	APPLICATIONQUESTIONNAIRE			
	Issuedby: QualityMngr.	**Eff.Date:0**2-02-2023	**Version:1.0**	**TQMS/F/AUD/AQ/01**

InstructionforCompletion:	This application form contain Section: A, B, C, D, E, and F. Kindly complete all section as applicable to your organization andreturntoTQMSCertifications Pvt. Ltd. for further actions.

A-ORGANIZATIONDETAILS:

CompanyName:	
Scope:	
Address:	
Certification Standard:	
Accreditation:	
Certification Type (Initial/SA/REA):	
ContactPerson'sName:	
Designation:	
TotalNo.ofEmployees:	
Contact Details:	
GST:	
PAN:	
Description of key Manufacturing/ Service Processes:	
Please identify Key Technical Resources and Equipment:	
Not Applicable Clause (s) and justification (s):	
Statutory/ Regulatory Requirement:	
details of your Management System Documentation status of structure and effective date:	
Do you have a specific time plan for activity Registration If Yes Please specifies?	
Last Internal Audit and MRM conducted:	
Any other information you would like	

to share with us:	
Applied Standard Name and Code:	☐ ISO 9001:2015(QMS) ☐ ISO 13485:2016(MDQMS)

B-PREVIOUSCERTIFICATE(S)DETAILS(IFTRANSFERTOTQMS):

CertificateNumber	Standard	ValidUntil	CertificationBody	Accreditation
1.Haveany complaints beenraisedagainstyourcompanybyyourcertification body?				
2.Isaregulatorybodycurrentlyengagedwithorinvestigatingyouin relationto activitiesyouarecertificated?				
3.Areyourcertificationscurrently activeandarenotinsuspensionorwithdrawal?				
4.WhatisthereasonforyourtransfertoTQMS?				
5.Doyouhaveanymajornon-conformities forwhichyour currentcertificationbodyhas notverifiedtheimplementationofyourcorrectionsandcorrectiveactions?				
6.Doyouhaveanyminornon-conformitiesforwhichyourcurrentcertificationbodyhas notyetacceptedyourcorrectiveactionplans?				
7.PleasesharelastAuditReportsandCertificatesissuedby previouscertificationbody?				

Note: If the required supporting documents are not provided a transfer may not be possible. Please note that TQMS may contactyour existing certification body to verify the validity of your certification. Also, please do not cancel your certification withyour existing certification body until the transfer process has been completed by TQMS Certification and you have receivedanTQMSCertificate.

C-CONSULTANT DETAILS:

Consultancy Name:		**Consultant's Name:**	
Mobile No.:			

D-QMS, MDQMS (MANAGEMENTSYSTEMDETAILS):

1.HowlonghasyourManagementSystembeeninplace?		
2.No.ofSitestobeaudited?		
3.Scope ofCertification		
4. Does the device require mains connection or batteries for operation?	☐ Yes	☐ No
5. Does the device feature a measuring function?	☐ Yes	☐ No
6. Does the device incorporate medicines or substances that may be used separately as medicinal products?	☐ Yes	☐ No
7. Does the device incorporate materials of animal origin?	☐ Yes	☐ No
8. Is the device mainly manufactured by Subcontractors?	☐ Yes	☐ No
9. Is the device placed on the market under your own name?	☐ Yes	☐ No
10. Has the device already gained any approval? If yes, which? (please include certificates)	☐ Yes	☐ No
11. Is your device manufactured as a sterile device?	☐ Yes	☐ No

12. Is the device packed and/or sterilized externally?	☐ Yes	☐ No
13. Is the devices non-sterile and intended to be sterilized at customer site?	☐ Yes	☐ No
14. Howmanyprocesslinesarethereinproduction	☐ Yes	☐ No
15. Isthereanyprocessthataffectsthe productconformityandisoutsourced?	☐ Yes	☐ No
16. Ifoutsourcedprocessesexist,thengivedetails	☐ Yes	☐ No

E-INTEGRATEDMANAGEMENTSYSTEMDETAILS:

1.HowlonghasyourIntegratedManagementSystembeeninplace?	
2.No.ofSitestobeaudited?	
3.Scope ofIMSCertification	
4.NamesofISOStandardsaddedinIntegratedManagementSystem?	
5.IntegratedManagementSystemPoints	**LevelofIntegration (Between1-10)**
IntegratedDocumentationSet,IncludingWorkInstructions	
ManagementReviewsthatconsidertheoverallbusinessstrategy andplan	
IntegratedApproachtoInternalAudits	
IntegratedApproachtoPolicyandObjectives	
IntegratedApproachtoSystemsProcesses	
Integratedapproachtoimprovementmechanisms	
Planning,withgooduseofbusinesswideriskmanagementapproaches	
Integratedmanagementsupportandresponsibilities	

F–MULTI SITE DETAILS:

Please state the company locations and branch offices, which should be included in the certification

	Headquarter	1st Additional Location	2nd Additional Location
Address:			
City, State ZIP:			
Contact Person:			
Position:			
Phone/fax:			
E-Mail:			

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Number of Employees:	Full Time: Part Time:	Full Time: Part Time:	Full Time: Part Time:
Number of shifts			
Employee number for each shift	*Shift 1:* *Shift 2:* *Shift 3:*	*Shift 1:* *Shift 2:* *Shift 3:*	*Shift 1:* *Shift 2:* *Shift 3:*
Employees Bifurcation:			
Management/ Administration / HR/ Office Staff			
Design			
Sterilization			
Sale & Marketing			
Maintenance			
Quality Assurance/ Quality Control/ Regulatory Affairs/ Compliance			
Production Service Provision/ Labelling and Packaging			
Miscellaneous (*Purchase and planning, Unskilled workers, Driver, Temporaries, Casuals, Trainees*)			
Performed activities on each location	☐Design and development ☐Manufacturing ☐Installation ☐Servicing ☐ Distribution ☐ Clean room ☐ Sterilization ☐ Sales ☐ QA ☐ RA ☐ Management	☐ Design and development ☐ Manufacturing ☐ Installation ☐ Servicing ☐ Distribution ☐ Clean room ☐ Sterilization ☐ Sales ☐ QA ☐ RA ☐ Management	☐ Design and development ☐ Manufacturing ☐ Installation ☐ Servicing ☐ Distribution ☐ Clean room ☐ Sterilization ☐ Sales ☐ QA ☐ RA ☐ Management
Critical subcontractor or crucial supplier of outsourced processes and material/components			
Critical subcontractor name and address			
Process description			
ISO *Please attach a copy of the certificate held by subcontractor/supplier, if any.*			
No of employees			
No of Shifts			

Client Representative Name:
Date:
Signature: