ANNEXURE 4 - REQUIREMENTS FOR SITE MASTER FILE (for overseas and local)

REQUIREMENT (tick the availability and upload)
1.GENERAL INFORMATION *Brief information of the site* *GUIDANCE* ➢ *Name and Address of the site* ➢ *Name and Address of the parent company (if applicable).* ➢ *Name and Address of the legal manufacturer (if applicable)* ➢ *Contact details* *Telephone* *Fax* *Email* ➢ *Details of the contact person (maximum only two persons)* *Name and designation* *Telephone* *Fax* *Email* ➢ *Site location marked in Google map (GPS)*
2. BRIEF INFORMATION OF THE MANUFACTURER ➢ *Brief information of the firm including the details of legal manufacturer, any information relevant to understand the manufacturing operations of the particular manufacturing site including contract manufacturing/Manufacturing under loan license etc.* ➢ *Detail of other manufacturing sites under this manufacturer* ➢ *Annual turn -over of the company for last three years* ➢ *List of exporting countries with evidence from two countries*
3. MANUFACTURING ACTIVITIES OF PARTICULAR MANUFACTURING SITE ➢ *Medical Device manufacturing activities as licensed by the Competent Authorities or third party authorized notified body (Design/Manufacturing (finished or bulk product)/Primary Packaging/Secondary Packaging/ Sterilization/Quality Control, assembling etc.)* *GUIDANCE* *Quote the (valid) relevant document as issued by the Competent Authority or third party authorized notified body. State period of validity of licence document. Any conditions and/or restrictions should be stated.*

4. PRODUCTION

- *List of medical devices actually manufactured at the site*

GUIDANCE
List should be in a tabulated form including the details of legal manufacturer

- *List of other products (except medical device) actually manufactured at the site.*

- *Indicate whether part of manufacturing process (eg: sterilization, refurbishing, secondary packaging, batch release etc.) or partially manufactured by other manufacturer for you?*

GUIDANCE
Information including the details of company should be submitted in tabulated form

- *Brief description of general policy for process validation*

5. PERSONNEL

- *Organizational chart*

- *Qualification, experience and responsibilities of key personnel*

(name, designation)

- *Outline of arrangement for training programme*

- *Number of employees engaged in the quality assurance, production, storage and distribution*

- *Health requirement for personnel engaged in production*

- *Personal hygine requirement including clothing*

6. PREMISES AND EQUIPMENTS

- *The size of the site, description of buildings and their ages.*
- *Brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (schematic drawings of the systems are desirable). Classification of the rooms used for the manufacture of sterile products should be mentioned.*
- *Special areas for the handling of highly toxic, hazardous and sanitizing materials*
- *Brief description of water systems (schematic drawings of the systems are desirable) including sanitation*
- *Maintenance (description of planned preventive maintenance programmes and recording system)*
- *Cleaning procedures for*
  a) Manufacturing area
  b) Equipment and machines
- *Procedure for Qualification , calibration and validation for equipment*

7. QUALITY CONTROL AND ASSURANCE

- *Number of specialized person in quality control and assurance*
- *Procedure for handling quality failures*
- *Have biocompatibility / biological evaluation /clinical trials carried out for your own product/s?*
- *Procedure of release of finished product*
- *Do you carried out real time stability studies for your product/s?*
- *Arrangement for handling of rejected materials and products*
- *Procedure for post marketing surveillance*
- *Details of own laboratories*
- *Details of third party laboratories used in addition to your own laboratories?*

8. QUALITY MANAGEMENT SYSTEM

- *Procedure for self-inspection*
- *Procedure for audits by external organizations*
- *Procedure for vendor qualification*

9. COMPLAINTS AND PRODUCT RECALL

- *Complaint handling system*
- *Recall procedure*