No. G-30018/01/2023-Scheme
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
***

Shastri Bhawan, New Delhi

Dated the 9th May, 2023

Guidelines for the Scheme for

"Assistance to Medical Device Clusters for Common Facilities (AMD-CF)"

1. Background

1.1. The Medical Devices sector in India is an essential and integral constituent of the Indian healthcare sector. The Medical Devices constitute a multi-disciplinary sector with the following broad classification a) Electronic equipment (b) Implants (c) Consumables and Disposable (d) Surgical instruments (e) In-Vitro Diagnostics Reagents. The growth of Medical Devices sector is primarily driven by growing demand for healthcare infrastructure, rise in preventive testing and spread of healthcare services and insurance programs. The Medical Device industry is highly capital intensive with long gestation period and requires development/induction of new technologies. The sector also requires continuous training of healthcare system providers to adapt to new technologies.

1.2. The Indian industry is currently the 4th largest Asian medical devices market after Japan, China and South Korea. However, the Indian Medical Device market has significant presence of several multi-national companies with about 75-80% of the sales generated from imported Medical Devices. Medical Device Industry associations have requested for a common infrastructure facility which provide support for strengthening of Common Infrastructure Facilities for pharma cluster i.e, on par with API-CF sub-scheme of Scheme called "Strengthening of Pharmaceutical Industry (SPI)".

1.3. This ***"Assistance to Medical Device Clusters for Common Facilities (AMD-CF)" Scheme*** aims to strengthen Medical Device clusters by providing financial assistance and to strengthen and / or establish more Testing Laboratories for Medical Devices to improve quality and sustainable growth.

2. Definitions

For purposes of this Scheme capitalized terms have the meanings set forth or referred to in this Section.

i. **"Articles of Association"** has the meaning set forth in Section 2(5) of the Companies Act, 2013.

ii. **"Beneficiary"** means the entity(s) chosen, on an application approved by the SSC, to receive the benefits of the Scheme.

iii. **"Cluster development"** means a development of clusters containing the Medical Devices manufacturing units where the focus is concentrated in a selected area.

iv. **"Common facilities"** means all facilities intended for the shared use by the subscriber and will consist of creation of tangible "assets" as Common Facility Centers (CFCs). The same is further elaborated under Clause 10.7. The indicative list of common facilities is illustrative, and each cluster could have its own specific requirement based on the nature of units being set up and the products proposed to be manufactured.

v. **"Effluent treatment plant"** means a treatment plant exclusively established to treat the process waste of any kind generated by pharma industries according to the prevailing law, statutes, or rules.

vi. **"Grant-in-Aid"** means any Grant issued by DoP as per Chapter-9 of GFR-2017.

vii. **"Medical device"** has the meaning as defined under Medical Devices Rules, 2017 r/w as defined under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and as modified from time to time and means all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of — (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; and (vi) control of conception.

viii. **"Incentive"** means the financial benefit to be provided to the selected applicant based on fulfilling the criteria as mentioned herein the Scheme.

ix. **"Logistic center"** means a place within which all activities relating to transport and the distribution of medical devices- both international and national transit, are carried out by various operators on a commercial basis.

x. **"Micro, Small and Medium Enterprises"** has the meaning set forth in the Micro, Small and Medium Enterprises Development Act, 2006 [No. 27 of 2006].

xi. **"Memorandum of Association"** has the meaning set forth in Section 2(56) of the Companies Act, 2013.

xii. **"Project Management Consultant or Project Management Agency"** refers to the agency appointed by the DoP to act on its behalf for receipt and appraisal of applications, verification of eligibility and examination of disbursement claims through any method / document deemed appropriate and for managing the Schemes in accordance with these guidelines.

xiii. **"Scheme"** means the ***"Assistance to Medical Device Clusters for Common Facilities (AMD-CF)" Scheme*** of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India dated

xiv. **"Scheme Steering Committee"** has the meaning as set forth in para 7.

xv. **"Special Purpose Vehicle"** means a legal entity registered under the Companies Act, 2013 or the Societies Registration Act, 1860 as amended from time to time, and constituted in a manner provided in para 8.1.2. of the Scheme.

xvi. **"Research and Development Lab"** means a place used for experimentation aimed at the discovery of facts, or scientific development of new products, Medical Devices, technologies, or applications; but excludes industrial and manufacturing operations other than those required as part of research.

xvii. **"Medical devices testing laboratory**" has the meaning set forth in subsection (ze) of section 3 of Medical Devices Rules,2017.

xviii. **"Technical Committee (TC)":** A Technical Committee constituted by DoP to assist the Scheme Steering Committee (SSC) for discharge its function.

2.1. Abbreviations and Acronyms

i.	**AoA**	**Articles of Association**
ii.	**CDSCO**	**Central Drugs Standard Control Organization**
iii.	**DCGI**	**Drug Controller General of India**
iv.	**ETP**	**Effluent treatment plant**
v.	**GFR**	**General Financial Rules**
vi.	**DoP**	**Department of Pharmaceuticals**
vii.	**MSME**	**Micro, Small and Medium Enterprises**
viii.	**PLI**	**Production linked incentive**
ix.	**MoA**	**Memorandum of Association**
x.	**NIPER**	**National Institute of Pharmaceutical Education and Research**
xi.	**CDL**	**Central Drug Laboratory**
xii.	**PMA**	**Project Management Agency**
xiii.	**SPV**	**Special Purpose Vehicle**
xiv.	**SSC**	**Scheme Steering Committee.**
xv.	**MDTL**	**Medical Devices testing Laboratory**
xvi.	**MDR, 2017**	**Medical Devices Rules, 2017**

3. Objectives of the Scheme

3.1. The Scheme aims to strengthen the existing and new Medical Device clusters by providing financial assistance for creation of Common Infrastructure Facilities which would help in boosting the domestic manufacturing capacity, improving the quality of clusters and sustainable growth of the Medical Device sector.

3.2. The Scheme further intends to support Central or State Government/s or Institutions or Organization to establish or strengthen the Testing Laboratories for Medical Devices to meet the needs arising due to roll out of the licensing regime of the MDR, 2017 and ensuring availability of more testing facilities for evaluation of Medical Devices on behalf of the manufacturers, as mandated under MDR, 2017 or as per the amendment thereon, from time to time.

4. Components of the Scheme

4.1. Assistance for Common Facilities (CF)

To strengthen the medical device clusters' capacity for their sustained growth by creating Common Infrastructure Facilities.

4.2. Assistance for Testing Facilities (TF)

To strengthen availability of more Medical Device Testing Laboratories in order to boost manufacturing of quality medical devices.

5. Physical and Financial Outlay

Financial Year	Physical Outlay		Financial Outlay (Rs. in crore)		
	Common Facilities	Testing labs	Common Facilities	Testing labs	Total Grant-in-Aid
2023-24	4	6	48	18	66
2024-25	8	6	128	30	158
2025-26	0	0	64	12	76
Total	**12**	**12**	**240**	**60**	**300**

6. Tenure of the Scheme: The tenure of the Scheme is from Financial Year 2023-24 to Financial Year 2026-27.

7. Technical Committee (TC):

7.1. A Technical Committee constituted by DoP to assist the Scheme Steering Committee (SSC) for discharge its function. The TC may also give its comments on any technical matter referred by PMA/DoP. The composition of the committee is as given below.

i. One representative from Central Drugs Standard Control Organization (CDSCO)

ii. One representative experts from industry and academia

iii. One representative experts from ICMR

iv. Two representative experts having knowledge and experience in the Process Development/ R&D/ Product Design/ Testing of Medical Devices/ Medical Devices Manufacturing etc. relevant institute (NIPER , IISc, IITs, Sree Chitra

Tirunal Institute for Medical Sciences and Technology (SCTIMST), Council of Scientific and Industrial Research (CSIR), NCL or Similar institutions.

