File No. 31026/19/2020-MD
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Date: 10.11.2026

Public Notice

Subject: Revised Guidelines for the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices – Reg.

The Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices was notified by the Department of Pharmaceuticals (DoP) vide Gazette Notification No. CG-DL-E-21072020-220617 dated 21.07.2020, with a total financial outlay of ₹3,420 crore. Out of the total approved outlay, approximately ₹2,700 crore is presently available for disbursement under the Scheme and shall be utilized for promoting and incentivizing domestic manufacturing of medical devices in the country.

2. Accordingly, the amended Scheme Guidelines are hereby published at **Annexure-I**. These Guidelines shall be applicable to all applicants submitting applications under the Scheme after 10.11.2026.

3. Applicants already approved under the Scheme up to 31.10.2026 shall continue to be governed by the Scheme Guidelines issued vide File No. 31026/19/2020-MD dated 25.02.2023.

4. This is issued with the approval of the Competent Authority.

10/11/2026

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Encl: as above

CC:

1. NIC, to upload on the DoP website.

Annexure-I

File No. 31026/19/2020-MD
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Dated:10Th November, 2026

Guidelines for the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices

1. Background

1.1. In the last ten years, the domestic medical device sector has grown phenomenally on account of enhanced access to healthcare in the country. However, imports still cater to a sizable part of the domestic demand for medical devices, especially high-end medical equipment. The PLI-MD scheme launched in 2020, has played an important role in promoting domestic manufacturing of medical implants, certain high end medical equipment as well as medical consumables. However, owing to the lack of medical component manufacturing ecosystem in the country, the domestic manufacturers face constraints in securing supply of quality critical components. Additionally, the domestic manufacturers also face multiple disabilities on account of high cost of finance, higher cost of power, logistics etc, which translate to 12-15% higher cost of manufacturing.

1.2. With a view to address multiple disabilities in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, a scheme called “Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices” was approved by the Government on 20th March, 2020. The first phase of the scheme would be completed in the current FY, and has led to significant gains in promoting domestic manufacturing of over 50 medical devices. This has benefitted the citizens, on account of substantial lowering of prices of such devices in the country.

1.3. The Production Linked Incentive Scheme (PLI) for promoting domestic manufacturing of Medical Devices (hereinafter referred to as ‘Scheme’) was notified vide Gazette Notification no. 31026/08/2020-MD, dated - 21/07/2020. The scheme is now extended upto FY 2035-36 and fresh applications shall be invited under the scheme.

1.4. The Scheme proposes a financial incentive to boost domestic manufacturing and attract large investments in the Medical Device Sector, while developing an ecosystem for manufacturing of finished medical devices and value chain items used therein.

1.5. These guidelines are being issued for effective and smooth implementation of the Scheme. These guidelines cover, inter alia, the following:

1.5.1. Definitions
1.5.2. Eligibility and Selection
1.5.3. Application and Online Portal
1.5.4. Project Management Agency (PMA), Project Evaluation Committee (PEC) and Empowered Committee (EC)

1.5.5. Approval under the Scheme
1.5.6. Calculation and disbursement of incentive

2. Definitions

2.1. **Applicant:** Applicant for the purpose of the Scheme shall be any company registered in India, proposing to manufacture goods under the 4 target segments under the Scheme. The applicant shall make committed investment in a Greenfield Project (wherever applicable as specified in **Annexure 2** of these guidelines). The aforesaid manufacturing can be carried out at one or more locations in India.

2.2. **Application:** Online application shall be submitted by an applicant to DoP as per the Application Form prescribed under these guidelines containing requisite information, along with supporting documents and application fee.

2.3. **Application Acknowledgement Date:** It shall be the date on which an application is acknowledged by DoP or the scheme PMA, after carrying out initial scrutiny in this regard.

2.4. **Application Approval Date:** Shall be the date on which approval letter under the Scheme is issued by DoP or the PMA on behalf of DoP.

2.5. **Application Window:** The application window shall be remain open over a period of time, and all applications received by the end of each month or even earlier (during the application window) shall be put up for processing.

2.6. **Base Year:** In case of manufacturers who are already manufacturing the product prior to the application date, the base year for such applicants shall be the year in which highest sales of the said product were achieved, in any of the last 3 years. In case of products, for which the applicant has no prior sales in any of the last 3 years, the base year shall be the year in which application was submitted viz year zero with zero sales

2.7. **Base Sales**:

2.7.1. **Existing Manufacturers:** In cases where an applicant entity, including all entities forming part of its group of companies, is already manufacturing the product for which the application is made and intends to establish additional production capacity, the base sales for such product shall be the highest annual sales (domestic and export combined) achieved in any of the three financial years preceding the date of submission of the application under the Scheme.

2.7.2. **New Manufacturers:** In cases where the applicant entity, including all entities forming part of its group of companies, is not engaged in the manufacturing of the product for which the application is made, the base sales shall be considered to be zero and incentive shall be payable on the entire sales done in the 5 performance years. The prescribed sales CAGR shall have to be achieved over the 1st year sales.

Note: *Incentive under this scheme shall be given on the sales generated form the additional/new production capacity (except TS4) created for an approved product.*

2.8. **Committed Investment**: The amount of fresh investment as defined in para 2.20

below, which the applicant shall commit by declaration at the time of applying under the scheme.

2.9. **Date of Commercial production:** The date on which the applicant raises the first GST invoice for the sale of Eligible Product(s) manufactured under the Scheme.

2.10. **Value chain integration:** In order to ensure quality of manufactured devices and reliability of the value chain, the applicants shall be required to ensure value chain integration in their manufacturing. The extent of value chain integration shall be assessed on the product wise Bill of Material (BoM) basis.

2.11. **Eligible Product:** Indicative list of eligible products in each of the four Target Segments is listed in **Annexure 1 and 1A** to these guidelines. Any application containing products beyond such indicative list, shall require prior approval of the competent authority.

2.12. **Employment:** Jobs which are directly involved in the production process or with related activities shall be considered for the calculation of the resulting employment generation under the scheme. Such employment shall include on-roll and contractual workforce deployed in India only.

2.13. **Empowered Committee (EC):** A committee constituted by DoP and comprising of the following members:

i. CEO, NITI Aayog (Chairman)
ii. Secretary, Department of Pharmaceuticals
iii. Secretary, Department of Health & Family Welfare
iv. Secretary, Department of Commerce
v. Secretary, Department for Promotion of Industry & Internal Trade
vi. Secretary, Ministry of Environment, Forest and Climate Change
vii. Director General of Foreign Trade

Experts may be invited as special invitees, as may be felt necessary, from time to time.

2.14. **Financial Year:** Financial Year begins on the 1st April of a year and ends on 31st March of the following year.

2.15. Force Majeure: Extraordinary events or circumstances beyond human control such as event described as an act of God (like a natural calamity) or events such as a war, strike, public health emergency, riots, crimes (but not including negligence or wrong-doing, predictable/ seasonal rain and any other events specifically excluded)**.**

2.16. **Greenfield Project:** A project wherein committed investment is proposed to be made by the applicant under this Scheme in a new production facility or in a new plant in the premises of an existing production facility. Separate records shall however be maintained for the new plant in the premises of an existing production facility for the purpose of the Scheme.

Note: If the applicant is an existing manufacturer, he may utilise existing ancillary utilities viz. ETP, Quality Control Lab, Warehousing Area and other Utilities for the manufacture of eligible product. However, the investment already made in the ancillary

utilities shall not qualify for the purpose of the committed investment to be made under the Scheme.

Any change in the location of greenfield project site shall be approved by DoP, and subsequently to be ratified by the EC

2.17. **Group Companies:** Group Company(ies) shall mean two or more enterprises which, directly or indirectly, are in a position to:

Exercise twenty-six percent or more of voting rights in other enterprise;

or

Appoint more than fifty percent of members of board of directors in the other enterprise. As defined in the FDI Policy Circular of 2020.

2.18. **Incentive:** Incentive is the financial benefit to be provided to each selected applicant based on the incremental sale of manufactured goods made by the selected applicant as compared to the Base sales.

2.19. **Incremental Sales of Manufactured Goods:** Sales of manufactured goods over a given period minus the base sales of manufactured goods. Base sales shall be taken as zero in case the applicant has reported zero sales of that product in the last 3 years.

2.20. **Investment:** Investment shall mean

2.20.1. Expenditure incurred on new Plant, Machinery, Equipment and Associated Utilities: This shall include expenditure on new plant, machinery, equipment and associated utilities as well as tools, dies, molds, jigs, fixtures (including parts, accessories, components, and spares thereof) of the same, used in the design, manufacturing, assembly, testing, packaging or processing of any of manufactured goods covered under Target Segments. It shall also include expenditure on packaging, freight / transport, insurance, and erection and commissioning of the plant, machinery, equipment and associated utilities. Associated utilities would include captive power and effluent treatment plants, essential equipment required in operations areas such as Clean Rooms, Sterilization Process Room, Air Curtains, Temperature and Air Quality Control Systems, Compressed Air, Water & Power supply and control systems. Associated utilities would also include IT and ITES infrastructure related to manufacturing including servers, software and ERP solutions. All non-creditable taxes and duties would be included in such expenditure.

2.20.2. Expenditure incurred on new Research and Development (R&D): This shall include capital expenditure on R&D and product development related to Target Segments. The term “related” here refers to all stages in the entire value chain of the goods proposed to be manufactured including software integral to the functioning of the same. Such expenditure shall also include

expenditure on in-house and captive R&D directly attributable to goods covered under the Target Segments, including all stages in the entire value chain of the goods proposed to be manufactured including software integral to the functioning of the same. Such expenditure shall include test and measuring instruments, prototypes used for testing, purchase of design tools, software cost (directly used for R&D) and license fee, expenditure on technology, IPR, Patents and Copyrights for R&D. All non-creditable taxes and duties would be included in such expenditure.

2.20.3. Expenditure related to Transfer of Technology (ToT) Agreements: This shall include cost of technology and initial technology purchase related to manufactured goods covered under Target Segments. All non-creditable taxes and duties would be included in such expenditure. ToT arrangement with a parent company or group company shall not count towards such investment; ToT from a unrelated entity shall only be counted as investment.

2.20.4. Expenditure incurred on Land and Building: The expenditure incurred on land and building (including factory building / construction) required for the project / unit shall not be covered under the Scheme and, therefore, shall not be considered for determining eligibility under the Scheme.

2.20.5. The cut-off date for calculating the investment under the Scheme shall be 1-4-2026

2.21. **Manufacturing:** In accordance with Central Goods and Services Tax (CGST) Act, 2017, manufacturing shall mean processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use and the term “manufacturer” shall be construed accordingly.

2.22. **Net Sales turnover**: Net Sales Turnover shall mean the Gross Sale Turnover net of credit notes (raised for any purpose), discounts (including but not limited to cash, volume, turnover, target or for any other purpose) and taxes applicable.

