Time			
Shift(General A,B and C)			
Repetitive work			

C. Process & Legal requirement

Statutory & Regulatory Requirements: (Related to the Nature Work & Management System Certification)	
Outsourced Process: if any; which effects the conformity of the product/service	
In case of outsourced process, what type and extent of controls have been applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of your MS?	
In case of outsourced process what is the process of evaluation and determined organization's ability to meet your requirement and legal compliances?	

D. Special information:

1)ISO 14065:2020

validation and verification of environmental information	☐ **Yes** ☐ **No**
Is the GHG included in the activities to be certified?	
Is there any Environmental that affects product conformity outsourced?	
Exclusions if any? -Such as: Special gases.	
GHG EFFECTS	

2). ISO 17029:2019

validation and verification	☐ Yes ☐ No
Is there any process that affects product conformity outsourced?	
Details of the sites; your company managing at the same time?	
A Register of Significant Environment aspect?	
An Environmental Management Manual?	
An Internal Environmental Audit Programme?	
Has the Internal Environmental Audit Programme been implemented?	
Have you identified list of significant aspects & license required?	
Storage condition & Permitted Quantities of hazardous material?	

3)Q/E/OHSMS:ISO 9001/14001/ 45001

ISO 45001:2018	☐ Yes ☐ No
Details of the sites; your company managing at the same time	
Key /Environmental hazards and OH&S risks identified?	
Critical QMS/ Ems/occupational health & safety risks identified?	
Main Environmental.Impact/hazardous materials used in the processes?	
QMS/EME/OHS Legal & Statutory Requirements?	

4)FSMS:ISO 22000

FSMS Certification ISO 22000:2018	☐ Yes ☐ No
Details & Number of HACCP implementation or Study/CCP identified	
How much sites your company managing at the same time?	
No. of process lines?	
No of shifts?	
Define Seasonality Issue (Please specify the production period, if any)	
Define specific Issue for locality, industry, legislation, organization if any	
Does your company have Valid Certification for relevant Management System like QMS?	☐ Yes ☐ No
Sterilization required or not and if how process implemented and controlled?	
Food chain category known? (A to K…)	

5)ISO 13485 MD QMS

What type of device as: Non-active **Medical Device** **Active Medical Devices (Non-implantable)** **Active Implantable Medical Devices** **In Vitro Diagnostic Medical Devices (IVD)** **Devices Incorporating/Utilizing Specific Substances/Technologies** **Parts and Services**	YES ☐ NO ☐
Emergency Response and Contingency Plan?	YES ☐ NO ☐
Statutory & Regulatory Requirements: (Related to the Medical Device manufacturing)-MDR?	
Is design Applicable?	
Technical area if known?	

6) FSSC 22000

Does your company have Valid Certification for relevant Food safety Management System like QMS/FSMS	☐ Yes ☐ No
Do you recruit, train, and evaluate your teaching and administrative staff? AS per above standards specific requirements?	
Do you safeguard sensitive Food safety requirements as per customer specific requirements?	

Controls on the site/operating areas and machines for the Hygiene?	
Sanitisation controls with the alarm system for emergency?	
Laboratory facilities?	
Water,Air,Power supply and controls with quality?	
Equipment suitability, cleaning and maintenance controls?	
Measures for prevention of cross contamination?	
Cleaning and sanitizing?	
Waste disposal plans and authorisation details with the license?	

7)Any Other Standard:

Number of employees involved in the (Management + Purchase + Compliance + Sales & Marketing)	
Has the organization documented the Management System?	
Has the organization implemented the Documented management System ?	

E. CERTIFICATION PROGRAMME REQUESTED

Initial Certification (Stage 1, Stage 2 audit)		**Recertification**	
Combination audit		Transfer Cum Surveillance	
In the case of several certification programmes, would you like the audits to be combined or carried out separately?			
If the answer is yes, please specify which combination			
IN case of recertification, please provide following information:			

F. Transfer of certificate Information:

Certificate number with CB details	Issue Date	Valid Until	Is there is any Change in Scope (give details)	Transition information if required	Important Change since initial audit and why transfer?

G. ADDITIONAL INFORMATION

Have You Specific Programme/Timescale For Achieving Registration?			
Have you called on the services of a consultant?			
If yes, please specify which one :			
Name of Business Developer:-			
Is any way Business developer/Promoting Firm involved other than marketing?			
Declaration: The information provide above is true to the best of our knowledge and Belief.			
Name		Seal & Signature	
Designation			
Date			

H. For official use only.

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Does accreditation request is available with the PBPL (Refer accreditation letter)	☐ **Yes**	☐ **No**
Does territory of the application is in active list (Refer accreditation letter)	☐ **Yes**	☐ **No**
Does Scope demand is available with the PBPL (Refer accreditation letter)	☐ **Yes**	☐ **No**
Does MSS request is available with PBPL (Refer Application/approval of AB//MSS documents)	☐ **Yes**	☐ **No**
REVIEWED BY:	DATE:	
Can the application be further processed?	☐ **Yes**	☐ **No**
Comment: (if Any)		

Guidance for filling out the form and reviewing the form for

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1. *. A site cannot be considered a virtual site where the processes must be executed in a physical environment, e.g., warehousing, manufacturing, physical testing laboratories, installation or repairs to physical products.*
2. *Application form can be filled online on MIS or may be submitted by filling in word or excel file.*
3. *Acceptance of the application can be executed by QM/TECHNICAL DIRECTOR, country head or any other authorized personal, acceptance of the application does not mean acceptance of application, but this is an acceptance o2f application for internal review purpose only.*

ANY OTHER GUIDANCE BY TECHNICAL TEAM

1.
2.
3.