



PLI SCHEME MEDICAL DEVICES

Department of Pharmaceuticals



Aatmanirbhar Bharat Vision

- With a vision to make India self-reliant, the Indian Government has been actively taking steps through various policies under the Aatmanirbhar Bharat initiative
- With an aim to fulfill the need of the hour and overcome the manufacturing disability, the Government of India has come out with Production Linked Incentive Scheme (PLI scheme) for promoting domestic manufacturing of Medical Devices to boost domestic manufacturing and attract large investments in the Medical Device Sector making India self-reliant in medical device manufacturing
- In these lines, the Union Cabinet announced a PLI scheme for promoting domestic manufacturing of Medical Devices, which was notified vide letter dated October 29th, 2020
- The duration of scheme will be from FY 2020-21 to FY 2027-28 (Incentive Period – FY 2022-23 TO FY 2026-27)

Eligible Entities

- Applicant for the purpose of the Scheme shall be any company or LLP, registered in India, proposing to manufacture goods under target segment of the Scheme and proposing to make committed investment in Greenfield Project
- Only companies and Limited Liability Partnership registered in India and having positive Net Worth as on the date of application will be eligible
- The project should be greenfield, and the applicant should not have been declared as bankrupt or willful defaulter/defaulters or reported as fraud by any bank or financial institution or non-banking financial company





Target Segments

Target Segments	Indicative Eligible Products under Category A (Cat-A)	Indicative Eligible Products under Category B (Cat-B)
Cancer care/Radiotherapy medical devices	Rotational Cobalt Machine, Linear Accelerator (LINAC)	Brachytherapy Systems, Radiotherapy Simulation Systems, Workstations- Radiotherapy Planning, Proton therapy system and other products* in this target segment.
Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	CT Scan, MRI, Ultrasonography, X-ray equipment, C-arm, Cath-Lab, Positron Emission Tomography (PET) Systems, Single photon emission tomography (SPECT), Mammography, Collimator, Flat Panel Detector, Surgical X Ray C-Arm, Fixed LF and HF X Ray Products, X Ray Panels, MRI Coils and Monitors	Cyclotrons, Positron Emission Tomography (PET) Systems, Single photon emission tomography (SPECT), X-Ray Tube and other products* in this target segment
All Implants including implantable electronic devices	Heart Valves, Stents, PTCA Balloon, Dilatation Catheter, Heart Occluders, PTCA Catheter, Hip Implants, Knee Implant and Trauma Implant, Drug Eluting Stents and Drug Eluting Balloons.	Cochlear Implants, Spinal and neuro-surgical implants, Urogynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid (CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted euro-stimulated device like Deep Brain Stimulator, Intraocular lenses and other products* in this target segment





Target Segments	Indicative Eligible Products under Category A (Cat-A)	Indicative Eligible Products under Category B (Cat-B)
Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardiorespiratory Category & Renal Care Medical Devices	Dialyzer, Anesthesia Unit Ventilators, Patient monitoring system, Anesthesia Workstation, Automated External Defibrillators (AEDs), ECG, Syringe Pump, Defibrillators, Stress Test System and Oxygen Concentrator, Dialysis Machine, Peritoneal Dialysis kits Fistula, Blood Line, Haemodialysis Catheter and Transducer Protector, Anaesthesia Unit Gas Scavengers, Anaesthesia Unit Vaporizers, Anaesthesia Unit Ventilators, Bi- Phasic Defibrillators, Infusion pumps - Syringe and Volumetric, Intensive Care Ventilators, Emergency Ventilators (Portable Ventilators), High Flow Oxygen Devices, Multiparameter Monitor, Suction Machine	Needles-Anesthesia, Syringes-Anesthesia,, , Anesthesia Kits, Masks –Anesthesia, , Biopsy KitsRenal, Dialyser reprocessing system, Lithotripters Extracorporeal –Renal and other products* in this target segment