2.23. **Net Worth:** Net worth would comprise of Paid-up Capital plus Free Reserves including Share Premium but excluding Revaluation Reserves, plus Investment Fluctuation Reserve and credit balance in Profit & Loss account, less debit balance in Profit & Loss account, Accumulated Losses and Intangible Assets.

2.24. **Non-originating Material:** Material and Services whose country of origin is other than the country in which that material / service is used in manufacturing and any material / service whose origin cannot be determined.

2.25. **Project Management Agency (PMA):** Refers to the agency appointed by 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 above-mentioned in accordance with these guidelines.

2.26. **Related Party(ies):** The term related party shall be as defined in Accounting Standard-18: Related Party Disclosures or Indian Accounting Standard (Ind-AS)-24 Related Party Disclosure, as may be applicable to the applicant, as notified by Ministry of Corporate Affairs or any other appropriate authority from time to time.

2.27. **Successor-in-Interest:** Successor-in-Interest shall mean the new or re-organized entity formed after the merger, de-merger, acquisition, transfer of business or significant change in ownership of an applicant.

2.28. **Target Segment (TS):** Target Segment shall mean one of the four segments viz.:

i. **TS1**- Consumables & Disposables & implants Medical Devices

ii. **TS2**- Critical Components used for manufacturing of medical devices

iii. **TS3**- High-end medical devices which are in nascent state of domestic manufacturing

iv. **TS4**- High-end medical devices where only assembly operations exist in the country

2.29. **Project Evaluation Committee (PEC):** A committee constituted by DoP through an executive order to evaluate the applications received under the scheme.

3. Tenure of the Scheme: The extended tenure of the Scheme is upto Financial Year 2035-36. This include a maximum of three years of gestation period and a maximum of five years of performance period. FY 2035-36 shall be utilized for processing and releasing the incentive for the last Performance Year.

4. Eligibility

4.1. Eligibility for selection

4.1.1. The project shall be a greenfield project (except for TS4) as defined under these guidelines.

4.1.2. Only companies and Limited Liability Partnership registered in India and having positive Net Worth (of applicant company including that of Group Companies).

4.1.3. The applicant should not have been declared as bankrupt or willful defaulter or defaulter or reported as fraud by any bank or financial institution or non-banking financial company.

4.2. Eligibility for incentive

4.2.1. Eligibility shall be subject to committed investment and incremental sales of manufactured goods (covered under Target Segments) over the Base Year.

4.2.2. To be eligible for the disbursement of incentives, applicants under this scheme must meet the criteria for minimum investment, value chain integration(self declared), and incremental sales growth wherever applicable in respect of each Target Segment as provided in **Annexure 2 and 3** of these guidelines.

4.2.2.1 **TS1, TS3 and TS4**: Minimum investment shall be Rs 50 Cr in setting up greenfield manufacturing facility (TS1 and TS3) or for achieving substantial value chain integration(TS4), for applicants whose average annual turnover in the last three years, is less than Rs 150 Cr. However, for applicants whose average turnover in last 3 years is at least Rs 150 Cr, there is no minimum investment condition.

In case of TS4, no requirement of greenfield investment is prescribed, as the incentive would be paid for achieving a higher value chain integration

4.2.2.2 **TS2**: No such condition for minimum investment shall apply to this target segment.

4.2.3. In case an applicant does not meet the criteria of committed investment, value chain integration(self declared) and sales growth CAGR for any given year, wherever applicable, in respect of each target segment as provided in **Annexure 2 and Annexure 3** of these guidelines, 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 sales CAGR are met for such subsequent years. The incentives may be carry forwarded to subsequent years as per the scheme guidelines.

4.2.4. Eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa.

Selection:

4.3. All eligible applicants shall be considered for selection, within the permissible limits decided on the basis of available scheme financial outlay, annual incentive bucket size and likely incentive outflow.

5. Investment for Determining Eligibility

5.1. General Terms and Conditions

5.1.1. Investment as defined in these guidelines shall be considered for determining eligibility under the Scheme provided such Investment is made on or after the scheme notification date

5.1.2. Expenditure on consumables and raw material used for manufacturing shall not be considered as Investment.

5.1.3. The date of purchase invoice would be considered as the date of investment under the Scheme.

5.1.4. The heads of Investment, based on which eligibility is being determined, should be capitalized in the books of accounts of the applicants as certified by the Statutory Auditor.

5.1.5. The applicant shall submit a certificate by a PMA empaneled Chartered Engineer, for committed investment by the applicant and shall be relied upon by PMA. Such Chartered Engineer shall issue the certificate after carrying out the physical inspection of the plant. PMA shall ensure that there are atleast 5 such Chartered Engineers in its panel.

5.1.6. The PMA will rely on certificates from an empaneled Chartered Engineer registered with Insolvency and Bankruptcy Board of India, and valuation considered under Customs Rules, wherever applicable, for the purpose of determining reasonableness of cost.

5.2. Plant, Machinery and Equipment

5.2.1. Expenditure incurred on new Plant, Machinery and Equipment as defined in Clause 2.20.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

5.2.2. New Plant, Machinery and Equipment should be purchased / leased in the name of the applicant. In cases where these are being leased, the lease should be in the nature of a financial lease within the meaning of Accounting Standard 19 – Leases or Indian Accounting Standard (Ind-AS) – 116 Leases, as may be applicable to the applicant, as notified by Ministry of Corporate Affairs or any other appropriate authority from time to time.

5.2.3. In such case that tools, dies, molds, jigs, fixtures and parts, accessories, components and spares are located outside the premises of an applicant, appropriate undertaking(s) from the person having custody of these equipment / components along with valid legal agreement(s) for the said transaction(s) shall be obtained. These equipment/ components should not be located outside the country.

5.2.4. Plant, Machinery and Equipment should be procured / leased through legally valid documents after payment of applicable taxes and duties.

5.2.5. The Plant, Machinery and Equipment of the Greenfield Project approved under the Scheme shall be used in regular course for manufacturing of the goods under the Target Segments that are approved in the approval letter issued by DoP. This does not preclude the usage of such machinery for manufacturing of other medical devices. The applicant must submit a declaration about usage of machinery for each year during the period that such applicant is claiming incentive under the Scheme.

5.3. Research and Development (R&D)

5.3.1. Expenditure incurred on Research and Development as defined in Clause 2.20.2 of these Guidelines shall be considered as Investment for determining eligibility under the Scheme.

5.3.2. The applicant shall provide a certificate from Statutory Auditor and purchase

agreements in respect of the cost of technology, Intellectual Property Rights (IPRs), patents and copyrights.

5.3.3. The software associated with R&D should have been procured / licensed through legally valid documents after payment of applicable taxes and duties.

5.3.4 The cost incurred by the Applicant, towards the of clinical trials of Eligible Product in India, shall be eligible towards investment. However, the investment on Clinical Trials (mentioned above) shall be capped at maximum 10% of Committed Investment for an Approved Applicant, irrespective of it being capitalized in the books of accounts or not. In case there is a doubt on the correctness & reasonableness of such claims of expenditure, a two-member Committee nominated by DCGI shall examine such claims & recommend to DoP to arrive at the final admissible amount.

5.4. Transfer of Technology Agreements

5.4.1. Expenditure incurred on Transfer of Technology Agreements as defined in Clause 2.20.3 of these Guidelines shall be considered as Investment for determining eligibility under the Scheme.

5.4.2. The applicant shall provide a certificate from Statutory Auditor in respect of expenditure related to Transfer of Technology Agreements.

5.5. Associated Utilities

5.5.1. Expenditure incurred on associated utilities as defined in Clause 2.20.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

5.5.2. The applicant shall provide a certificate from Statutory Auditor in respect of expenditure related to associated utilities.

6. Application

6.1. The Scheme shall be open for submitting applications, based on the notice issued by DoP on its official website. The application window shall remain open for a considerable period, and all applications submitted by the last day of every month(within the application window) shall be taken up for further processing.

6.2. An applicant can submit any number of applications in each of the four Target Segments. However, the applicant shall be required to separately meet the eligibility criteria of investment threshold requirement, value chain integration(self declared) and sales growth CAGR of Manufactured Goods for each target segment wherever applicable as provided in **Annexure 2 and 3** of these guidelines.

6.3. An Application shall be made online, in the format provided in **Annexure 4** of these guidelines.

6.4. An applicant shall submit an undertaking in the format of **Annexure 5** consenting audit of their manufacturing site/ offices for verification of information/data submitted along with the application.

6.5. On receipt of an application in the prescribed format, PMA will conduct an examination as per checklist in **Annexure 6** as whether the application prima facie meets the eligibility threshold criteria as prescribed in **Annexure 2 and Annexure 2A** of these guidelines. The aforesaid prima facie examination shall be completed within 15 working days from the date of receipt of the original application or any subsequent submission of the revised application, if the original filling was returned as incomplete earlier. In case, on the above-mentioned examination, an application is found to be incomplete, PMA shall inform the applicant accordingly, within 15 working days of receipt of the application. An applicant must complete an incomplete application within 15 working days of such communication from PMA, failing which, the application will be closed under intimation to the applicant

6.6. For an application which prima facie meets the eligibility threshold criteria as prescribed in **Annexure 2** of these guidelines, PMA shall issue an acknowledgement of receipt of the application within 15 working days of receipt of application. This acknowledgement shall not be construed as approval under the Scheme. In case, where on examination it is found that an original or a revised application does not prima facie meet the criteria as prescribed, the PMA shall inform the applicant accordingly within 15 working days of receipt of application and the application shall be closed.

6.7. A non-refundable application fee, as mentioned in **Annexure 7** of these guidelines, would be payable for each application. The application fee would be accepted electronically only.

7. Online Portal

7.1. All applications will be submitted to the PMA. Details of the detailed methodology for submitting an application under the scheme shall be published on the website of the Department.

7.2. Upon successful submission of an application, a unique Application ID shall be issued to the applicant for all future references pertaining to the Scheme.

8. Project Management Agency (PMA)

8.1. The Project Management Agency (PMA) appointed by DoP for the scheme shall be responsible for providing secretarial, managerial and implementation support and carrying out other responsibilities as assigned by DoP from time to time.

8.2. The PMA shall be responsible, inter alia, for:

8.2.1. Setting up an online portal or any other mechanism for accepting applications under the scheme

8.2.2. Examination and processing of applications and issuing acknowledgements.

8.2.3. Conduct field visits to the applicant sites/offices, if required

8.2.4. Weekly submission to DoP, the status of applications received and processed under the Scheme.

8.2.5. PMA may seek inputs from the PEC as may be deemed necessary.

8.2.6. Making appropriate recommendations to the EC for approval of applications under the Scheme.

8.2.7. Verification of investment threshold requirement, incremental sales growth, value chain integration of Manufactured Goods for each target segment wherever applicable(self declared) as provided in **Annexure 2 and 3** for determining eligibility for disbursement of incentive.