8. Scheme Steering Committee (SSC):

8.1. The Department of Pharmaceuticals (DoP) will provide overall policy, coordination and management support for the implementation of the Scheme. The proposals under the scheme will be considered for approval by the Scheme Steering Committee (SSC), whose composition will be as follows: -

i. Secretary, DoP – Chairperson;
ii. Financial Adviser, DoP - Member;
iii. Drug Controller General of India - Member;
iv. Joint Secretary (Schemes & Medical Devices), DoP - Member;
v. Representative of Ministry of MSME - Member;
vi. Representative of Ministry of MeitY – Member;
vii. Representative of Ministry of DPIIT - Member
viii. Director / Deputy Secretary (Schemes), DoP – Convener;

8.2. The SSC may co-opt representatives of any Pharma and Medical Devices Industry Associations, Financial Institutions/Program Management Consultant, R&D Institutions and Other Government/ Private sector expert organizations as members or special invitees as may be necessary from time to time.

8.3. **Functions of the Scheme Steering Committee (SSC)**

i. To provide direction for effective implementation of the Scheme;
ii. To evaluate & recommend proposals for approval;
iii. To monitor the implementation of the scheme;
iv. To take decisions on any deviations in approved projects;
v. To take all decisions required for successful implementation of the Scheme, including recommending the modifications, if any, required in guidelines of scheme;
vi. In case of a force majeure event, the SSC may amend, modify or withdraw any clause under the scheme;
vii. To conduct a periodic review of selected applicants with respect to approved common facilities and testing labs under the scheme.

9. Project Management Agency (PMA)

9.1. The SSC would engage the services of an agency, through an open transparent and competitive bid process, that has experience in developing labs and common facilities, financing or executing the cluster development / technology up gradation projects or Upgradation projects from the stage of conceptualization to commissioning. PMA, a bridge between the SSC and the SPV, would act as a catalyst in expeditious implementation of the projects in a systematic, professional and transparent manner. The period of consultancy will depend on the requirement of individual cluster and testing labs as approved by the SSC.

9.2. The PMA will report directly to the SSC and shall have the following responsibilities:

i. Assist SSC in drafting and issuing Expression of Interest (EoI)/ Request for Proposal (RFP) and formulating criteria for evaluation to select the Projects from the Proposals received in response to RFP.

ii. Devise the prescribed application formats and list the supporting documents as well as the appraisal methodology for approval of SSC/ DoP.

iii. Preliminary examination of the proposals, and preparation of evaluation/appraisal reports that shall be placed before the SSC for final selection of proposals.

iv. Sensitization of the Industry/potential beneficiaries on the Scheme and its benefits and also guiding them to apply for benefits under the scheme.

v. Preparing the Draft Agreement for selected beneficiaries for implementation of the scheme as per guidelines.

vi. Developing an online portal to receive the applications, disbursement of incentive and maintain the MIS and data of the applicants with all the details.

vii. Assist the selected beneficiary in the selection of agencies/ experts for various services such as capacity building, business development, technical or engineering support, in developing suitable O&M framework for making the project more effective

viii. Monitoring the approved projects through physical inspection, monitor implementation schedule based on Quarterly Review Report & submit monthly & quarterly review of the projects report to DoP/SSC for timely disbursement and utilization of the funds.

ix. Provide other need based advisory services to the SPV in effective implementation of the scheme

9.3. The Evaluation of the PMA shall be done on the basis of quality and timeliness of appraisal of new projects brought to DoP/SSC for final approval, monitoring for ensuring completion of the projects within the stipulated timelines mentioned in the approved DPR/Projects. If progress and performance of the PMA is not satisfactory, DoP/SSC reserve the right to remove the PMA at any time during the tenure of the scheme after serving a notice and considering its reply thereto.

10. Sub-Scheme: Assistance for Common Facilities (CF)

10.1. Objective: To strengthen the Medical Device clusters' capacity for their sustained growth by creating "Common Infrastructure Facilities".

10.2. Intended Beneficiaries

i. Medical Devices manufacturing units in a cluster who have come together to form a Special Purpose Vehicle (SPV) to execute the project of developing common facility. There shall be a minimum of 5 Medical Device manufacturing units as members of SPV.

ii. Medical Devices clusters promoted by the State Governments: Such a Project Implementing Agency shall be legal entity under the Indian law with foresight of the State Governments. Such a cluster may be exempted from the requirement of formation of SPV & will be deemed to be an SPV for the purpose of this Scheme, provided separate accounts are maintained for the funds to be used for the projects assisted under AMD-CF and an Executive Committee (EC) is set up for implementation of the project.

10.3. **Eligibility Criterion for SPV**

i. The SPV or the Executive Committee, as the case may be, will have representatives from cluster members, financial institutions, State and Central Government and R&D organization.

ii. Individual manufacturing unit cannot hold more than 40% in the SPV.

iii. Medical Devices enterprises shall hold at least 51% equity of the SPV

iv. The combined net worth of members of SPV shall be equivalent to total grant amount applied for and each SPV member must have a net worth of at least 1.5 times of their proposed equity contribution.

v. The SPV members shall be legally independent entities without any related-party relationship with each other as described under Accounting Standard (AS) 18 of the Companies (Accounting Standard) Rules, 2006.

10.4. Incentive under the Scheme : For Common Infrastructure Facilities (CIF) for the Medical Device (MD) clusters, the limit of support will be 70% of the approved project cost or Rs. 20 cr., whichever is less, as per the approval of SSC. In the case of Himalayan States and States in the North East Region, the grant-in-aid would be Rs. 20 Crore per Cluster or 90% of the project cost of the CIF, whichever is less.

10.5. **Physical and Financial Outlay**

Financial Year	Physical Outlay	Financial Outlay (Rs. in crore)
2023-24	4	48
2024-25	8	128
2025-26	0	64
Total	**12**	**240**

10.6. Modalities for utilization of incentive

i. The cost of project shall include cost of land, building, internal infrastructure, administrative and management support expenses including the salary of CEO, engineers, other experts and staff during the project implementation period (before commissioning), preliminary expenses, machinery & equipment, miscellaneous fixed assets and other support infrastructure such as water supply, electricity and margin money for working capital. However, *Grant-in-Aid from DoP will not be utilized towards land component of the project or construction of rest house, administrative buildings or any other building*, which in the opinion of SSC may be categorized as non-essential construction for the technical requirements of project.

ii. In case the SPV provides an existing land and building, the cost of the same will be decided on the basis of valuation report prepared by an approved agency of Central / State Government Departments / Financial Institutions (FIs) / Public Sector Banks and the cost of land and building may be taken towards contribution for the project.

iii. In case the SPV provides an existing land and building on lease separately, then the *period minimum period of lease must be 30 years* for both land and Building. In case the SPV provides an existing land, building on the same land on lease, then the period minimum period of lease for combined land and building must be 30 years.

iv. *Minimum of 30% of the approved project cost has to be contributed by SPV* as well for the project & there is to be no duplication of funding for the same component/ intervention. SPVs may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. Resource raised through such dovetailing will be in addition to the 30% contribution of the SPV.

v. Assistance for Administrative and other management support of SPV during the project implementation period *shall not exceed 5 % of the Grant-in- aid*.

vi. Proportionate contribution by the SPV or the beneficiaries' share should be made upfront. Necessary infrastructure like land, access road, water and power supply, etc. must be in place or substantial progress should have been made in this regard before DoP assistance is released. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds will also be necessary before release of DoP assistance.

vii. Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the SPV. The Central Government shall not accept any financial liability arising out of operation of any Common Facility.

viii. Project Implementing agency / SPV shall be responsible for obtaining all necessary statutory clearances in a timely manner.

ix. The Grants-in-Aid shall not be available to any individual production units, if any, owned by a member of the SPV.

x. The Common Facility may be utilized by the SPV members and also by other pharma units on 'user charges' basis to be decided by the SPV.

xi. User charges for services of Common Facility will be graded in such a manner that average charges will be lesser than prevailing market prices, as decided by the Governing Council of the SPV or the executive committee as the case may be. The SPV members would be given reasonable preference in user charges

