 <b>भारतीय मानक ब्यूरो</b> <b>BUREAU OF INDIAN STANDARDS</b> <b>MANAGEMENT SYSTEMS CERTIFICATION</b>		<b>FORMS</b>	
<b>TITLE: QUESTIONNAIRE FOR OBTAINING PRELIMINARY INFORMATION AND DECLARATIONS FROM THE APPLICANT FOR OBTAINING LICENCE FOR CERTIFICATION OF MEDICAL DEVICES MANAGEMENT SYSTEMS AGAINST IS/ISO 13485</b>			
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PREPARED BY: HEAD (MSCD)		APPROVED BY: DDG (MSCD)	

### FORM - XVI

#### 1. DETAILS OF THE ORGANIZATION

1.1 Name : \_\_\_\_\_

1.2 Address : \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

1.3 Contact Details : \_\_\_\_\_  
 1.3.1 Telephone : \_\_\_\_\_  
 1.3.2 Email : \_\_\_\_\_

1.4 Address of the Registered Office : \_\_\_\_\_  
 (if different from 1.2 above) \_\_\_\_\_  
 1.4.1 Telephone : \_\_\_\_\_  
 1.4.2 Email : \_\_\_\_\_

1.5 Status of Organization: \_\_\_\_\_  
*(Large/Medium/Small/Micro Scale Industry Service Enterprises/small enterprise).*  
*(Enclose copy of Registration Certificate from the concerned authority).*

1.6 Indicate whether the unit is a part of some larger organization: Yes/No.  
 (if yes give the name and address of the holding organization)


1.6.1 Name : \_\_\_\_\_  
 1.6.2 Address : \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

1.7 Does the organization have branches at different locations or multiple-sites of operations. Yes/No.  
*(If yes, give name(s) & address(es) along with the brief description of processes carried out at all such locations/sites for which certification is sought on separate sheet.)*

1.7.1 Number of Shifts (with timings of each shift) : \_\_\_\_\_

#### 1.8 Number of Employees

1.8.1 Number of part-time personnel covered in the scope of certification converted to full time personnel (based on 8 hours/day working): \_\_\_\_\_  
 1.8.2 Number of personnel partially involved in the scope of certification converted to full time personnel (based on 8 hours/day working) : \_\_\_\_\_  
 1.8.3 Number of personnel in simple functions (Finance, Admin, Security, Transport, Drivers, Canteen, Gardening, etc): \_\_\_\_\_  
 1.8.4 Total number of personnel in general shift/Shift 1: \_\_\_\_\_  
 1.8.5 Total number of personnel in other shifts: \_\_\_\_\_  
 1.8.6 Total Number of personnel in other shifts for mutually exclusive operations/functions other than that in general shift/Shift 1: \_\_\_\_\_

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## 2. INFORMATION RELATING TO QUALITY MANAGEMENT SYSTEMS

### 2.1 Management Representative (MR)

2.1.1 Name : \_\_\_\_\_

2.1.2 Designation : \_\_\_\_\_

2.1.3 Telephone(Mobile) : \_\_\_\_\_

2.1.4 Email : \_\_\_\_\_

2.2 Scope for which certification is sought \_\_\_\_\_

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2.3 List of devices included in the scope for which customer end installation is required(use separate sheet if necessary):

### 2.4 Quality Management System Documentation & Implementation

2.4.1 Quality Manual (*mention Title of Manual, Issue No. & Date, No. of Amendments, if any*)

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2.4.2 Details of 'outsourced processes' used, if any, that affects conformity to requirements and type & extent of controls applied over such processes(*use separate sheet, if required*)

2.4.3 List of legal and statutory requirements applicable to products including output resulting from the product realization processes (use separate sheet, if required)

2.4.4 Date on which the Management Review was last held: \_\_\_\_\_


2.4.5 Date(s)/Period during which Internal Audit was last held: \_\_\_\_\_

## 3. CONSULTANCY

3.1 In case the quality management system is established, implemented or maintained through use of consultancy, the following information be provided:

3.1.1 a)Name & Address of the consultancy organization/personnel

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- b) Type of consultancy provided(*such as preparing manual, procedures etc; giving specific advice, instructions or solutions for development and implementation of management system.*)
- c) Status of consultancy Continues/Ended

3.1.2 d) Date on which consultancy ended, if applicable \_\_\_\_\_

**4. DETAILS OF OTHER MANAGEMENT SYSTEMS LICENCE/CERTIFICATION HELD OR ASSESSMENT HELD, IF ANY**

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**5. DECLARATIONS**

I/We hereby declare that:

- a) I/We will comply with the certification requirements,
- b) I/We will inform about the following changes, if and when such changes happen:
- i) legal, commercial, organizational status or ownership,
  - ii) organization and management (e.g. key managerial, decision-making or technical staff),
  - iii) contact address and sites,
  - iv) scope of operations under the certified management system, and
  - v) major changes to the management system and processes.
- c) I/We will make all necessary arrangements for the conduct of the audits, including provision for examining documentation and the access to all processes and areas, records and personnel for the purposes of initial certification, surveillance, recertification and resolution of complaints
- d) I/We will make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation auditors or trainee auditors),
- e) I/We will permit BIS to make the information regarding certification granted and its status accessible to public.

Signature \_\_\_\_\_

Name \_\_\_\_\_

Seal of the Firm

Designation \_\_\_\_\_

Date: \_\_\_\_\_ For and on behalf of M/s \_\_\_\_\_