8.2.8. Examination of claims for disbursement of incentive and making appropriate recommendations to the EC.

8.2.9. Verification of the reconciliation of disbursement claims with prescribed documents.

8.2.10. Compilation of data regarding progress and performance of the Scheme through Quarterly Review Reports as per **Annexure 8** and other information / documents.

8.2.11. Providing secretarial and other support to the PEC/EC/DoP for carrying out its responsibilities.

8.3. The PMA may request for additional information, details and documents from the applicant as deemed necessary.

8.4. The PMA will have the right to carry out physical inspection of an applicant's manufacturing units and offices through site visit.

9. Project Evaluation Committee (PEC)

9.1. An internal Committee shall be constituted by DoP through an executive order, to examine and evaluate the proposals received under the Scheme. With the approval of Secretary, DoP, such proposals shall thereafter be placed before the EC for final approval.

10. Empowered Committee (EC)

10.1. The EC shall meet as often as necessary to ensure timely consideration of applications and disbursement claims and conduct periodic review of the Scheme.

10.2. The EC will consider applications, as recommended by the PMA, for approval under the Scheme. The EC may seek such additional information, as considered necessary for approval.

10.3. Make any additions to the indicative list of items in any TS.

10.4. The EC shall review the annual incentive bucket size and ensure that the bucketed

amount is in sync with the expected incentive outflow under the scheme. The EC will conduct a periodic review of selected applicant with respect to their investments, employment generation and production under the Scheme.

10.5. Grant extension for project commissioning

10.6. The EC will consider claims for disbursement, as examined and recommended by the PMA, for disbursement of incentive.

10.7. The EC may carry out any amendments in the Scheme and these guidelines.

10.8. In case of a Force Majeure event, the EC may amend, modify or withdraw any Clause under the Scheme.

10.9. The EC may hold stakeholder consultation as and when deemed necessary during the tenure of the Scheme.

10.10. Applicants to be able to change the approved products mid-course, from among the indicative list of devices in the Target Segments, with the approval of the EC

11. Approval under the Scheme

11.1. The PMA will process the applications and make appropriate recommendations to the EC for approvals under the Scheme.

11.2. The EC will consider applications, as recommended by PMA, for approval under the Scheme.

11.3. All the applications will be finalized within 60 days from the date on which the received applications are harvested from the scheme portal.

11.4. After receiving approval from the EC, the PMA/ DoP will issue a letter to the selected applicant within 5 working days, communicating approval under the Scheme. The approval letter shall clearly state the following:

i. Name of Applicant
ii. Target Segment
iii. Eligible Product(s)
iv. Proposed Committed Investment
v. Base Year and Base Sales of each of the approved products (if applicable)
vi. Scheduled date of commencement of production
vii. Sales CAGR to be achieved
viii. Current as well as projected value chain integration status
ix. Any other condition imposed by the PEC/EC/DoP.

11.5. The selected applicant shall submit, within three weeks of date of issuance of approval letter, a bank guarantee along with undertaking in the format as per **Annexure 9** of an amount equivalent to Rs. 30 lakh per application, in favor of DoP, valid for 365 days to be rolled over till at least 50% of the committed investment is grounded.

11.6. The bank guarantee will be invoked if applicant fails to ground atleast 50% committed investment, even after 3 years from the date of approval of the application.

11.7. The bank guarantee will be released upon achievement of at least 50% committed investment, within a period of 3 years from the date of approval of the PLI application.

11.8. The aforesaid approval letter shall not be construed as a guarantee for disbursement of incentive as the same will be dependent upon verification of eligibility after submission of disbursal claim(s) and other criteria defined in these guidelines.

11.9. If a selected applicant is found to be ineligible at any stage, or if it has not complied with notifications, orders, guidelines etc. of the Scheme, or declines the offer of the approval under the Scheme at any stage, for any reason, the envisaged incentive claim of such selected applicant shall be forfeited and the bank guarantee shall be invoked (if not released in line with Clause 11.7), and the offer letter issued shall stand cancelled. In such case, the offer shall be extended to the waitlisted applicant for the period remaining.

12. Post Approval

12.1. PMA shall monitor the progress of the project made by the selected applicant as and when required with respect to investment committed.

12.2. PMA shall monitor the rollover of the bank guarantees and shall take timely action for releasing / invoking the bank guarantees as per these guidelines.

13. Calculation of Incentive

13.1. The incentive applicable for a selected applicant shall be computed as follows:

Net Incremental Sales of Eligible Product(s) x Rate of Incentive

Where

a) Eligible Product(s) means the products as stated in the approval letter.

b) Sales of eligible product means the sales of the eligible product manufactured by the applicant in the manufacturing facility approved and set-up under these guidelines.

c) Incremental Sales shall be Net Sales Turnover of Eligible Product(s) for the period of which claim for disbursement of incentive pertains minus the Base Sales.

d) In case of return of Sales of Eligible Product(s), the Gross Sales Turnover shall be reduced by the amount corresponding to such return of sales. If the corresponding sales have been considered for claim processing for the earlier period, the sales return shall be adjusted with Gross Sales Turnover

for the period in which the actual sales return takes place.

e) Rate of incentive: As per **Annexure 3** of these guidelines.

f) In case of in-house consumption of eligible product by the selected applicant, the net sales of eligible product shall mean the actual cost of production of the said product, as certified by a Cost Accountant, who is a member of the Institute of Cost Accountants of India.

g) In case of in-house consumption of the eligible product, actual cost of production, as certified by a Cost Accountant, shall be considered as net sales of the approved eligible product.

Note: Eligible sales shall exclude GST and other indirect taxes, discounts, rebates, credit notes, sales returns, trading/resale value, installation, maintenance, warranty, financing and non-manufactured services/content. In case of sales generated form bundled systems (product and services like AMC, transport, etc. sold together), the eligible product sales value shall be allocated on a consistently applied, excluding installation, maintenance, warranty, financing and non-manufactured services/content.

14. Disbursement of Incentives

14.1. Applications shall be considered for consideration of approval by the EC, subject to the eligibility of applicants and suitability of their proposals. Disbursement shall be subject to the annual incentive outlay and availability of funds under the Scheme.

14.2. The remaining incentive outlay of approximately ₹2,700 crore (out of the total approved outlay of ₹3,420 crore) shall be allocated across seven annual incentive buckets for the 2nd to the 8th Scheme years as follows: ₹150 crore, ₹250 crore, ₹500 crore, ₹600 crore, ₹700 crore, ₹300 crore and ₹200 crore, respectively. Each annual bucket shall be divided into two equal half-yearly sub-buckets. Any change in the annual allocation shall require EC approval, within the overall approved outlay.

14.3. Allocation and disbursement of incentives shall be governed by the following:

(i) The two half-yearly sub-buckets shall correspond to Q1–Q2 and Q3–Q4 of each financial year.

(ii) Unutilized funds from a half-yearly sub-bucket shall be carried forward to the subsequent half-year.

(iii) Where eligible claims exceed the funds available, incentives shall be disbursed on a pro-rata basis, in proportion to the admissible claims. The unpaid portion shall be treated as an outstanding shortfall.

(iv) After meeting eligible claims of the current half-year, any surplus shall first be used to meet outstanding shortfalls of the previous half-year on a pro-rata basis. Any remaining balance shall be carried forward.

(v) Unutilized funds and outstanding shortfalls at the end of a financial year shall be carried forward to subsequent Scheme years, subject to the overall approved outlay.

The PMA shall maintain records of allocations, disbursements, shortfalls and carry-forwards.

14.4. Applicants shall submit incentive claims to the PMA in the prescribed format given in Annexure 10, along with supporting documents. The PMA may seek additional information or documents required for verification.

14.5. An applicant may submit a maximum of two claims for each financial year:
(i) First claim covering eligible sales during Q1 and Q2, within three months from the end of Q2.
(ii) Second claim covering eligible sales during Q3 and Q4, within three months from the end of the financial year.

The two claims shall cover distinct periods, and no sales shall be claimed more than once. A claim, once submitted, shall not be revised or supplemented through another claim. However, a rectified claim for any disallowed amount may be submitted within 30 days of communication of the disallowance.

14.6. The PMA shall verify each claim and determine the admissible incentive. Where audited financial statements supporting the claim are furnished and verified, 100% of the approved admissible incentive may be released. Where the claim is supported by management-certified statements and other prescribed documents(except audited financial statement), 80% of the approved admissible incentive may be released, and the remaining 20% shall be retained for subsequent verification under Para 14.7. The 80:20 split shall apply to the admissible amount actually allocated after pro-rata distribution, wherever applicable. All disbursements shall be subject to fund availability and pro-rata allocation under Para 14.3.

14.7. Applicants who receive 80% incentive under Para 14.6 shall submit annual audited financial statements and reconciled statements of sales and eligible investments, along with relevant supporting records, by 15 October following the end of the relevant financial year. The PMA shall verify these documents and release the retained 20% against both claims of the preceding financial year within 30 days of receipt of complete documents. In case of non-submission of the documents by the prescribed date, release of the retained amount shall remain withheld until submission and verification. Any excess payment identified shall first be adjusted against the retained amount, and any remaining excess shall be recovered in accordance with these Guidelines.

Applicants who receive 100% incentive on the basis of audited financial statements shall not be required to make a separate annual submission under this Para. However, the DoP may seek annual audited or certified statements and other relevant records from such applicants, whenever required, for verification or audit purposes.

14.8. Incentive shall not be payable separately on components manufactured by an applicant

and consumed internally in the manufacture of finished medical devices. Incentive on such components shall be admissible only on sales to third parties.

14.9. Applicants seeking incentives under more than one Target Segment shall submit separate applications for each Target Segment.

14.10. There shall be no annual or overall ceiling on the incentive amount claimable by an applicant or its group companies, subject to eligibility, the annual incentive outlay and half-yearly sub-buckets.

14.11. The PMA shall examine claims, verify the eligibility of applicants and admissibility of incentives, and submit its recommendations to the EC within 45 days of receipt of complete claims. It shall also monitor and verify the physical progress of approved projects in accordance with the approval conditions. For this purpose, the PMA may verify supporting documents, sales realisation, bank statements, investment records and auditor certificates, and seek any additional information required. The PMA shall report material deviations or non-compliance to the DoP. Matters requiring clarification shall be referred to the DoP, whose decision shall be final.

14.12. The EC may approve, modify or reject claims based on the PMA's recommendations. Reasons for modification or rejection shall be recorded in writing.

14.13. The DoP shall disburse approved incentives after completion of prescribed formalities, through PFMS or any other approved mechanism, directly into the applicant's bank account.

14.14. Any excess incentive disbursed shall be refunded by the applicant along with interest at the three-year SBI MCLR prevailing on the date of disbursement, compounded annually from the date of disbursement until refund.

14.15. Where an applicant has obtained eligibility or incentive through misrepresentation or falsification of information, the DoP may require refund of the incentive along with interest at the rate specified in Para 14.14, after giving the applicant an opportunity of being heard.