10.7. **Eligible Activities:** An indicative list of eligible activities, for the CIF for the MD clusters, under this Scheme are as under:

i. Research and Development Labs
ii. Designing and Testing Centre/ESDM/PCB/Sensors facility
iii. Biomaterial / Biocompatibility /Accelerated Aging testing Centre
iv. Medical grade moulding/milling/injection moulding/machining/tooling Centre
v. 3D designing and printing for medical grade products.
vi. Sterilization/ETO/Gamma Centre
vii. Animal Lab and Toxicity testing Centre
viii. Radiology Tube (Radiation)/Flat Panel Detectors/MRI Magnets/ Piezo electrical crystals/power electronics facility
ix. Solid waste management/ETP/STP/Electronic Waste management unit
x. Common Warehouse & Logistics (Clearing and Forwarding, Insurance,
xi. Emergency Response Centre/Safety/Hazardous Operations audit Centre
xii. Centre of Excellence/Technology Incubator/Training Centre
xiii. Facilities for rapid prototyping microfluidics based medical devices
xiv. Facilities for rapid prototyping of medical devices using biomaterial and tissue engineering.
xv. Electro-magnetic interference & Electro Magnetic Compatibility Centre

The above list of activities is indicative and other allied activities can be taken up based on recommendations of SSC.

10.8. **Project Proposal and its components**

i. The project proposal must have technical recommendation from competent technical body (e.g. for ETP, the State Pollution Control Board may be the competent body and in case of Research Labs and Testing centers, NIPERs/IITs/CDL/ Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) /NIITs/ IISC/Certified MDTL Testing Laboratories notified by CDSCO (MD-40) may be the competent authority to grant technical recommendations).

ii. In case of PMA / SSC not being satisfied with the technical recommendations, the PMA / SSC may ask the SPV to obtain technical recommendations from specific competent experts.

iii. Project proposal may have the following details:

a. Business plan including processes of the cluster units like manufacturing process, Gap Analysis and proposed operations of the Common Facility such as technology, marketing, quality control, testing, purchase, outsourcing.
b. Final projections and financial viability report.
c. Identification of impediments and bottlenecks
d. Action plan for enhancing competitiveness of the units of the cluster and positioning the cluster on a self-sustaining trajectory of growth. The proposal will have direct linkages between the impediments/bottlenecks identified and the measures recommended for improvement.
e. Implementation schedule for action plan to contain:
    1. Activity-wise time schedule
    2. Milestone for payments
    3. Excepted date of Commissioning
    4. Delay and expected Risk
    5. Monitorable quantified targets for reporting on outcomes.

iv. The Indicative chapters that may be included in the DRP is mentioned in the **Annexure-I**

10.9. **Implementation Process & Timeline**

i. PMA to invite project proposals for assistance in the scheme by issuing open advertisements in newspaper and website, setting up a cut-off date for receiving applications.

ii. Applicants who may be an industry association/group of entrepreneurs/SPVs to Submit complete project proposal in prescribed formats, as per *clause 8.1.7* of these guidelines, to PMA.

iii. PMA to scrutinize the project proposals and submit it appraisal report with recommendations to SSC within one month of last day of receipt of application for considering grant of in-principle approval.

iv. In-principle approval will be granted to those applicants who submit a complete project proposal with technical recommendation and have availability of land.

v. Such *'in-principle'* approval will be valid for a period of 6 months from the date of approval. In case final approval is not accorded to the project within 6 months, in-principle approval will automatically lapse, unless it is specifically extended by the SSC.

vi. PMA may guide the applicants, who obtain the 1st stage approval, to fulfill all necessary conditions in the guidelines within 6 months.

vii. A project may be accorded final approval by the SSC, if the following conditions are fulfilled:

   a. Establishment of project specific SPV;
   b. Execution of share-holders agreement and other related agreements between the SPV and members;
   c. Preparation of Project Proposal by SPV and its appraisal by PMA;
   d. Procurement of requisite land by the SPV;
   e. Establishment of project specific account with Scheduled Commercial Banks by the SPV. DoP would credit funds into this account;
   f. Tying up of sources of funds for the balance amount.

viii. Projects to be completed *in 2 years*. However, SSC can grant an extension of 1 year for delays due to reasons not in control of SPV.

ix. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for continuation of project.

10.10. Selection Criteria

i. Preference in assistance will be given to project proposals shall be made by SSC, based on category of project as per **Clause 10.7** of guidelines.

ii. Preference in assistance will be given to those proposals which will utilize leverage for scaling up production & financing of common cluster facility.

10.11. **Schedule for Release of Grant**

i. The release of funds by the Department will be based on scrutiny by the PMA, approval by the Scheme Steering Committee (SSC) in the following manner: -

Instalment	Percentage of Funds	Remarks/Pre-requisite
1st	**30**	• Mobilization advance against an Indemnity Bond, on final approval of the project by SSC.
2nd	**30**	• Against the production of Bills • 75% utilization of 1st instalment • Proportionate expenditure incurred by the SPV.
3rd	**30**	• Against the production of Bills • 100% utilization of 1st instalment • 75% utilization of 2nd instalment • Proportionate expenditure incurred by the SPV.
4th	**10**	• 100% utilization of 2nd and 3rd instalment • SPV has mobilized and spent its 100% share in proportion of the first three grants.

ii. The SPV shall submit the Utilization Certificate (UC) in prescribed form (GFR-12A), generated through PFMS portal, duly certified by CA and countersigned by Head of SPV for the amounts utilized in accordance with GFR-2017. Also, the expenditure details need be uploaded in the CNA module of PFMS before processing the case for subsequent instalments. Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India.

10.12. Maintenance and Ownership of Assets

i. SPV shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/users;

ii. SPV shall ensure that the services of the facilities created under the scheme are extended to the cluster in general, in addition to the member enterprises;

iii. The Assets acquired by the SPV out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.

iv. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by Government of India should be maintained as per GFR.

v. If for any reason SPV is liquidated, Government of India shall have the first right to recover the grant funds provided by it. The assets created with such grant funds and any unutilized fund shall be vested with the Central Government. The Memorandum of Association & Articles of Association of the SPV with the Government shall incorporate this provision.

10.13. **Expected Benefits**

i. Improvement in quality standards of medical devices

ii. Improvement in regulatory compliance specified for medical device

iii. Increased availability of trained personnel for Medical Devices clusters

iv. Increased competitiveness of Medical Devices units in cluster

v. Reduction in the manufacturing cost of Medical Devices

10.14. Monitoring

10.14.1. The PMA shall carry out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMA shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and DoP in monitoring the Scheme.

10.14.2. PMA will provide full access to scheme monitoring portal to the Department of Pharmaceuticals for monitoring purpose and shall monitor approved projects through physical inspection, implementation schedule based on Program Evaluation and Review Technique (PERT)/ Critical Path Method (CPM)/ Gantt Chart and submit monthly & quarterly reports of review of the projects to DoP/SSC for timely disbursement and utilization of the funds.

10.14.3. PMA shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the Monitoring reports.

11. Sub-Scheme: Assistance for Testing Facilities (TF)

11.1. **Objective:** To strengthen availability of more Medical Device Testing Laboratories in order to boost manufacturing of quality medical devices.

11.2. **Intended Beneficiaries and Eligibility Criteria**

i. National or State level Government or Private institutions interested to establish or strengthen testing facilities for medical devices to test Class A, B, C and D medical devices including In vitro diagnostic medical devices under MDR, 2017.

ii. Such legal entity under the Indian law will open a separate account for the funds to be utilized for the projects assisted under the sub-scheme.

11.3. Incentive under the scheme: For Testing Facilities (TF) of Medical Device (MD) products, the limit of support will be 70% of the approved Testing Facilities project cost or Rs. 5 cr., whichever is less, as per the approval of SSC. In the case of Himalayan States and States in the North East Region, the grant-in-aid would be Rs. 5 Crore per Cluster or 90% of the project cost of the CIF, whichever is less. Any expenditure above the prescribed limit shall be borne by the selected applicant.