■ *Note: Other Products in respective segments not mentioned above will be subject to Technical Committee decision about their eligibility under the Target Segment. A key component which constitutes major part of the finished medical device (such as Rotating Anode Tube, Stationary Anode Tube, MRI Magnet, Flat Panel Detector and similar components), and has a distinct HS code for itself, will be considered as included in the corresponding target segment.*





Evaluation Criteria

Sr. No.	Parameters for Category A	Parameters for Category B	Score	Max Score (Cat - A)	Max Score (Cat - B)
1	Global Medical Devices manufacturing turnover of applicant and / or group company in FY 19 should be more than INR 60 Crore	Global Medical Devices manufacturing turnover of applicant and / or group company FY 19 should be more than INR 20 Crore	5	50	30
	For every additional INR 60 Crore	For every additional INR 20 Crore	5		
2	Average of last 5 years Investment of applicant and group company in medical devices sector > INR 5 Crore i.e. FY 17 to FY 21		5	NA	20
	For every additional INR 3 crore in medical device sector		5		
3	Existing Patent/technology transfer with applicant and/or group Company in Target Segment		5	20	20
	For every additional Patent/Technology Transfer		5		
4	Existing ISO 13485 as on the date of application available with the applicant and/or group company		10	10	10
5	Existing Product CDSCO / AERB approved / regulatory product approval in USA (USFDA), UK, Australia, Japan, Canada, European Union (CE) as on the date of application available with the applicant and / or group company. Any one approval out of above list		5	10	10
	For additional regulatory out of the above list		5		





Sr. No.		Score	Max Score (Cat - A)	Max Score (Cat - B)
6	Average R&D expense of applicant or group for FY 18 to FY 19 as a percentage of sales revenue (5 to 10 %)	5	10	10
	For more than 10 %	5		
	Total		100	100

Incentive

Sr. No.	Particulars	FY- 23	FY- 24	FY- 25	FY- 26	FY- 27
1	Incentive Rate on Incremental Sales	5%	5%	5%	5%	5%
2	Minimum Threshold of incremental sale (FY24 onwards, threshold sale shall be computed at 10% growth over the minimum threshold incremental sale required in the previous financial year)	INR 20 Crore	INR 22 Crore	INR 24.2 Crore	INR 26.62 Crore	INR 29.28 Crore
3	Maximum Incentive per applicant per target Segment	INR 2.5 Crore	INR 5.0 Crore	INR 8.5 Crore	INR 11 Crore	INR 13 Crore

 **Note:** Maximum Incentive per applicant per target segment– INR 40 Crore (Incentive = Net Incremental Sales of Eligible Product(s) x Rate of Incentive)





Key Points for Consideration

- Eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa
- For determining eligibility of an applicant to meet the criteria of Committed Investment for any year, the cumulative value of investment done till such year (including the year under consideration) over the Base Year shall be considered
- Investment done on or after April 1, 2021, will be considered as Eligible Investment
- An application shall make only one application per target segment in a particular product category
- In case, two applicants have same score, the selection shall be made on the scores obtained against the parameter "Global Medical Device manufacturing turnover of applicant and / or group company in the Target Segment for FY19". In case of tie in this parameter also, the selection shall be made based on the score obtained against the next parameter mentioned in seriatim till tie breaks
- Incremental Sales shall be Net Sales Turnover of Eligible Product(s) for the period of which claim for disbursement of incentive pertains minus the Net Sales Turnover of said Eligible Product(s) for the base year
- In case an applicant does not meet criteria of committed investment and minimum threshold sales for any given year, the applicant shall not be eligible for disbursement of incentive for that particular year
- However, the applicant will not be restricted from claiming incentive for subsequent years during the tenure of the Scheme, provided eligibility criteria of committed investment and minimum threshold sales are met for such subsequent years
- There shall be no restriction on any applicant applying in more than one target segment per product category. However, the applicant shall be required to submit a separate application along with the application fee for each target segment and shall be required to separately meet the eligibility criteria of committed investment and minimum threshold sales of Manufactured Goods for each target segment





Say Hello



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