14.16. The DoP shall make necessary budgetary provisions for disbursement of incentives. The PMA shall submit half-yearly fund requirements and quarterly progress reports to the DoP, including details of claims received, examined, recommended, approved and disbursed; outstanding claims and shortfalls; unutilized funds carried forward; physical progress of approved projects; and reasons for rejection or delay.

15. Review

15.1. Periodic reviews will be undertaken by the EC with respect to progress and performance of the Scheme.

15.2. All approved applicants shall be required to furnish self-certified Quarterly Review Reports (QRRs) within 30 days from the end of each quarter in the format provided in **Annexure 8** of these guidelines.

16. Residual

16.1. An applicant shall intimate the PMA of any change in the shareholding pattern during the tenure of the Scheme, after updation with the Registrar of Companies (RoC).

16.2. Any change in the shareholding pattern of an applicant leading to a successor-in-interest during the tenure of the Scheme, shall be intimated by PMA for approval of the EC to consider for disbursal of incentives.

16.3. In case of a successor-in-interest, all Investment undertaken by the applicant to whom approval was accorded under the Scheme, would be considered for determining eligibility, subject to approval and compliance with any other condition stipulated by the EC, as may be deemed appropriate.

16.4. All transactions by the selected applicant with Related Parties will be subject to provisions of relevant statutes and Accounting Standards – 18 and corresponding Indian-AS, as amended from time to time. In case of any proceedings under any Act leading to adjustment of pricing in the transactions between related parties, effect shall be given in calculation of incentive and / or eligible committed investment.

16.5. To obviate any malpractices in the financial matters where disbursements are made to industry by the Government, it has been decided to provide a deterrent against corrupt practices for promotion of transparency and equity. Therefore, keeping in view the sensitivities involved in the process and taking cue from the instructions of the Central Vigilance Commission regarding adoption of an Integrity Pact in the matter of procurement, it has been decided to obtain undertaking(s) from applicants under the Scheme.

16.6. Two formats of undertakings are enclosed as **Format-A** and **Format-B** in **Annexure 11.** These undertakings are to be furnished by applicants, duly signed by CEO / MD / Director and depicting the designation along with authorization to do so.

16.7. The undertaking in **Format-A** shall be provided by all applicants whose applications or claims are under consideration for approval or disbursement of incentives. The applications or claims of those applicants who do not submit the undertaking shall not be processed and considered. The undertaking in **Format-B** for confirming the compliance of integrity will be provided by applicants after the submission of claims for disbursement of incentive and in any case before release of funds. The release of incentives shall be withheld until the above-mentioned undertaking is provided.

17. These guidelines supersede the earlier guidelines of the scheme issued on this subject vide no 31026/19/2020-MD dated 27.07.2020, 29.10.2020 and 18.08.2022, 25.02.2023, 19.12.2023,12.03.2024.

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New Delhi,
Date:

Annexure 1 Target

Segments under the Scheme and indicative list of products

Target Segment No.	Description of Medical Devices covered under Target Segment
Target Segment (TS) 1	Consumables & Disposables & implants Medical Devices
Target Segment (TS) 2	Critical Components used for manufacturing of medical devices
Target Segment (TS) 3	High-end medical devices which are in nascent state of domestic manufacturing
Target Segment (TS) 4	High-end medical devices where only assembly operations exist in the country

ANNEXURE 1A

Indicative list of eligible items under each target segment is enclosed. For applications concerning products not specifically mentioned in the indicative list, the EC shall be empowered to approve such applications.

Table 1 Indicative list of items in TS1-Indicative list of Consumables & Disposables & implants Medical Devices

S. No.	Name of Medical Device
1	Disposable hypodermic syringes
2	Auto-disable syringes
3	Insulin syringes
4	Safety syringes
5	Hypodermic needles
6	Pen needles
7	Dental needles
8	IV cannulas
9	Safety IV cannulas
10	Scalp-vein sets
11	IV infusion sets
12	Blood transfusion sets
13	3-way stopcocks
14	Needle-free connectors
15	Extension tubes
16	Flow regulators
17	Blood collection sets
18	Blood collection needles
19	Blood collection tubes
20	Central venous catheters (CVC)
21	PICC lines
22	Central venous access guidewires
23	Introducer sheaths
24	Blood bags
25	Blood tubing sets
26	Blood-bank filters
27	Plasma collection sets
28	Haemodialysis blood tubing sets
29	AV fistula needles
30	Haemodialysis catheters
31	Dialysers / haemodialyzers
32	Transducer protectors
33	Dialysis concentrate containers

34	Peritoneal dialysis transfer sets
35	Dialysis drainage sets
36	Foley urinary catheters
37	Nelaton catheters
38	Ryle's tubes
39	Urine drainage bags
40	Urine measuring bags
41	Ureteral catheters
42	DJ stents
43	Ureteric stents
44	Suprapubic catheters
45	Urological drainage sets
46	Irrigation sets
47	Urodynamic catheter sets
48	Endotracheal tubes
49	Nasal endotracheal tubes
50	Tracheostomy tubes
51	Oxygen masks
52	Nasal oxygen cannula
53	Nebulizer kits
54	Ventilator circuits
55	Breathing circuits
56	HME filters
57	Bacterial/viral filters
58	Anaesthesia masks
59	Guedel airways
60	Yankauer suction sets
61	Suction catheters
62	Closed suction systems
63	Ambu bags / manual resuscitators
64	CPAP/BiPAP masks
65	Oxygen tubing
66	Surgical gloves
67	Examination gloves
68	Surgical masks
69	Surgical caps
70	Surgical gowns
71	Disposable drapes
72	Surgical blades
73	Disposable scalpels
74	Diathermy electrodes
75	Suction tubing
76	Surgical suction sets

77	Surgical drainage sets
78	Specimen collection containers
79	Surgical marking pens
80	Sterile gauze
81	Gauze swabs
82	Absorbent cotton
83	Bandages
84	Elastic bandages
85	Adhesive bandages
86	Adhesive tapes
87	Surgical dressings
88	Angiographic catheters
89	Diagnostic cardiac catheters
90	Guiding catheters
91	Arterial cannulas
92	Venous cannulas
93	Manifolds
94	High-pressure tubing
95	Pressure-monitoring tubing
96	Angiography extension lines
97	PTCA balloon catheters
98	Peripheral stents
99	Guidewires
100	Inflation devices
101	Feeding tubes
102	Gastrostomy tubes
103	PEG tubes
104	Suction tubes
105	Endoscopic irrigation tubing
106	Endoscopic biopsy forceps
107	Polypectomy snares
108	Injection needles
109	Endoscopic clips
110	Dilatation balloons
111	Biliary drainage catheters
112	Nasobiliary drainage catheters
113	Umbilical cord clamps
114	Umbilical catheters
115	Neonatal oxygen cannulas
116	Neonatal masks
117	Neonatal breathing circuits
118	Neonatal endotracheal tubes
119	Neonatal suction catheters

120	Neonatal IV sets
121	Neonatal scalp-vein sets
122	Neonatal blood collection systems
123	Bone cement
124	Cement mixing sets
125	Cement delivery systems
126	Disposable arthroscopy tubing
127	Arthroscopy fluid-management tubing
128	Arthroscopy shaver blades
129	Ophthalmic cannulas
130	Phaco tubing sets
131	Ophthalmic surgical instruments
132	Intraocular lenses
133	Ophthalmic injection devices
134	ICSI pipettes
135	Embryo-transfer catheters
136	Oocyte aspiration needles
137	Follicular aspiration sets
138	Semen-analysis chambers
139	Embryo culture dishes
140	Embryo vitrification devices
141	Vacutainer tubes
142	Blood collection tubes
143	Microcentrifuge tubes
144	PCR tubes
145	PCR plates
146	Pipette tips
147	Antimicrobial-coated central venous catheter
148	Closed/needle-free IV access system
149	Antimicrobial-coated haemodialysis catheter
150	Hydrophilic-coated advanced vascular catheter
151	Nitinol/high-performance steerable guidewire
152	Drug-coated balloon
153	Bioresorbable vascular scaffold
154	Intravascular lithotripsy catheter
155	IVUS catheter
156	Atherectomy catheter
157	Large-bore thrombectomy catheter
158	Flow-diverter stent
159	Stent-retriever system
160	Advanced aspiration thrombectomy catheter
161	Advanced braided microcatheter
162	Embolic protection device

163	TAVR/TAVI delivery system
164	TEER delivery system
165	3D mapping/ablation catheter
166	Cryoablation catheter
167	Advanced antimicrobial wound dressing
168	Automatic biopsy & Co-Axial Needles
169	Spinal Needles
170	Epidural Kits
171	De-Compression Needles
172	Arterial Blood Gas Syringes
173	Securement Devices
174	Peripheral Nerve Block Needles
175	Suture Needles
176	Standard & Safety Huber Needles
177	Vial Access Spikes
178	Arterial Catheters
179	Trocars
180	Prefilled Syringes
181	Swab Caps
182	High Pressure Vacuum Bottles
183	Enteral Feeding Syringes & Accessories
184	Disposable dental examination kits
185	Disposable dental mirrors
186	Disposable dental probes/explorers
187	Disposable dental forceps/dressing forceps
188	Disposable dental excavators
189	Disposable dental spatulas
190	Disposable dental impression trays
191	Dental impression materials
192	Dental polishing cups & brushes
193	Dental burs – diamond/carbide
194	Endodontic files and reamers
195	Gutta-percha points
196	Endodontic paper points
197	Dental matrix bands
198	Dental wedges
199	Rubber dam sheets and accessories
200	Saliva ejectors / disposable suction tips
201	Disposable air-water syringe tips
202	Dental barrier sleeves/covers
203	Disposable dental applicators / microbrushes
204	Dental finishing & polishing strips/discs
205	Disposable periodontal probes/curettes

206	Disposable dental surgical curettes
207	Disposable dental elevators/extraction instruments
208	Dental haemostatic sponges/wound dressings
209	IVD reagents and reagent kits
210	Calibrators and controls for IVD
211	Rapid diagnostic test consumables/components
212	Viral transport media
213	ELISA reagent kits
214	FIA reagent kits
215	CLIA reagent kits
216	Sutures, staplers & closure devices
217	Surgical mesh
218	Disposable laparoscopic instruments
219	Molecular diagnostic/PCR reagent kits
220	Temporary pacing leads/electrodes
221	ECG/EMG/EEG electrodes
222	Pressure-monitoring disposable transducers
223	Cardioplegia sets
224	Bone graft substitutes
225	Trauma Implants/Knee/Hip/Spinal implants
226	Disposable external-fixation components
227	Dental liners/bases
228	ECMO-type disposable circuits
229	biopsy instruments/accessories
230	Surgical Instruments
231	Dental implants
232	Maxillofacial implants
233	Oxygenator cartridges
234	CSF drainage systems
235	Neurovascular coils
236	Cranial fixation plates/screws
237	Contrast Media
238	Cold Kits
239	Ventricular shunt systems
240	IOL injectors
241	IOL cartridges
242	Corneal implants
243	Tissue expanders