11.4. **Physical and Financial Outlay**

FinancialYear	**Physical Outlay**	**Financial Outlay (Rs. in Crores)**
	Testing labs	**Testing labs**
FY 2023-24	6	18
FY 2024-25	6	30
FY 2025-26	0	12
Total	12	60

11.5. **Modalities for utilization of incentive**

i. The cost of project shall include cost of land, building, internal infrastructure, administrative and management support expenses including the salary of Manager, Lab Technicians, Medical Device Officers and other experts and staff during the project implementation period (before commissioning), preliminary expenses, machinery & equipment, miscellaneous fixed assets and other support infrastructure such as water supply, electricity and margin money for working capital. However, *Grant-in-Aid from*

DoP will not be utilized towards land and building components of the project or construction of rest house, administrative buildings or any other building, which in the opinion of SSC may be categorized as non-essential construction for the technical requirements of project.

ii. In case, the National or State Government or private Institution provides an existing land and building, the cost of the same will be decided on the basis of valuation report prepared by an approved agency of Central / State Government Departments / Financial Institutions (FIs) / Public Sector Banks and the cost of land and building may be taken towards contribution for the project.

iii. In case, the National or State Government or private Institution provides an existing land and building on lease separately, then the *period minimum period of lease must be 30 years* for both land and Building. In case the National or State Government or private Institution provides an existing land, building on the same land on lease, then the period minimum period of lease for combined land and building must be 30 years.

iv. *Minimum of 30% of the approved project cost has to be contributed by private Institution* for the project & there is to be no duplication of funding for the same component/ intervention. *For the National or State Government Institution, the SSC will take a decision on its contribution.* The National or State Government or private Institution may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. Resource raised through such dovetailing will be in addition to the 30% contribution of the SPV.

v. Assistance for Administrative and other management support of SPV during the project implementation period *shall not exceed 5 % of the Grant-in- aid.*

vi. Proportionate contribution by the National or State Government or private Institution' share should be made upfront. Necessary infrastructure like land, access road, water and power supply, etc. must be in place or substantial progress should have been made in this regard before DoP assistance is released. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds will also be necessary before release of DoP assistance.

vii. Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the National or State Government or private Institution. The Central

Government shall not accept any financial liability arising out of operation of the testing facility.

viii. National or State Government or private Institution shall be responsible for obtaining all necessary statutory clearances in a timely manner.

ix. User charges for services of Testing facilities will be graded in such a manner that average charges will be lesser than prevailing market prices.

x. The Testing Facility may be utilized by the respective National or State Government or private Institution on 'user charges' basis as to be decided by it.

11.6. **Eligible Activities:** An indicative list of eligible activities, for the testing facilities for the MD clusters, under this Scheme are as under:

i. Component Testing Centre for ESDM/PCB/Sensors facility
ii. Electro-magnetic interference & Electro Magnetic Compatibility testing lab
iii. Biomaterial / Biocompatibility /Accelerated Aging testing lab
iv. Electronic and Electrical measuring, calibration and testing center
v. AERB and NABL Certified X-ray Radiation testing lab
vi. Other Medical Devices testing lab etc.

The indicative Medical Devices is mentioned in Annexure –II as per the notification of CDSCO dated 21.11.2022 regarding MDTL under MDR.2017.

11.7. Project Proposal and its components

i. The project proposal must have technical recommendation from competent technical body (e.g. CDSCO/ National Institute of Biologicals (NIB)/ National Accreditation Board for Testing and Calibration Laboratories (NABL), NIPERs/ IITs, Council of Scientific and Industrial Research (CSIR), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) etc.) may be the competent authority to grant technical recommendations). In case of PMA / SSC not being satisfied with the technical recommendations, the PMA / SSC may ask the SPV to obtain technical recommendations from specific competent experts.

ii. Proposal is to proposed to support minimum of 12 Medical Devices testing facilities under the scheme

iii. Project proposal may include have the following details:

a. Details about the Medical Devices testing Facilities;
b. Benefit/Objective/ Salient features of the Medical Devices Testing Facilities
c. Premises showing location and area of the different sections;
d. Qualification, experience of technical staff employed for testing and the person in-charge of testing;
e. List of equipment with specifications and their utilisation procedure;
f. Classes of medical Devices and list / type of tests that are proposed to be performed in the facility along with the Procedure of testing going to be followed; This should contain the Standards of Medical Devices – BIS or ISO or the respective Standards.
g. Tests and the purpose of the testing should also be furnished.
h. Type of support provided by Medical Devices Testing Facilities to manufacturer and Medical Devices Industry.
i. PERT/Critical Path Method (CPM)/ Gantt Chart for competing the Medical Devices Testing Facilities;
j. Action Plan for getting MD-40 issued by the CDSCO to get notified as MDTL under MDR-2017.
k. Action Plan for getting accreditation certificate issued by National Accreditation Body for Testing and Calibration Laboratories or any other similar body as may be notified by the Central Government.
l. Details of Fees to be charged for Medical Devices product testing from users.
m. Operation & Maintenance plan of the Medical Devices Testing Facilities
n. Action plan for enhancing competitiveness of Medical Devices Testing Facilities and positioning the Medical Devices Industry on a self-sustaining trajectory of growth. The proposal will have direct linkages between the impediments/bottlenecks identified and the measures recommended for improvement.
o. Implementation schedule to contain:
    I. Activity-wise time schedule

II. Milestone for payments
III. Excepted date of Commissioning
IV. Delay and expected Risk
V. Monitorable quantified targets for reporting on outcomes

11.8. Implementation Process & Timeline

i. PMA to invite project proposals for assistance under the scheme by issuing open advertisements in newspaper and website, setting up a cut-off date for receiving applications.

ii. PMA shall handhold an applicant to get registered and notified as a Medical Device Testing Laboratory to carry out testing or evaluation of a medical device on behalf of a manufacturer shall be made to the Central Licensing Authority accompanied with a fee through online portal of the Central Government as per the mandate under Medical Device Rules, 2017 and as further amendments from time to time.

iii. PMA to scrutinize the project proposals and submit it appraisal report with recommendations to SSC within one month of last day of receipt of application for considering grant of in-principle approval.

iv. In-principle approval will be granted to those applicants who submit a complete project proposal with technical recommendation and have availability of land.

v. Such in-principle approval will be valid for a period of 6 months from the date of approval. In case final approval is not accorded to the project within 6 months, in-principle approval will automatically lapse, unless it is specifically extended by the SSC.

vi. PMA will guide the applicants, who obtain the 1st stage approval, to fulfill all necessary conditions in the guidelines within 6 months.

vii. A project will be accorded final approval by the SSC if the following conditions are fulfilled:

a. Registration of Institutions or Entrepreneur;
b. Business plan including processes, Final projections and financial viability report and Identification of impediments and bottlenecks
c. Execution of shareholder's agreement and other related agreements between the Institutions or Entrepreneurs in case of partnership, collaboration etc.;
d. Preparation of Project Proposal by Institutions or Entrepreneurs and its appraisal by PMA;

e. Procurement of requisite land by the Institutions or Entrepreneurs;

f. Establishment of project specific account with Scheduled Commercial Banks by the Institutions or Entrepreneurs. DoP would credit funds into this account;

g. Tying up of sources of funds for the balance amount.

h. Project Specific bank account shall be opened by Institutions or Entrepreneurs

viii. Projects to be completed in 2 years from the date of final approval of SSC. However, SSC can grant an extension of 6 months for delays due to reasons not in control of SPV or License holder.

ix. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for continuation of project.

11.9. **Selection Criteria**

i. The selection of beneficiary shall be based on first come first serve basis.

ii. Preference in assistance will be given to project proposals by SSC, based on category of project as per clause 11.6 of the guidelines.

iii. Preference in assistance will be given to those proposals which will utilize leverage for scaling up production & financing of common cluster facility.

