ISO 13485 Audit Application

1. Company Data:

Company name			
Address of the site to be audited			
		Pin code	
Mailing Address			
		Pin code	
Contact Person			
Audit representative			
Working Hours & Off Days			
Telephone		Extension	
Telefax		E-Mail	
Mobile		Web-Site	

2. Company Structure

Legal form (Pvt. Ltd. etc.)	
Branch offices or plants/ subsidiaries / Group Companies	
In India	
In other countries	
As planned to be indicated in the Certificate	
1) Address	
2) Scope of the Audit	
* Main Products	
* Main raw materials and supplied parts used or processed	
* Core processes	
* Outsourced processes	
Last Year's Turnover	
Professional association membership / SSI	
Major Customers	

3. List all locations to be covered under the Audit Scope (Please List – including Marketing):

Address of Site	Activity To Be Audited	Distance from Major City/Airport & The Main Site

For additional Sites please attach annexure in the format.

ISO 13485 Audit Application

4. No. of Temporary sites* (If applicable mention details including type of activities at this site):

5. Product Specific Legal requirements*:

6. Number of employees in entire company: _____ (All shifts = Permanent (Per.) + Casual (Cas.) including unskilled employees)

Break down employee information by Units/Shifts:

Location	Department	General Shift		Shift I		Shift II		Shift III	
		Permanent	Casual	Permanent	Casual	Permanent	Casual	Permanent	Casual
Unit 1	Administration (Incl. Mktg. / Others)								
	Design								
	Production (Incl. Quality)								
	Unskilled employees								
Unit 2	Administration (Incl. Mktg. / Others)								
	Design								
	Production (Incl. Quality)								
	Unskilled employees								
	Total								

For additional sites please attach annexure in the same format.

7. Which of the following industries best describe your organization?

Non-Active Medical Device
☐ General non-active, non-Implantable medical Devices
☐ Non-active dental devices and accessories
☐ Non-active medical devices other than specified above (please specify device category)

ISO 13485 Audit Application

☐ Non-active implants		
☐ Devices for wound care		
Active (Non-implantable) Medical Devices		
☐ General active medical devices	☐ Devices for imaging	☐ Monitoring devices
☐ Devices for radiation therapy and thermo therapy		
☐ Active (non-implantable) Medical devices other than specified above (Please specify device category)		
Active Implantable Medical Devices		
☐ General active implantable Medical devices	☐ Implantable medical devices Other than specified above (please specify device category)	
In-vitro Diagnostic Medical Devices (IVD)		
☐ Reagents and reagent products, calibrators and control materials for:(Clinical Chemistry,immunochemistry (Immunology), Haematology / Haemostasis / Immunohematology, Microbiology, Infectious Immunology Histology/Cytology Genetic Testing)		
☐ In Vitro Diagnostic Instruments and software		
☐ IVD medical devices other than specified above (please specify device category)		
Sterilization Methods For Medical Devices		
☐ Ethylene Oxide Gas sterilization (EOG)	☐ Moist Heat	☐ Aseptic processing
☐ Radiation sterilization (e.g. gamma, x-ray, electron beam)	☐ Sterilization method other than specified above (Please specify sterilization method employed)	
Devices Incorporating / Utilizing Specific Substances / Technologies		
☐ Medical devices incorporating medicinal substances	☐ Medical devices utilizing tissues of animal origin	☐ Medical devices incorporating derivates of human blood
☐ Medical devices utilizing micromechanics	☐ Medical devices utilizing nanomaterials	☐ Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed

Describe What your Organization does as a Manufacturer and / or service provider	
Are there any employees that you did not include in the above-mentioned table because you consider them to be outside the scope of the audit?	☐ Yes ☐ No If yes Please Explain:
Who Designs the Products / Services that you provide to your customer?	Check all that apply: ☐ Customers provide product designs that we produce. ☐ We design our own products at the site to be certified.

ISO 13485 Audit Application

	☐ Our company designs products at another location that we produce at the site to be certified. ☐ We outsource design activities to suppliers / subcontractors. ☐ We are a distributor of products that are designed and manufactured by another company.

- Do employees in all shifts do similar activities: ☐ yes ☐ no ☐ not applicable?
- What Functions are performed centrally (Marketing, Purchasing, etc)?

  _____

  _____

  _____
- Have consultancy services or in-house training been performed on the subject of ISO 9001 / ISO 13485 / ISO 14971 / any other related training?
- If yes, by whom and when were they performed? _____
- Do you have a Quality / Management system manual for the entire group? ☐ Yes ☐ No ☐ not applicable
- Are the manuals of the subsidiaries based on the group manual? ☐ Yes ☐ No ☐ not applicable

The audit should be based on the following standards:

☐ ISO 13485: 2016 (with / without design)	☐ ISO 9001:2015 + ISO 13485:2016 (with / without design)
☐ ISO 13485: 2016 + Others (with / without design)	

- Does the company have any other valid certificates? If yes, please list.

Target Date	Pre Audit	Stage 1 Audit	Certification Audit

8. Any Significant changes (from last audit)? (applicable only for RA, SA, expansion audits)

☐ Yes ☐ No (IF YES – MENTION THE DETAILS BELOW)

I confirm that the data submitted above is accurate:

Date		Company stamp/ Signatures	

Name and Designation _____

ISO 13485 Audit Application

Note:

If available, please attach:

- Copy of a facility layout with the identity of all manufacturing areas and process flowchart.
- Copy of the organisation chart and any company/product brochures.

* *In case of space constraint the relevant details may be attached in separate list*