Table 2 Indicative list of items in TS2- Critical Components used for manufacturing of medical devices

S. No.	Critical Component	End Medical Device / Application
1.	X-ray tube	X-ray, CT, C-arm
2.	X-ray tube insert	X-ray, CT
3.	X-ray rotating anode	X-ray, CT
4.	X-ray cathode assembly	X-ray, CT
5.	X-ray high-voltage generator	X-ray, CT
6.	X-ray high-voltage transformer	X-ray, CT
7.	X-ray collimator	X-ray, fluoroscopy
8.	X-ray flat-panel detector	Digital X-ray, C-arm
9.	X-ray detector scintillator	Digital X-ray, CT
10.	X-ray detector photodiode array	Digital X-ray
11.	Anti-scatter grid	X-ray systems
12.	Image intensifier	Fluoroscopy/C-arm
13.	CT detector module	CT scanner
14.	CT detector crystal array	CT scanner
15.	CT data acquisition system	CT scanner
16.	CT detector ASIC	CT scanner
17.	CT gantry slip-ring assembly	CT scanner
18.	CT X-ray tube assembly	CT scanner
19.	CT DAS electronics	CT scanner
20.	CT reconstruction processor	CT scanner
21.	Mammography X-ray tube	Mammography
22.	Mammography detector	Mammography
23.	Mammography compression mechanism	Mammography
24.	Dental X-ray tube	Dental imaging
25.	Dental digital detector	Dental imaging
26.	MRI superconducting magnet	MRI
27.	MRI superconducting wire	MRI
28.	MRI cryocooler/cold head	MRI

S. No.	Critical Component	End Medical Device / Application
29.	MRI cryogenic system	MRI
30.	MRI gradient coil	MRI
31.	MRI gradient amplifier	MRI
32.	MRI RF coil	MRI
33.	MRI RF amplifier	MRI
34.	MRI RF power transistor/module	MRI
35.	MRI shim system	MRI
36.	MRI patient-positioning actuator	MRI
37.	MRI helium recovery system	MRI
38.	Ultrasound transducer/probe module	Ultrasound
39.	Piezoelectric crystal array	Ultrasound
40.	CMUT transducer array	Ultrasound
41.	Ultrasound beamformer	Ultrasound
42.	Ultrasound front-end ASIC	Ultrasound
43.	Ultrasound pulser/receiver module	Ultrasound
44.	Ultrasound T/R switch	Ultrasound
45.	Ultrasound probe cable assembly	Ultrasound
46.	Ultrasound probe connector	Ultrasound
47.	Ultrasound acoustic lens	Ultrasound
48.	Ultrasound matching layer	Ultrasound
49.	PET detector module	PET/PET-CT
50.	PET scintillation crystal	PET/PET-CT
51.	SiPM detector	PET/diagnostic imaging
52.	Avalanche photodiode	PET/optical diagnostics
53.	Photomultiplier tube	PET/gamma camera/IVD
54.	Gamma-camera detector	SPECT
55.	Radiation detector module	Nuclear medicine
56.	Radiation scintillator	Nuclear medicine
57.	Radiation collimator	Nuclear medicine

S. No.	Critical Component	End Medical Device / Application
58.	Radiation shielding module	Imaging/radiotherapy
59.	Ionisation chamber	Radiotherapy
60.	Dosimetry detector	Radiotherapy
61.	LINAC klystron	Radiotherapy
62.	LINAC magnetron	Radiotherapy
63.	LINAC RF waveguide	Radiotherapy
64.	LINAC electron gun	Radiotherapy
65.	LINAC accelerating structure	Radiotherapy
66.	Multileaf collimator module	Radiotherapy
67.	MLC motor/actuator	Radiotherapy
68.	Radiotherapy beam-monitoring chamber	Radiotherapy
69.	EPID detector	Radiotherapy
70.	Brachytherapy source-drive mechanism	Brachytherapy
71.	Brachytherapy source capsule	Brachytherapy
72.	Laser diode module	Surgical/diagnostic laser
73.	Medical laser source	Laser therapy
74.	Laser optical delivery module	Laser therapy
75.	Medical optical fibre	Endoscopy/laser
76.	HIFU (High-Intensity Focused Ultrasound) transducer	Cancer therapy
77.	HIFU focusing assembly	Cancer therapy
78.	RF ablation generator	Ablation/oncology
79.	RF power amplifier	Ablation
80.	Microwave ablation generator	Oncology
81.	Microwave power amplifier	Oncology
82.	Microwave antenna assembly	Oncology
83.	Cryoablation probe functional assembly	Oncology
84.	Electrosurgical RF generator	Electrosurgery
85.	Electrosurgical power module	Electrosurgery
86.	Ultrasonic surgical generator	Surgery

S. No.	Critical Component	End Medical Device / Application
87.	Ultrasonic surgical transducer	Surgery
88.	Defibrillator HV capacitor	Defibrillator
89.	Defibrillator HV transformer	Defibrillator
90.	Defibrillator charging module	Defibrillator
91.	Defibrillator energy-delivery module	Defibrillator
92.	ECG analogue front-end	Patient monitoring
93.	EEG amplifier module	Neurological monitoring
94.	EMG amplifier module	Neurological monitoring
95.	SpO_2 sensor module	Patient monitors
96.	NIBP (Non-Invasive Blood Pressure) pressure transducer	Patient monitors
97.	NIBP pump module	Patient monitors
98.	NIBP valve module	Patient monitors
99.	Airway pressure sensor	Ventilator
100.	Differential-pressure sensor	Ventilator
101.	Mass-flow sensor	Respiratory
102.	CO_2 sensor module	Capnography
103.	Oxygen sensor	Ventilator/anesthesia
104.	Respiratory flow sensor	Ventilator
105.	Ventilator turbine	Ventilator
106.	Medical blower	Ventilator/CPAP
107.	Medical diaphragm pump	Ventilator/suction
108.	Proportional solenoid valve	Ventilator/anesthesia
109.	Pneumatic control valve	Respiratory
110.	Oxygen proportional valve	Respiratory
111.	Medical gas mixer	Ventilator/anesthesia
112.	Anesthesia vaporizer mechanism	Anesthesia
113.	Anesthesia gas analyser module	Anesthesia
114.	Oxygen concentrator compressor	Oxygen concentrator
115.	Oxygen concentrator PSA valve	Oxygen concentrator

S. No.	Critical Component	End Medical Device / Application
116.	CPAP/BiPAP blower	CPAP/BiPAP
117.	CPAP pressure sensor	CPAP/BiPAP
118.	Nebulizer piezoelectric actuator	Nebulizer
119.	Infusion-pump drive mechanism	Infusion pump
120.	Infusion-pump stepper motor	Infusion pump
121.	Infusion-pump pressure sensor	Infusion pump
122.	Air-in-line sensor	Infusion pump
123.	Occlusion-pressure sensor	Infusion pump
124.	Syringe-pump drive assembly	Syringe pump
125.	Autoinjector drive mechanism	Drug delivery
126.	Insulin-pen dosing mechanism	Drug delivery
127.	Dialysis blood-pump module	Dialysis
128.	Dialysis ultrafiltration pump	Dialysis
129.	Dialysis balancing chamber	Dialysis
130.	Dialysis conductivity sensor	Dialysis
131.	Dialysis pressure transducer	Dialysis
132.	Dialysis air detector	Dialysis
133.	Dialysis blood-leak detector	Dialysis
134.	ECMO centrifugal pump module	ECMO
135.	ECMO membrane oxygenator module	ECMO
136.	ECMO heat exchanger	ECMO
137.	Cardiopulmonary-bypass oxygenator module	Heart-lung machine
138.	Apheresis centrifuge module	Apheresis
139.	Apheresis pump module	Apheresis
140.	Implant-grade titanium alloy	Orthopaedic implants
141.	Cobalt-chromium alloy	Implants
142.	Nitinol alloy	Stents/interventional
143.	Implant-grade PEEK	Orthopaedic/spinal
144.	UHMWPE implant-grade polymer	Joint implants

S. No.	Critical Component	End Medical Device / Application
145.	Implant-grade alumina/zirconia	Implants/dental
146.	Porous titanium	Orthopaedic implants
147.	Porous tantalum	Orthopaedic implants
148.	Medical-grade silicone	Implants/tubing
149.	Medical-grade TPU	Tubing/catheters
150.	Medical-grade PVC compound	Tubing/sets
151.	Medical-grade PTFE	Catheter components
152.	Medical-grade polyimide	Catheter components
153.	Catheter-grade engineering polymer	Interventional devices
154.	Radiopaque marker material	Catheter systems
155.	Hydrophilic coating	Catheter systems
156.	Antithrombogenic coating	Blood-contact devices
157.	Drug-compatible polymer	Drug delivery
158.	Cytotoxic-drug-compatible polymer	Oncology infusion
159.	Cytotoxic-drug-compatible tubing	Oncology infusion
160.	Dialysis hollow-fibre membrane	Dialysis
161.	Dialysis membrane material	Dialysis
162.	Blood-filtration membrane	Blood purification
163.	Plasma-separation membrane	Apheresis
164.	Leukocyte-reduction filter media	Blood processing
165.	Molecular sieve	Oxygen concentrator
166.	Medical-grade activated carbon	Blood/gas purification
167.	Immunoadsorption resin	Therapeutic apheresis
168.	Protein A/G affinity resin	Immunoadsorption
169.	IVD magnetic beads	Immunoassay/molecular diagnostics
170.	Functionalised magnetic nanoparticles	IVD
171.	Nitrocellulose membrane	Rapid diagnostics
172.	IVD monoclonal antibodies	IVD
173.	IVD recombinant antigens	IVD

S. No.	Critical Component	End Medical Device / Application
174.	IVD enzymes	IVD
175.	IVD primers	Molecular diagnostics
176.	IVD probes	Molecular diagnostics
177.	PCR master mix	Molecular diagnostics
178.	IVD calibrators	IVD analysers
179.	IVD multi-level calibrators	IVD analysers
180.	IVD quality-control materials	IVD analysers
181.	Molecular positive controls	Molecular diagnostics
182.	Molecular negative controls	Molecular diagnostics
183.	IVD reference materials	IVD
184.	IVD optical detection module	IVD analysers
185.	IVD chemiluminescence detector	Immunoassay analyser
186.	IVD fluorescence detector	IVD analyser
187.	IVD spectrophotometer module	Clinical chemistry
188.	IVD photodiode array	IVD analyser
189.	IVD PCR optical module	Molecular diagnostics
190.	IVD PCR thermal module	Molecular diagnostics
191.	IVD precision pipetting module	Automated analyser
192.	IVD reagent dispensing pump	Automated analyser
193.	IVD reagent valve manifold	Automated analyser
194.	IVD sample-probe assembly	Automated analyser
195.	IVD reaction-cuvette system	Automated analyser
196.	IVD electrochemical sensor/ISE	Electrolyte/blood-gas analyser
197.	IVD blood-gas sensor module	Blood-gas analyser
198.	IVD flow-cytometry detector/laser module	Flow cytometer
199.	Dental Motors & Hand Pieces	Dental Root canal instruments
200.	CT large bearing and slip rings	CT & X-ray machines

Note 1: Above is an indicative list. Applicant may apply if their proposed component meets below

criteria:

Note:2: Where an applicant is already manufacturing the component, only the sales generated from the proposed additional manufacturing capacity over and above the baseline sales shall be considered for determining the incentive.