11.10. Schedule for release of Grant

i. The release of funds by the Department will be based on scrutiny by the PMA and approval by the Scheme Steering Committee in the following manner: -

Installment	Percentage of Funds	Remarks/Pre-requisites
1st	**30%**	• Mobilization advance against an Indemnity Bond, on final approval of the project by SSC.
2nd	**30%**	• Against the production of Bills • 75% utilization of 1st instalment • Proportionate expenditure incurred by the SPV.

3rd	**30%**	• Against the production of Bills • 100% utilization of 1st instalment • 75% utilization of 2nd instalment • Proportionate expenditure incurred by the SPV.
4th	**10%**	• 100% utilization of 2nd and 3rd instalment • The Institution has mobilized and spent its 100% share in proportion of the first three grants*. • Submission of Accreditation certification from NABL/AERB and Notified as Medical Device Testing Laboratory by Central Licencing Authority (CDSCO)

**- wherever SSC decided to do away with the contribution of Central or State Government Institution, the mobilization of the share does not arise.*

ii. The Institution(s) or organization shall submit the Utilization Certificate (UC) in prescribed form (GFR-12A), generated through PFMS portal, duly certified by CA and countersigned by Head of Institution(s) or organization for the amounts utilized in accordance with GFR-2017. Also, the expenditure details need be uploaded in the CNA module of PFMS before processing the case for subsequent instalments. Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India.

11.11. Maintenance and Ownership of Assets

i. Institution(s) or organization shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/users;

ii. Institution(s) or organization shall ensure that the services of the facilities created under the scheme are extended to the cluster in general, in addition to the member enterprises;

iii. The Assets acquired by the Institution(s) or organization out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.

iv. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by Government of India should be maintained as per GFR.

v. If for any reason Institution(s) or organization is liquidated, Government of India will have the first right to recover the grant funds provided by it. The assets created with such grant funds and any unutilized fund shall be vested with the Central Government. The Memorandum of Association & Articles of Association of the Institution(s) or organization with the Government shall incorporate this provision.

11.12. Monitoring

11.12.1. The PMA shall carry out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMA shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and DoP in monitoring the Scheme.

11.12.2. PMA will provide full access to scheme monitoring portal to the Department of Pharmaceuticals for monitoring purpose and shall monitor approved projects through physical inspection, implementation schedule based on Program Evaluation and Review Technique (PERT)/ Critical Path Method (CPM)/ Gantt Chart and submit monthly & quarterly reports of review of the projects to DoP/SSC for timely disbursement and utilization of the funds.

11.12.3. PMA shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the Monitoring reports.

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Annexure -I

Indicative chapters that may be included in the DRP to apply under the sub-scheme of Assistance for Common Facilities (AMD-CF)

Sl. No.	Contents
1.0	SPV Details with Checklist (minimum of 5 Medical Devices units, Medical Devices enterprises shall hold at least 51% equity of the SPV.)
2.0	Introduction
3.0	States: Diagnostic Study
3.1	Demographic Profile
3.2	Existing Infrastructure
3.3	Enterprise Profile
3.4	Market Characteristics
3.5	Raw Material Sourcing
3.6	Product Mix
3.7	Industry Analysis
3.8	Weak Supply of Raw Material (based on Project)
3.9	Slow Growth in Market (based on Project)
4.0	Need Assessment
4.1	Quality Assurance and Standardization
4.2	Availability of Raw Material (based on Project)
4.3	Access to Technology (based on Project)
4.4	Access to Market (based on Project)
4.5	Human Resource (based on Project)
4.6	Access to Funds (based on Project)
4.7	Description of Project (based on Project)
4.8	Project Rationale (based on Project)
4.9	Location of the Project (based on Project)
4.10	Management Details
5.0	Potential Entrepreneurs
5.1	Member Activity Description

Annexure –II

The list of indicative Medical Devices as per the notification of CDSCO dated 21.11.2022 regarding MDTL under MDR.2017. (as amended from time to time)

S. No.	Details of Medical Devices
1.	Copper-T
2.	Condoms
3.	Sterile Hypodermic Needles
4.	Tubal ring
5.	Hypodermic Syringe
6.	Blood Bags
7.	Bilirubin (Total and Direct) Test Reagents/Kits
8.	Creatinine test reagents/kit
9.	Aspartate Amino Transferase (ALT/SGOT) Test
10.	Uric Acid Test Reagents/Kits
11.	Total Protein test reagents/Kits
12.	Activated partial thromboplastic time (APTT) test
13.	PT (Prothrombin Time) Test reagents/Kits
14.	Sterilized Surgical Ligatures
15.	Sterilized Disposable Device
16.	3 Sterilized Surgical Sutures
17.	Cardio Vascular Devices (Biological Evaluation as per ISO 10993)
18.	Neuroprosthesis (Biological Evaluation as per ISO 10993)
19.	Orthopedic Implants(Biological Evaluation as per ISO 10993)
20.	All medical devices and Materials (Biological Evaluation as per ISO 10993)
21.	Dental Implants (Biological Evaluation as per ISO 10993)
22.	Orthopaedic devices (Biological Evaluation as per ISO 10993)
23.	Ocular Devices (Biological Evaluation as per ISO 10993)
24.	Surgical Devices and Sutures (Biological Evaluation as per ISO 10993)
25.	Respiratory Devices (Biological Evaluation as per ISO 10993)
26.	Gastrointestinal devices (Biological Evaluation as per ISO 10993)

S. No.	Details of Medical Devices
27.	Urological devices (Biological Evaluation as per ISO 10993)
28.	Haematological devices and IV sets (Biological Evaluation as per ISO 10993)
29.	Dental devices (Biological Evaluation as per ISO 10993)
30.	Personal care products and family planning (Biological Evaluation as per ISO 10993)
31.	Neurological devices (Biological Evaluation as per ISO 10993)
32.	All medical devices and Materials (Biological Evaluation as per ISO 10993)
33.	Catheters (Biological Toxicity)
34.	Disposable Hypodermic Needles (Biological Toxicity)
35.	Surgical dressings (Biological Toxicity)
36.	Orthopaedic implants (Biological Toxicity)
37.	Blood bags (Biological Toxicity)
38.	Drug eluting stent (Biological Toxicity)
39.	Intra Ocular Lenses (Biological Toxicity)
40.	Sutures (Biological Toxicity)
41.	Condoms (Biological Toxicity)
42.	Heart Valves (Biological Toxicity)
43.	Disposable perfusion sets (Biological Toxicity)
44.	Cardiac stents (Biological Toxicity)
45.	Copper - T (Biological Toxicity)
46.	Scalp Vein Set (Biological Toxicity)
47.	Disposable perfusion sets
48.	Cardiac stents
49.	Drug eluting stent
50.	Catheters (Class D)
51.	Catheters (Class B)
52.	Catheters (Class C)
53.	Heart Valves
54.	Intra Ocular Lenses
55.	I.V. Cannula

S. No.	Details of Medical Devices
56.	Bone Cements
57.	Internal Prosthetic replacements
58.	Peritoneal dialysis sets
59.	Intra-uterine Devices
60.	Surgical dressings
61.	Scalp Vein Sets
62.	Ligatures and Sutures
63.	Disinfectant (Sterility and Antimicrobial activities as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)
64.	Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0 IP 2018, BP 2018) – Class A
65.	Surgical Sutures (physical parameters, Sterility and BET as per ISO 11737- 2, USP 42, EP 9.0 IP 2018, BP 2018) – Class B
66.	Surgical Dressings (Sterility, Bioburden and BET as per IS 758, IS 1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018, EP 9.0) – Class A
67.	Surgical Dressings (Sterility, Bioburden and BET as per IS 758, IS 1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018, EP 9.0) – Class B
68.	Surgical Dressings (Sterility, Bioburden and BET as per IS 758, IS 1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018, EP 9.0) – Class C
69.	Surgical Dressings (Sterility, Bioburden and BET as per IS 758, IS 1954, ISO 11737-1 and 2, IP 2018, USP 42, BP 2018, EP 9.0) – Class D
70.	Blood Bags with and without anticoagulants solutions (Mechanical, Sterility and BET as per ISO 3826, IS 15102, ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)
71.	Contraceptives (Condoms-Male/Females (Mechanical parameters, Bioburden and Pathogens as per ISO 4074-2015, WHOUNAIDS 2010, ISO 25841-2017, WHOUNAIDS 2012, Schedule R, IS 11737-1, IP 2018, USP 42)
72.	Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class B
73.	Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class C

S. No.	Details of Medical Devices
74.	Disposable Hypodermic Needles (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class C
75.	Disposable perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class B
76.	Disposable perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class C
77.	Intra Ocular Lenses (Sterility, Bioburden and BET and Pathogen identification as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)
78.	Orthopaedic implants (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class C
79.	Orthopaedic implants (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class D
80.	Cardiac Stents (Sterility Test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) – Class C
81.	Cardiac Stents (Sterility Test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) – Class D
82.	Contraceptives (CuT) (Mechanical parameters, Sterility, Bioburden as per WHO UNFPA 2016, ISO 7439, ISO 11737 1 and 2, IP 2018, USP 42, BP 2018, EP 9.0)
83.	Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018) – Class B
84.	Catheters (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class D
85.	Disposable Hypodermic Needles (Sterility, Bioburden and BET as per ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class B
86.	Disposable Perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class A
87.	Intra Ocular Lenses (Sterility, Bioburden, BET and Pathogen identification as per ISO 11737-part 1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)
88.	Internal Prosthetic replacements (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)

S. No.	Details of Medical Devices
89.	Heart valves (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)
90.	Surgical Sutures (physical parameters, Sterility and BET as per ISO 11737- 2, USP 42, EP 9.0 IP 2018, BP 2018) – Class C
91.	Contraceptives (Tubal ring) (mechanical parameters and Sterility as per IS 13009-2000, ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)
92.	Disposable Perfusion sets (Physical testing, Sterility, Bioburden and BET as per ISO 1135-Part 4, IS 9824-3, ISO 11737-1 and 2, USP 42, EP 9.0, IP 2018, BP 2018) – Class B
93.	Internal Prosthetic Replacements (Sterility test as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)
94.	IV Cannualae (Sterility, Bioburden, Pathogen identification as per ISO 11737- 1 and 2, USP 42, EP 9.0, IP 2018, BP 2018)
95.	Disposable Hypodermic Syringes (Sterility and BET as per ISO 11737-2, USP 42, EP 9.0, IP 2018, BP 2018)
96.	Catheters – Class A
97.	Catheters (excluding Bio-compatibility testing) – Class B
98.	Catheters (excluding Bio-compatibility testing) – Class C
99.	Disposable Perfusion sets (excluding Bio-compatibility testing) – Class C
100.	Disposable Hypodermic Needles (excluding Bio-compatibility testing) – Class C
101.	Disposable Hypodermic Needles (excluding Bio-compatibility testing) – Class D
102.	Disposable Hypodermic Syringes – Class A
103.	Disposable Hypodermic Syringes (excluding Bio-compatibility testing) – Class B
104.	Disposable Hypodermic Syringes (excluding Bio-compatibility testing) – Class C
105.	Disposable Hypodermic Syringes (excluding Bio-compatibility testing) – Class D
106.	IV Cannualae – Class A
107.	IV Cannualae (excluding Bio-compatibility testing) – Class B
108.	IV Cannualae (excluding Bio-compatibility testing) – Class C
109.	IV Cannualae (excluding Bio-compatibility testing) – Class D
110.	Scalp Vein Set – Class A
111.	Scalp Vein Set (excluding Bio-compatibility testing) – Class B
112.	Scalp Vein Set (excluding Bio-compatibility testing) – Class C

S. No.	Details of Medical Devices
113.	Scalp Vein Set (excluding Bio-compatibility testing) – Class D
114.	Surgical Dressing – Class A
115.	Surgical Dressing (excluding Bio-compatibility testing) – Class B
116.	Surgical Dressing (excluding Bio-compatibility testing) – Class C
117.	Surgical Dressing (excluding Bio-compatibility testing) – Class D
118.	Contraceptives – Class A
119.	Contraceptives (excluding Bio-compatibility testing) – Class B
120.	Contraceptives (excluding Bio-compatibility testing) – Class C
121.	Contraceptives (excluding Bio-compatibility testing) – Class D
122.	Disinfectant – Class A
123.	Catheters (excluding Bio-compatibility testing) – Class D
124.	Disposable Hypodermic Needles – Class A
125.	Disposable Hypodermic Needles (excluding Bio-compatibility testing) – Class B
126.	Disinfectant (excluding Bio-compatibility testing) – Class B
127.	Disinfectant (excluding Bio-compatibility testing) – Class C
128.	Disinfectant (excluding Bio-compatibility testing) – Class D
129.	Disposable Perfusion sets – Class A
130.	Disposable Perfusion sets (excluding Bio-compatibility testing) – Class B
131.	Catheter (Test as per IS/ISO 10555) – Class A
132.	Disinfectants (As per IP, BP, USP) – Class B
133.	Disposable Hypodermic Needles (Test as per IS 10654) – Class B
134.	Disposable Perfusion Set (Test as per IS 12655) – Class A
135.	Disposable Perfusion Set (Test as per IS 12655) – Class B
136.	Catheter (Test as per IS/ISO 10555) – Class B
137.	I.V. Cannulae (Test as per IS/ISO 10555) – Class B
138.	Disposable Hypodermic Syringes (Test as per IS 10258) – Class B
139.	Scalp Vein Set (Test as per IS 16097) – Class B
140.	Surgical Dressing (Cotton and gauze, Bandage) – Class B
141.	Surgical Dressing (Cotton and gauze, Bandage) – Class A

S. No.	Details of Medical Devices
142.	Disposable Hypodermic Syringes – Class D
143.	Surgical Dressing – Class D
144.	Contraceptives - Class D
145.	Disposable Hypodermic Needles - Class C
146.	IV Cannualae – Class C
147.	Scalp Vein Set – Class B
148.	Catheters – Class D
149.	Disinfectant – Class B
150.	Disposable Perfusion sets – Class C
151.	Surgical Sutures - Class D
152.	Urine Collection Bag – Class B
153.	Surgical Gloves (Sterile/Non Sterile) – Class D
154.	Endotracheal (ET) Tube – Class B
155.	Disposable Hypodermic Syringes – Class C
156.	Blood Bag (Single Blood Bag, Double Blood Bag, Triple Blood Bag, Quad Blood Bag) – Class C
157.	Vascular devices and IV Sets – Class D
158.	Tubal Rings – Class C
159.	Copper T – Class C
160.	Sutures – Class C
161.	Disposable Hypodermic Syringes – Class B
162.	Blood Bags – Class B
163.	Condoms - Class C
164.	Coronary Stents - Class D
165.	Intra Ocular lenses Implants – Class D
166.	Orthopaedic Implants and Devices – Class D
167.	Drug Eluting Stents – Class D
168.	Internal Prosthetic replacements – Class D
169.	Ablation devices – Class D

S. No.	Details of Medical Devices
170.	NIBP – Class B
171.	IBP – Class C
172.	Nebulizer – Class C
173.	Thermometer – Class B
174.	Glucometer – Class B
175.	Disposable Hypodermic Needles – Class B
176.	Disposable Perfusion sets – Class B
177.	Catheters – Class B
178.	Surgical Dressing – Class B
179.	IV Cannualae – Class B
180.	Cardiac Stents (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class-C and D
181.	Catheters (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class – A,B,C,D
182.	Disposable Perfusion Set (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class – A,B,C
183.	Drug Eluting Stents (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class – D
184.	Heart Valves (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class-D
185.	Intra Ocular Lenses (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class-C
186.	I V Cannulae (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class – B, C
187.	Orthopaedic Implants (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class –B,C,D
188.	Scalp Vein Set (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class-B
189.	Surgical Dressings (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class –A,B,C,D