Table 3 Indicative list of items in TS 3- high-end medical devices which are in nascent state of domestic manufacturing

S.N.	Product name
1.	Continuous Glucose Monitoring System
2.	3 Tesla MRI Scanner and components
3.	Ultrasound probes
4.	High-end ICU beds
5.	High Throughput Fully Automatic IVD analyzers
6.	X-ray and CT scanner critical components
7.	CT scanner – 256 slice
8.	Dual-source CT – 256/384+ slice
9.	Photon-counting / spectral CT
10.	Mobile high-end CT scanner
11.	Intraoperative CT
12.	Intraoperative MRI
13.	Digital PET-CT
14.	Digital PET-MRI
15.	Solid-state / CZT cardiac SPECT
16.	High-end SPECT/CT
17.	Advanced gamma camera
18.	Mobile/intraoperative CBCT
19.	High-end biplane DSA
20.	O-arm / 2D-3D intraoperative imaging
21.	Advanced mobile flat-panel C-arm
22.	Hybrid OR imaging system
23.	Advanced high-energy LINAC
24.	Mobile LINAC

S.N.	Product name
25.	Intraoperative radiotherapy mobile LINAC
26.	MRI-guided LINAC
27.	HDR brachytherapy system – advanced
28.	Image-guided brachytherapy platform
29.	Proton therapy system
30.	Pencil-beam scanning proton therapy
31.	Carbon-ion therapy system
32.	Particle therapy gantry
33.	Leadless pacemaker
34.	MRI-compatible advanced pacemaker
35.	Implantable cardioverter defibrillator (ICD)
36.	Intra-aortic balloon pump (IABP)
37.	Percutaneous ventricular assist device
38.	Complete ECMO system
39.	3D electro-anatomical cardiac mapping system
40.	Intracardiac echocardiography (ICE) system
41.	Intravascular ultrasound (IVUS)
42.	FFR/iFR system
43.	Coronary atherectomy system
44.	Intravascular lithotripsy system
45.	TAVR/TAVI with self-expanding valve
46.	Transcatheter mitral valve repair – TEER
47.	Left atrial appendage closure device
48.	Percutaneous large-vessel thrombectomy system
49.	Pharmacomechanical thrombectomy system
50.	Embolic protection system
51.	Flow-diverter stent
52.	Intrasaccular aneurysm device
53.	Advanced detachable neurovascular coils
54.	Stent retriever for acute ischemic stroke

S.N.	Product name
55.	Advanced braided microcatheter
56.	Neurovascular steerable guidewire
57.	Intracranial self-expanding stent
58.	Carotid stent + embolic protection
59.	Advanced spinal/cranial navigation system
60.	3D exoscopy system for neurosurgery
61.	3D/4K neuroendoscopy system
62.	Stereo-EEG / SEEG system
63.	Laser interstitial thermal therapy (LiTT)
64.	Advanced deep-brain stimulation system
65.	3D/4K flexible endoscopy system
66.	3D/4K laparoscopic imaging platform
67.	Endoscopic ultrasound (EUS) system
68.	Endobronchial ultrasound (EBUS)
69.	Capsule endoscopy system
70.	Balloon-assisted enteroscopy
71.	Cholangioscopy system
72.	Third-space endoscopy platform
73.	Endoscopic suturing/plication system
74.	Tissue-differentiation endoscopy
75.	Advanced 4-direction tip-control bronchoscope
76.	Powered endoscopic resection system
77.	Robotic surgery system
78.	Surgical navigating system
79.	O-arm + navigation integrated platform
80.	High-frequency oscillatory neonatal ventilator
81.	Advanced neonatal ventilator with automated control
82.	Continuous renal replacement therapy (CRRT) machine
83.	Automated peritoneal dialysis machine
84.	Advanced haemodynamic monitoring platform

S.N.	Product name
85.	Bioreactance cardiac-output/fluid-management system
86.	Advanced perfusion system
87.	Cell-saver system
88.	Advanced blood/gas/metabolic monitoring system
89.	High-throughput NGS sequencer
90.	Long-read sequencing platform
91.	Single-cell sequencing/analysis platform
92.	Digital PCR / droplet digital PCR
93.	FIA Analysers
94.	Automated high-throughput molecular diagnostic platform
95.	Multiplex PCR platform
96.	Film-array multiplex molecular diagnostic system
97.	Automated capillary DNA sequencer
98.	High-end flow cytometer
99.	High-speed cell sorter
100.	High-throughput single-cell analyser ≥10,000 cells per sample/run
101.	Digital pathology whole-slide scanner
102.	Automated high-throughput liquid-based cytology system
103.	Fully automated immunoassay analyser – ECLIA/CLEIA/ELFA –Min sample capacity 100 samples & ≥200 tests/hour
104.	Integrated clinical chemistry + immunoassay system
105.	High-throughput 5/6-part haematology analyser ≥100 samples/hour
106.	Automated microbial ID + AST system
107.	Automated blood-culture monitoring system
108.	LC-MS/MS clinical diagnostic platform
109.	ICP-MS clinical/trace-element platform
110.	Bio-layer interferometry platform
111.	Femtosecond laser for LASIK/SMILE
112.	Femtosecond laser for cataract surgery

S.N.	Product name
113.	OCT with advanced angiography (OCTA)
114.	OCT catheter system
115.	Swept-source OCT
116.	Ultra-widefield retinal imaging system
117.	AI-enabled digital fundus camera
118.	Advanced retinal laser system
119.	Femto-phaco platform
120.	Continuous vision IOL
121.	Time-lapse embryo imaging system
122.	Embryo-selection AI imaging platform
123.	Laser embryo biopsy system
124.	Piezo micromanipulator for ICSI
125.	Automated IVF workstation
126.	Automated oocyte aspiration system
127.	Electronic witnessing system for IVF
128.	Advanced embryo culture incubator with automatic gas control
129.	Automated semen analysis / CASA platform
130.	Embryo/gamete cryostorage system
131.	AI-based embryo assessment system
132.	Patient-specific 3D-printed spinal implants
133.	3D-printed porous titanium implants
134.	K-wireless minimally invasive spinal fixation
135.	Expandable corpectomy device
136.	High-viscosity vertebroplasty system
137.	Quad-thread cement-augmented fenestrated pedicle screw
138.	Robotic/AI-assisted joint-replacement instrumentation
139.	Thulium fibre laser – advanced surgical platform
140.	GreenLight laser prostate system
141.	CUSA / ultrasonic surgical aspirator
142.	Advanced bipolar vessel-sealing system

S.N.	Product name
143.	Advanced ultrasonic vessel-sealing system
144.	Cryoablation system
145.	Microwave tumour-ablation system – high-end
146.	Electrochemotherapy system
147.	Isolated limb perfusion system
148.	Renal denervation system
149.	Denal CBCT machine

Table 4 Indicative list of items in TS4- high-end medical devices where assembly operations are there in domestic manufacturing

S. No.	Medical device	Suggested components for deepening value addition by domestic indigenization
1	Patient Monitors	ECG/SpO_2/NIBP modules, displays, ICs, sensors
2	Multiparameter monitors	Patient-monitoring modules, sensors, displays
3	Infusion pumps	Motor/drive systems, sensors, controllers
4	Ventilators	Blowers, valves, sensors, flow/pressure modules
5	Anaesthesia workstations	Flow sensors, valves, vaporizers, modules
6	CPAP/BiPAP machines	Blower assemblies, pressure sensors, motors
7	Defibrillators	HV capacitors, IGBT/MOSFET, paddles/pads, PCB
8	Electrosurgical units	RF power modules, capacitors, transformers
9	Ultrasound systems	Transducer probes, beamformer electronics, ICs
10	X-ray systems	X-ray tube, detector, generator components
11	CT scanners	X-ray tube, detector modules, slip rings, DAS
12	MRI systems	Superconducting magnet, RF coils, gradients, electronics
13	Digital radiography systems	Flat-panel detector, scintillator, TFT array
14	C-arms	X-ray tube, detector, generator
15	Mammography systems	X-ray tube, detector, compression system
16	Blood gas analysers	Electrodes, sensors, pumps, cartridges

S. No.	Medical device	Suggested components for deepening value addition by domestic indigenization
17	Clinical chemistry analysers	Optical modules, pumps, probes, photodetectors
18	Immunoassay analysers	Optical detection modules, PMTs/photodiodes, magnets
19	Haematology analysers	Lasers, detectors, reagents, pumps
20	PCR machines	Peltier modules, optical detection module, LEDs
21	Molecular diagnostic analysers	Magnetic-bead systems, optics, heating modules
22	Blood coagulation analysers	Optical modules, sensors, pumps
23	Dialysis machines	Pumps, valves, sensors, dialysis control modules
24	Haemodialysis systems	Pumps, sensors, valves, balancing chambers
25	Patient warming systems	Heating elements, sensors, controllers
26	Surgical tables	Actuators, motors, control systems
27	Automated external defibrillators	Defibrillation module, battery, PCB
28	Laparoscopic systems	Image sensors, optical components
29	Surgical microscopes	Precision optics, image sensors
30	Ophthalmic OCT systems	OCT light source, detectors, interferometer
31	Autorefractometers	Optical modules, sensors, processors
32	Glucometers	Biosensor strips, ASICs, optical/electronic components

Annexure 2

Investment Threshold, Incentive structure and Sales Threshold

Target Segment	Investment threshold requirement
TS1, TS3 & TS4*	**Annual Turnover in last 3 years < Rs. 150 Cr:** Mandatory Rs. 50 Cr minimum investment in greenfield manufacturing facilities **Annual Turnover in last three years ≥ Rs.150 Cr:** No minimum investment is required
TS2	No minimum investment is required

**In case of TS4, no requirement of greenfield investment to be prescribed as the incentive would be paid for achieving a higher value chain integration.*

Note for TS1 to TS4: In cases where a component/device is listed under more than one Target Segment due to its potential applications across multiple segments, an applicant shall be eligible to apply for such component/device under only one Target Segment. Where a broad category of products (such as intraocular lenses, IVD analysers, reagents, IVD Kits, etc.) is listed under one Target Segment, and any specific product falling within that category is separately specified under another Target Segment, And the applicant proposing to manufacture such specific product, then the applicant shall apply under the Target Segment in which that specific product is specifically listed.