S. No.	Details of Medical Devices
190.	Disposable Hypodermic Needles (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class –B
191.	Disposable Hypodermic Syringes (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008) Class –B,C
192.	Ablation Device (Test – Ethylene Oxide residue, Standard/Specification- ISO 10993-7-2008)
193.	Infusion/Syringe Pump (Flow Rate, Volume, Occulsion Pressure, Electrical Safety)(Reference Standard IEC 60601-2-24, IS13450 (Part 2 Sec 24) and IEC 60601-1) Class-C
194.	Aspirator (Vaccum Testing, Electrical Safety) (Reference Standard ISO 10079-1 and IEC 60601-1) Class-C
195.	Glucometer (Glucose Concentration Testing) (Reference Standards IS/ISO 15197.2013) Class-C
196.	Blood Pressure Monitoring Devices (leak Test, NIBP Pressure Accuracy) (Reference Standard IEC60601-2-30.2009) Class-B
197.	Nebulizer (Flow Rate, Aerosol Output, Aerosol Output Rate, Electrical Safety) (Reference Standard ISO 27427.2013 and IEC 60601-1) Class- C
198.	Digital Thermometer (Temperature Testing) (Reference Standard – IS/ISO 80601-2-56.2017 and IS 3055 Part 1 and 2 and IS 6274)
199.	Tubal Rings/Fallopian Rings (Shape, Dimensions, Fracture Test, Memory Test, Friction Force Test, Fatigue Test, Radio opacity, Sterility, Identification of Polymer)
200.	Male Latex Condoms (Dimensions, Press Building, Burst volume and pressure test, Water Leakage test, Quantity of lubricant, Colour Fastness, Integrity of individual package seal, Labelling packaging and storage)
201.	COPPER-T 380A (Physical Parameters and Dimensions Pouch burst strength, Amount of copper wire, Strength of the Tie, Copper collar pull force, Sterility)
202.	Implantable Medical Devices (Physical Parameters and Dimensions, Sterility Test, BET Test, Bio-Burden Test)
203.	IUCD-375 (Visual Inspection, Sealed Pouch peel strength, Frame dimensions, Copper wire weight, Insertion Tube dimension, Thread, Flange displacement force, Sterility)

S. No.	Details of Medical Devices
204.	Disposable Hypodermic Needles (Acidity or Alkalinity, Extractable Metals, Physical Parameters and Dimensions, Performance Bond -Hub and Needle tube, Patency of lumen, Sterility, Bacterial Endotoxin)
205.	Disposable syringe (Extraneous matter, Acidity or Alkalinity, Extractable Metals lubricant, Physical Parameters and Dimensions, Sterility Test, Bacterial Endotoxin)
206.	Surgical dressings (Threads, weight, Length and width, foreign matter, fluorescence, packaging, labelling and storage)
207.	Sterile Hypodermic Syringe for Single use (Sterility Test, Bacterial Endotoxin Test)
208.	Cardiac Stent (Sterility test)
209.	Blood Bags (Sterility Test, BET, Chemical Analysis, Physical Dimensions)
210.	Catheters (Dimension, Sterility Test)
211.	Umbilical Tapes (Physical Test, Adhesive, Strength, Length dia)
212.	IV Cannula (Dimensions, Sterility)
213.	Copper-T (Sterility Test, Membrane Filtration method)
214.	Suture absorbable / Suture non-absorbable Synthetic (Sterility Test, Direct Inoculation Method)
215.	Tubal Ring (Sterility Test, Membrane Filtration Method)
216.	Infusion Set Class B
217.	Transcatheter Aortic Valve Class D
218.	Blood Collection Sets Class D
219.	Intraocular Lens Class C
220.	CT scan Equipment
221.	MRI Equipment
222.	Defibrillators
223.	Bone Marrow cell separator
224.	PET Equipment
225.	X-Ray Equipment
226.	Dialysis Machine
227.	Orthopaedic Implants
228.	Intraocular lens

S. No.	Details of Medical Devices
229.	Disposable Hypodermic Needles
230.	Disposable Hypodermic Syringe
231.	IV Cannulae
232.	Intrauterine Devices
233.	Orthopaedic Implants – Class C
234.	Blood Bags – Class C
235.	X-ray Equipment for Radiography and Radioscopy — Class C
236.	Cardiac Defibrillators — Class C
237.	Invasive Blood Pressure Monitoring Equipment - Class C
238.	Mammographic X-ray Equipment and Mammographic Stereotactic Devices - Class C
239.	Peritoneal Dialysis Equipment - Class C
240.	Ultrasonic Medical Diagnostic and Monitoring Equipment - Class B
241.	X-ray Equipment for Interventional Procedures - Class C
242.	Foley Catheter Two way (Test Parameter BET and Sterility) – Class D
243.	Disposable Electrode Recording Catheter (Test Parameter-BET and Sterility) – Class D
244.	Introducer Sheath Catheter (Test Parameter-BET and Sterility) - Class D
245.	Double Lumen Catheter Set (Test parameter-BET and Sterility) – Class D
246.	Disposable Central Venous Catheter (Test parameter-BET and Sterility) – Class D
247.	Dolphin Sutures Set (Test parameter and Sterility) – Class C
248.	Disposable Embolectomy Catheter (Test parameter-BET and Sterility) – Class D
249.	Disposable Thermodilution Catheter (Test Parameter-BET and Sterility) – Class D
250.	Foley Catheter Two way (Test Parameter BET and Sterility) – Class B
251.	Male Catheter (Test Parameter BET and Sterility) - Class B
252.	Ryles Tube 14FG (Test Parameter-BET, Bioburdan and Sterility) - Class B
253.	Endotracheal tube (Test Parameter-BET, Bioburdan and Sterility) - Class B
254.	Coronary Artery Cannula (Test Parameter-BET and Sterility) - Class B
255.	Natural rubber latex condom (Test Parameter-BET) - Class B
256.	Urethreal Catheter (Test Parameter-BET and Sterility) -Class D
257.	Multiple Lumen Catheter (Test Parameter-BET and Sterility) –Class B

S. No.	Details of Medical Devices
258.	Lint Bandage - Dimensions, pH value, Scouring Loss, Freedom from Opticals witness Class-A
259.	Heart Valves - Heavy toxic metals as Arsenic, Lead, Cadmium, Mercury Particulate Contamination, Sterility Class-D
260.	Disposable Perfusion set - Particulate contamination, Tubing length, Flow rate, Heavy Metals, Acidity or alkalinity, Residue on evaporation, UV absorption of extract solution, Sterility Class B
261.	Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Mercury Class D
262.	Ablation Devices -Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class C
263.	Ablation Devices -Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class D
264.	Cardiac Stents - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class D
265.	Disposable Hypodermic Syringe - Capacity, Fiducial Line, Limits for acidity or alkalinity, Metal, Lubricant, Scale, Barrel, Piston Nozzle, Performance, Reducing substances, Sterility Class B
266.	Bone Cements - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Sterility Class-C
267.	Contraceptives- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Water Leakage test, Bursting volume and pressure test, dimension, Sterility Class C
268.	Contraceptives- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Water Leakage test, Bursting volume and pressure test, dimension, Sterility Class D
269.	Disinfectant-Efficacy Test Class B
270.	Disposable Hypodermic Needles - Limits for acidity or alkalinity, Limits for extractable metals, Size designation, Colour coding, Needle hub, tube, point, Sheath, Performance, Sterility Class B
271.	IVD Kits - Sterility Class B
272.	IVD Kits - Sterility Class C
273.	IVD Kits - Sterility Class D