Annexure 3

Target Segment	Incentive on incremental sales	Sales Threshold	Additional requirement for Eligibility for Incentive:
TS1:	Tapering incentive of 7%, 7%, 4%, 3% and 3% from 1st to 5th performance year.	(i) No minimum sales threshold shall apply. (ii) However, sales should grow @ 10% CAGR in order to claim the incentive. CAGR shall be calculated over the base year sales viz best of the last 3 years sales, from the application year. (iii) In case of new entities or new products with no past sales, 1st year sales shall become the base sales and 10% CAGR would be required in subsequent years	Requirement for securing regulatory approval from any Stringent Regulatory Authority (SRA) country (USA, EU, Canada, Japan, Australia, Switzerland and UK) and making sales in such country/countries (any quantity)
TS2	Tapering incentive of 10 %, 10%, 10%, 8% and 6 % from 1st to 5th perfor mance year.	(i) No minimum sales threshold shall apply. (ii) Sales shall grow at a CAGR of 2%, 3%, 4% and 5% in the 2nd, 3rd, 4th and 5th performance years, respectively, over and above the1st year sales. (iii) Applicants shall be eligible for incentives at the rate of 7%, 7%, 7%, 5% and 3% in the 1st to 5th performance years, respectively, even if the committed value chain integration requirement is not met. (iv) An additional incentive of 3% shall be payable for the entire scheme period upon achievement	

		of the committed value chain integration requirement. (v) Applicants shall be permitted to make up for any shortfall in the minimum sales growth requirement for a particular performance year in the subsequent performance year, without becoming ineligible for the incentive for the year in which the shortfall occurred.	
TS3	Tapering incentive of 10%, 10%, 10%, 8% & 6% from 1st to the 5th performance year.	(i) No minimum sales threshold required and no sales CAGR required. (ii) The applicant shall be eligible to claim incentives at the rate of 7%, 7%, 7%, 5% and 3% in the 1st to 5th performance years, respectively, even if the committed value chain integration requirement has not been met. (iii)However, achievement of the committed value chain integration requirement shall be mandatory. (iv) Upon fulfilment of this requirement, an additional incentive of 3% shall be payable for the entire scheme period.	
TS4	**Incentive Rate and Base Year** (i) The incentive rate shall be 7%, 7%, 7%, 5% and 4% for the 1st to 5th performance years, respectively. (ii) For applicants under PLI 1.0 (applicants approved under PLI before Dec 2026), incremental sales shall be calculated over the base-year sales, with the base year being the	No minimum sales threshold and no CAGR in sales. No new greenfield facility is required to be set up in this TS; only deepening of value chain is essential.	(i) Committed Value chain integration, assessed on a Bill of Materials (BoM) basis, shall be mandatory for claiming incentives and shall be achieved through the localization of key functional components. (ii) The committed value chain integration requirement shall be fulfilled by the end of

	1st year in which a GST invoice was generated for a product covered under PLI 1.0. (iii) For applicants not covered under PLI 1.0, the base year shall be the year in which the highest sales were achieved during the preceding three years.		the 5th performance year to qualify for incentives for the entire five-year period, with retrospective effect. No incentive shall be payable until the prescribed value chain integration requirement is fulfilled.

Annexure 4

Application Form: Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices

1. Instructions:

1.1. The application shall be duly signed by authorized signatory of the Company.

1.2. Applicants are advised to follow the format provided in this template for submitting their applications. Applicants are requested to provide information and enclose all supporting documents as detailed.

1.3. All applications will be submitted through an online portal set up by the Project Management Agency (PMA). Entity Locker ID is mandatory to make an application through online portal.

1.4. A non-refundable application fee of Rs. 1,00,000 (One lakh only) would be payable for each application. The application fee, as mentioned in **Annexure 7** of these Guidelines, would be accepted electronically only.

1.5. Applicants may go through the Guidelines carefully before filling up the details in the application.

1.6. If any document which is required to be submitted along with the application is available on a government website, the website link where this document can be viewed may be provided. The responsibility of the correctness / veracity of contents rest with the applicant(s).

1.7. Credit History: Please provide details of presence in RBI's Defaulter and Willful Defaulter Lists, SEBI Debarred List and CIBIL Score.

1.8. Annual turnover of the Applicant and / or group companies as on the date of application.

1.9. Documents to be furnished: Certificate from Statutory Auditor

1.10. Key Personnel Details: Contact details of three senior employees of applicant. Details would include Name, Designation, Address, phone, email.

1.11. Documents to be furnished: Certificate from Company Secretary / Board of Directors

2. Proposal

2.1. Eligible Product and Target Segment

2.2. Projections (self-certified):

a) Forecasted Revenue – Total and target Segment – Manufacturing Sales Segregated into Export and Domestic (during any five performance years between FY2028-29 to FY2034-35)

b) Existing (if any) and Proposed Value Chain Integration

c) Expected Employment Generation in India (FY 2027-28 to FY 2034-35)

3. Regulatory Requirements

a) Provide information on Licenses, permits and third-party approvals necessary to execute the project.

b) Proposed process and timelines for obtaining clearances.

4. Proof of the Application Fee Submission

5. Application details	
Name of the Manufacturer	
Address of the proposed Manufacturing unit	
Address of the Registered office	
Contact person: Name, Tel no., email	
Contract Manufacturer YES / NO	
Company Registered in India YES / NO	
Global Medical Device manufacturing average turnover of applicant and / or group company for FY 2024-25, FY2025-26 & FY2026-27	
Average R&D expenses of the applicant and / or group companies for the period of FY2024-25 & FY 2025-26 as a percentage of sales revenue (which is capitalized in the books of account and / or in capital work in progress).	
Manufacturing Segment	
Brief about company and history of medical device manufacturing	
Existing Product CDSCO regulatory product approval in USA (USFDA), UK, Australia, Japan, Canada, Switzerland, European Union (CE) as on the date of application available with the applicant and / or group company	
Existing Patent / Technology transfer with the applicant and / or group company in target segment	
Financial status of the Applicant: ▪ Financial statements of last 3 years.	

- Share Capital of the Applicant.
- Any legal issues pending as reflected in the annual report / annual accounts, which will have adverse impact on Applicant's status.
- Status of assets mortgaged / hypothecated.
- Any other Liability.
- Baseline for Sales of Manufactured Medical Devices covered under Target Segment

6. Investment

Total committed cumulative Investment for the Segment during the tenure of Scheme (i.e. Gestation period)	

7. Projected investment and sales CAGR, committed value chain integration wherever applicable

Segment:

Financial Year	Projected Investment (cumulative)	Sales CAGR of Manufactured Medical Devices	Committed Value chain integration

8. Is any IP License required to carry out the Segment Manufacturing

9. Any Regulatory, Environmental or Other Clearance required:

10. List of Enclosures:

i. Copy of Incorporation Certificate
ii. Copy of Audited Balance Sheet and Profit and Loss Statement (of Last 2 Years)
iii. Copy of PAN Card
iv. Copy of GST Details
v. Copy of Articles of Association
vi. Copy of Memorandum of Association
vii. Letter authorizing the signing authority
viii. Copy of Shareholder Ownership in case of foreign companies

Annexure 5

Consent for audit of their manufacturing site / offices

(To be signed by full time Director / CEO / MD of the company duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

1. Whereas, the applicant namely *(name of manufacturer with address)* has submitted an application under Production Linked Incentive Scheme (PLI) for promoting domestic manufacturing of medical devices to Department of Pharmaceuticals (DoP), Government of India seeking incentives for the application pertaining to manufacturing…… (Eligible Product) at ..... (location(s)).

2. Now, therefore, the applicant or its agencies or its consultants engaged with the process of manufacturing of eligible products shall allow the PMA or any other authority as designated by DoP for verification of facility and documents submitted for the approval of application and disbursement of incentives under PLI Scheme.

Date *Signature*

(Name & designation with address) Director / CEO / MD

Annexure 6

Documents / information to be checked for preliminary assessment of application

1. Submission of prescribed Application Fee.
2. Net Worth
3. Products proposed are covered under Target Segments.
4. Applicant is eligible for proposed Target Segment.
5. Proposed investment, wherever applicable (as per Annexure 2 of the Guidelines)
6. Proposed incremental sales, year wise along with CAGR
7. Committed value chain integration
8. Prima facie completeness of the application

Note: It may be noted that acknowledgement based on above does not qualify an applicant for claiming incentives under the Scheme. The applicant would be eligible for incentives after approval, baseline determination and achieving eligibility as per procedure defined in the Scheme Guidelines.

Annexure 7

Application Fee under the Scheme

An application fee of INR 1,00,000 shall have to be paid electronically through NEFT/ RTGS / to the DoP/PMA. The details of bank account for fee payment is given below:

Bank Account Name	**:**
Account Number	**:**
Name of the Bank	**:**
IFSC Code	**:**
Branch Code	**:**
Branch Name	**:**
Bank Address	**:**

Annexure 8

Quarterly Review Report

An applicant shall be required to provide the following information (self-certified) for quarterly review within 30 days from the end of each quarter:

1. Name of Applicant
2. Target Segment
3. Eligible Product(s)
4. Application Acknowledgement Date
5. Application Approval Date
6. Manufacturing Location(s)
7. Customer Brand(s) (in case of Contract Manufacturers)
8. Investment Actualized for Manufacturing of Target Segment (amount in INR)
Source of Funding (Equity, Debt, Internal Accrual etc.)
9. **Value chain integration status on Bill of Material basis**
10. Employment as on date (in numbers)
On-roll labor / employees
Contractual
Apprentice
11. Installed Production Capacity for Target Segment and Eligible Medical Device (in numbers)
12. Revenue from Operations – Domestic Sales [net of credit notes, discounts and taxes applicable]
a) Manufacturing Activity
i. Eligible Product
ii. Other Goods in Target Segment
iii. Other Goods
b) Trading Activity
i. Target Segment
ii. Other Goods
c) Services Activity
13. Revenue from Operations – Exports [net of credit notes, discounts and taxes applicable]
a) Manufacturing Activity
i. Eligible Product

ii. Other Goods in Target Segment
iii. Other Goods
b) Trading Activity
i. Target Segment
ii. Other Goods
c) Services Activity
14. Total Revenue from Operations
15. Details of Import– CIF value of Imported Goods at the Importation
a) Raw Material / Parts / Components
i. Eligible Product
ii. Other Goods in Target Segment
iii. Other Goods
b) Spare Parts
i. Eligible Product
ii. Other Goods in Target Segment
iii. Other Goods
c) Finished Goods
i. Eligible Product
ii. Other Goods in Target Segment
iii. Other Goods
d) Capital Goods
i. Target Segment
iii. Other Goods
e) Import of Services pertaining to Target Segment

Annexure 9

Bank Guarantee

(From any scheduled commercial bank)

This Deed of Guarantee executed on this______________day of____________, 20- at_________by_____________(from any scheduled commercial bank), having its Head Office / Registered Office at______________________________and inter-alia a Branch Office at____________________________(hereinafter referred to as the Bank or 'the Guarantor', which expression shall unless it be repugnant to the subject or context hereof be deemed to include its successors and assigns).