S. No.	Details of Medical Devices
274.	Blood Bags - Length, Width, Diameter, Leakage test, Limit of acidity or alkalinity, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Sterility Class-C
275.	Disposable Hypodermic Needles - Limits for acidity or alkalinity, Limits for extractable metals, Size designation, Colour coding, Needle hub, tube, point, Sheath, Performance, Sterility Class-C
276.	IV Cannula - Limits for acidity or alkalinity, Intravascular Catheter, Distal end, Hub, Effective length, Outside Diameter, Corrosion Test, Peak tensile force, Freedom from leakage, Sterility Class C Prosthesis - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury Particulate Contamination, Sterility Class-D
277.	Surgical Dressing-Bleached Gauze, Length, Width, Weight in gm/m2, Scouring loss/Foreign matter, Absorbency, Freedom from optical Whitness, pH value of aqueous extract, Sterility Class-A
278.	Orthopaedic Implants- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class-D
279.	Surgical Dressing IHS As per manufacturer specifications Class-D
280.	Internal Prosthesis - Heavy toxic metals as Arsenic, lead, Cadmium, Mercury Particulate Contamination, Sterility Class-C
281.	Disposable Perfusion set - Particulate contamination, Tubing length, Flow rate, Heavy Metals, Acidity or alkalinity, Residue on evaporation, UV absorption of extract solution, Sterility Class-A
282.	Surgical Dressing-Bleached Gauze, Length, Width, Weight in gm/m2, Scouring loss/Foreign matter, Absorbency, Freedom from optical Whitness, pH value of aqueous extract, Sterility Class-C
283.	IV Cannula - Limits for acidity or alkalinity, Intravascular Catheter, Distal end, Hub, Effective length, Outside Diameter, Corrosion Test, Peak tensile force, Freedom from leakage, Sterility Class-B
284.	Crepe Bandages - Dimensions, Weight per unit area, Stretch ability, breaking load, | Chemical Neutrality Class-A
285.	POP Bandages - Setting Time, Tensile Strength, Compressive strength Class-A

S. No.	Details of Medical Devices
286.	Disposable Perfusion set -Particulate contamination, Tubing length, Flow rate, Heavy Metals, Acidity or alkalinity, Residue on evaporation, UV absorption of extract solution, Sterility Class-C
287.	Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class-A
288.	Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class-B
289.	Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class-C
290.	Catheters- Length, Diameter, Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class-D
291.	Orthopaedic Implants- Heavy toxic metals as Arsenic, lead, Cadmium, Mercury, Particulate Contamination, Sterility Class-C
292.	Surgical Dressing-Bleached Gauze, Length, Width, Weight in gm/m2, Scouring loss/Foreign matter, Absorbency, Freedom from optical Whitness, pH value of aqueous extract, Sterility Class-B
293.	Rolled Bandage - Dimensions, pH Value, Scouring Loss, Freedom from optical Witness Class-A
294.	Medical Electrical Equipments -IEC/EN 60601-1/IS 13450 (Part 1) Class-A
295.	Electrical Safety Testing – Pulse Oximeter, Oxygen Concentrator, Electrocardiograph Class-C
296.	Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC) - Electro Medical Equipments Class-C
297.	Personal Protectives (Coverall, Surgical Masks, Filter type Particulate Matter Respirator, Medical Textile, Face Mask, Surgical Gowns and Surgical Drapes) Class-A
298.	Personal Protectives (Coverall, Surgical Masks, Filter type Particulate Matter Respirator, Medical Textile, Face Mask, Surgical Gowns and Surgical Drapes) Class-B
299.	Bioburden Testing (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class-A

S. No.	Details of Medical Devices
300.	In - Vitro Cytotoxicity Test (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class-A
301.	Electrical Safety Testing – Pulse Oximeter, Oxygen Concentrator, Electrocardiograph Class-B
302.	Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC) - Electro Medical Equipments Class-A
303.	Electrical Safety Testing – Pulse Oximeter, Oxygen Concentrator, Electrocardiograph Class-A
304.	Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC) - Electro Medical Equipments Class-B
305.	Bioburden Testing (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class-B
306.	Medical Electrical Equipments -IEC/EN 60601-1/IS 13450 (Part 1) Class-B
307.	Medical Electrical Equipments -IEC/EN 60601-1/IS 13450 (Part 1) Class-C
308.	In - Vitro Cytotoxicity Test (Disposable Hypodermic Needles, Surgical Dressings, Medical Textile) Class-B
309.	Surgical Gloves (Physiochemical, BET and Sterility) Class-A
310.	Catheters (Physiochemical, BET and Sterility) Class-C
311.	Cardiac Stents (BET and Sterility) Class-D
312.	Disposable Hypodermic Needles (Physiochemical, BET and Sterility) Class-B
313.	Blood Bags (Physiochemical, BET and Sterility) Class-C
314.	Surgical Dressings (Physiochemical, BET and Sterility) Class-B
315.	Scalp Vein Sets (Physiochemical, BET and Sterility) Class-B
316.	Face Mask (BET and Sterility) Class-A
317.	Orthopaedic Implants (Physiochemical, BET and Sterility) Class-C
318.	Disposable Hypodermic Syringe (Physiochemical, BET and Sterility) Class-B
319.	Disposal perfusion Set (Physiochemical, BET and Sterility) Class-B
320.	Surgical Sutures (Physiochemical, BET and Sterility) Class-C
321.	IV Cannula (Physiochemical, BET and Sterility) Class-B
322.	Suprapubic or non disposable cannula (Test parameter- Sterility and BET) Class-B

S. No.	Details of Medical Devices
323.	Disposable Hypodermic needles (Test parameter- Sterility and BET) Class-B
324.	Nasogastric Tube/ Ryles Tube (Test parameter- Sterility and BET) Class-B
325.	Gastrointestinal Tube (Test parameter Sterility and BET) Class-B
326.	Feeding Tube (Test parameter-Sterility and BET) Class-B
327.	Gastro-Enterostomy Tube (Test parameter- Sterility and BET) Class-B
328.	Bolster Suture (Test parameter-Sterility and BET) Class-A
329.	Blood Transfusion set (Test parameter Sterility and BET) Class-B
330.	Urinary Drainage Unit — (Test parameter Sterility and BET) Class-B
331.	Upper Urinary tract catheter (Test parameter- Sterility and BET) Class-B
332.	Foley Catheter (Test parameter-Sterility and BET) Class-B
333.	Coude catheter (Test parameter-Sterility and BET) Class-B
334.	Alcohol Swabs (Test parameter-Sterility and BET) Class-A
335.	Nasopharyngeal Catheter (Test parameter- Sterility and BET) Class-A
336.	Contraceptives (Test parameter-Sterility and BET) Class-C
337.	Intraocular Lens (Test parameter-Sterility and BET) Class-C
338.	Surgical Stapler (Test parameter-Sterility and BET) Class-B
339.	Orthopaedic implants (Test parameter Sterility and BET) Class-B
340.	Internal Prosthetic placements (Test parameter- Sterility and BET) Class-C
341.	Ablation device (Test parameter- Sterility and BET) Class-C
342.	IV cannula (Test parameter- Sterility and BET) Class-B
343.	Medical Electrical Equipments (EN/IEC 60601-1-2) Class-A
344.	In Vitro Diagnostic (IVD) Medical Electrical equipments (IEC 61326-2-6) Class-A
345.	In Vitro Diagnostic (IVD) Medical Electrical equipments (IEC 61326-2-6) Class-C
346.	Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC)-Electro Medical and IVD Equipments (Basic Standard) Class-A
347.	Electro Magnetic Interference and Electro Magnetic Compatibility (EMI/EMC)-Electro Medical and IVD Equipments (Basic Standard) Class-C
348.	Medical Electrical Equipments (EN/IEC 60601-1-2) Class-C
349.	In Vitro Diagnostic (IVD) Medical Electrical equipments (IEC 61326-2-6) Class-B
350.	Medical Electrical Equipments (EN/IEC 60601-1-2) Class-B