In favour of

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, Kartavya Bhawan-2, New Delhi-110001 (hereinafter referred as "DoP") represented by <PMA Name>, having its registered office at ____, acting as the Project Management Agency (PMA) for Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices.

WHEREAS

A. [….......................], a company within the meaning of the Companies Act, 2013 OR meaning under----------------and having its Registered Office at [-------------] (herein after referred to us 'the Applicant" which expression unless repugnant to the subject or context includes its successors. Legal representatives and permitted assigns) and has been awarded approval under the above scheme vide Letter Reference - _____dated________.

B. In terms of the undertaking dated --------------- and Clause --------- of the Guidelines Reference No. -------- dated ---------, the Applicant has to provide a Bank Guarantee for an amount equivalent to INR -------------- which is calculated in line with the undertaking.

C. At the request of the Applicant, the Guarantor has agreed to provide this guarantee, being these presents, guaranteeing the due and punctual performance / discharge by the Applicant of its obligations.

NOW THEREFORE THIS DEED WITNESSETH AS FOLLOWS

A. The Guarantor hereby irrevocably guarantees the due and compliance of terms by the Applicant of all its obligation under the said undertaking and approval letter, as amended from time to time.

B. The Guarantor shall, without demur, pay to DoP / <PMA Name> sums not exceeding in aggregate --------------- (INR -------------------) within five (5) bank working days (as per the Reserve Bank of India) of receipt of a written demand thereof from DoP /

<PMA Name> stating that the Applicant has failed to meet its obligations under the said undertaking. The Guarantor shall have not to go into the veracity of any breach or failure on the part of the Applicant or validity of the demand so made by DoP / <PMA Name> and shall pay the amount specified in the demand notwithstanding any direction to the contrary given or any dispute whatsoever raised by the Applicant or any other person. The Guarantor's obligations hereunder shall subsist until all such demands are duly met and discharged in accordance with the provisions hereof;

C. The Guarantor agrees that its liability under this guarantee shall in no manner be affected by any such variation, alteration, modification, waiver dispensation and that no further consent of the Guarantor is required for giving effect to any such variation, altercation, modification, waiver dispensation with or release of security;

D. This Guarantee shall be irrevocable and shall remain in full force and effect till---_____.

E. Until and unless discharged / released earlier by DoP / <PMA Name> in accordance with the provisions of the said undertaking, the Guarantor's liability in aggregate shall be limited to a sum of INR---------- (INR--_____);

F. This Guarantee shall not be affected by any change in the constitution or winding up of the Applicant / Guarantor or and absorption, merger or amalgamation of the Applicant / Guarantor with any other person;

G. The Guarantor has power to issue this Guarantee and discharge the obligations contemplated herein, and the undersigned is duly authorized to execute this Guarantee pursuant to the power granted under.

All future correspondence with reference to this Guarantee shall be made to. . .....(Bank Name and Address).

The jurisdiction in relation to this Guarantee shall be the Courts at New Delhi and Indian Law shall be applicable.

IN WITNESS WHEREOF THE GUARANTOR HAS SET ITS HANDS HEREUNTO ON THE: DAY, MONTH AND YEAR FIRST HEREINABOVE WRITTEN

SIGNED AND DELIVERED by_____
Bank by the hand of_____-----_____ its_____and authorized official.

FORMAT OF UNDERTAKING FOR BANK GUARANTEE AGAINST PROPOSED INVESTMENT

(Undertaking from the Applicant on the letterhead)

1. We,……., hereby, acknowledge that the incentive that would / may be provided to us under the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, notified by Department of Pharmaceuticals (DoP) vide DoP notification no. ……dated……. and other relevant guidelines, communications, will be provided to us based on, and after relying upon, the information provided by us to avail the said incentive.
2. We hereby confirm that the information provided by us for availing the said incentive is true, correct and complete in all respects and that no material fact / information that may have an adverse impact on the information provided by us for availing the said incentive has been concealed.
3. In case of the Investment in the project, as per the approval letter, is to be made by us within a specified period from the date of approval letter.
4. With regard to the aforesaid transactions, we hereby undertake the following:

   A. We undertake to provide Bank Guarantee from a schedule commercial Bank for the amount which is mentioned below:

S. No	Particulars	Details
1.	Date of issuance of Approval Letter	
2.	Validity period of BG *	
3.	Amount of BG	Rs. 30 lakh

   * valid for 365 days to be rolled over till the proposed date of commercial production as per clause 11.5.

   B. We understand and agree that, we are legally bound to renew the BG / issue fresh BG, failing which DoP / PMA may invoke the BG.

   C. In case of loss, mutilation, force majeure or any other eventualities, with respect to Original BG (favouring DoP / PMA, held at PMA), DoP / PMA will not be liable for the same and the onus would be with us to arrange for alternate / duplicate BG in place of the original BG.

   D. We also understand that the BG will be released to us in line with the Clause 11.7.

Annexure 10

Disbursement Claim Form: Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices

1. Applicant Name
2. Target Segment
3. Eligible Product(s)
4. Application Acknowledgement Date
5. Ref. No. and Date of Approval Letter
6. Investment, Sales growth CAGR, committed value chain integration of Manufactured Medical Devices wherever applicable for determining eligibility
7. Period for which Incentives are being sought
8. **Certificate from Statutory Auditor covering details in the format below:**

S. No.	Particulars	Unit	Base Year	Period of Claim
1	**Investment as on Date of Filing Claim (Cumulative)**	*INR Crore*		
2	**Employment as on Date of Filing Claim (Cumulative)**	*Numbers*		
3A	**Revenue from Operations – Domestic Sales [net of credit notes, discounts and taxes applicable]**	*INR*		
	a) Manufacturing Activity			
	i. Eligible Product(s)			
	ii. Other Goods in Target Segment			
	iii. Other Goods			
	b) Trading Activity			
	i. Target Segment			
	ii. Other Goods			
	c) Services Activity			
3B	**Revenue from Operations – Exports [net of credit notes, discounts and taxes applicable]**			

S. No.	Particulars	Unit	Base Year	Period of Claim
	a) Manufacturing Activity			
	i. Eligible Product(s)			
	ii. Other Goods in Target Segment			
	iii. Other Goods			
	b) Trading Activity			
	i. Target Segments			
	ii. Other Goods			
	c) Services Activity			
3C	**Total Revenue from Operations (Domestic Sales & Exports)**			
4	**Sales Quantity [net of credit notes, discounts and taxes applicable]**	*Numbers*		
	a) Manufacturing Activity			
	i. Eligible Product(s)			
	ii. Other Goods in Target Segment			
	iii. Other Goods			
	b) Trading Activity			
5	**Details of Import**	*INR*		
	CIF value of Imported goods at the time of Importation			
	a) Raw Material / Parts / Components used for manufacturing			
	i. Eligible Product(s)			
	ii. Other Goods in Target Segment			
	iii. Other Goods			
	b) Spare Parts used for manufacturing			
	i. Eligible Product(s)			
	ii. Other Goods in Target Segment			
	iii. Other Goods			
	c) Finished Goods used for manufacturing			
	i. Eligible Product(s)			
	ii. Other Goods in Target Segment			
	iii. Other Goods			

S. No.	Particulars	Unit	Base Year	Period of Claim
	d) Capital Goods used for manufacturing			
	i. Target Segment			
	iii. Other Goods			
	e) Import of Services pertaining to Target Segment			

9. Details of exports made to SRA countries

10. Certificates / undertakings stating / covering the following:

10.1 No deviation in Eligible Product(s)

11. Certificate(s) from Company Secretary stating:

11.1 All clearances required by law like statutory clearances, environmental clearances etc. have been obtained

12. Certificate(s) from Statutory Auditor stating / covering:

12.1 Committed Investment applicable has been achieved for the year in consideration

12.2 Details of Investment till date

12.3 Capitalization of Investment in the books of accounts of the applicant is in line with the relevant accounting standards issued by ICAI

12.4 Investment has been made in accordance with Scheme Guidelines and approval accorded by DoP

12.5 Threshold of Incremental Sales of Manufactured Goods applicable has been achieved for the year in consideration

12.6 Value Chain Integration achieved in the approved product to the extent which was promised/self declared by the applicant at the time of submitting the PLI application. The Value Chain Integration shall be based on the Bill of Materials (BoM)

Percentage of value addition = [Domestic Bill of Material / Total Bill of Material] × 100

Where in

Dom-BOM is Domestic Bill of Material which is sum of the costs of all domestic inputs which go into the product (including duties and taxes levied on procurement of inputs except those for which credit/set-off can be taken) and which have not been imported directly or through a domestic trader or an intermediary.

Total Bill of Material is the market price of the item (excluding net domestic indirect taxes) excluding post-production freight, insurance, advertisement, and other handling costs minus profit after tax, minus warranty costs

13. Documents / certificates from Chartered Engineer:

13.1 Certificate stating that the plant, machinery & equipment have been installed, the price is reasonable, as per the market value and the same are being used exclusively for manufacturing of approved Target Segment.

14. List of documents to be submitted post approval of claim

14.1 An undertaking from the applicant as per format given in **Annexure 11**

14.2 An agreement / indemnity bond on prescribed formats as per **Annexure 10 A** from the applicant that if at a later stage its claim is found to be false or excessive it would be liable to return the amount disbursed with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually.

14.3 Board resolution to the effect that the applicant agrees by the terms and conditions as laid down in the PLI Scheme and Guidelines while securing the incentive amount.

Annexure 10 A

FORMAT OF UNDERTAKING

(Undertaking from the Applicant on letterhead)

1. We, ……., hereby, acknowledge that the incentives that would / may be provided to us under the Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices, notified by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers will be provided to us based on, and after relying upon, the information provided by us to avail the said incentives.

2. We hereby confirm that the information provided by us for availing the said incentives is true, correct and complete in all respects and that no material fact / information that may have an adverse impact on the information provided by us for availing the said incentives has been concealed. We acknowledge and confirm that the foregoing averment is on an on-going basis and further undertake to immediately apprise the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers about any change in the status of the information provided by us to avail the said incentives.

3. We further undertake that in the event of (i) any of the information provided by us to avail the said incentives being found false, incorrect or incomplete, or (ii) in the event of the undertakings and confirmations stated at para 2 above being found false, incorrect, incomplete or breached; we will (a) refund the entire amount of incentives availed by us along with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually, for the period between excess payment and date of refund.

4. We acknowledge that the remedy provided in para 3 (a) above is not the exclusive remedy available with the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers and are without prejudice to any legal remedies available with Department of Pharmaceuticals for events mentioned in para 3 (i) and (ii) above.

Annexure 11

Subject: Performa for Integrity compliance in PLI-Initial Undertaking(s)

(To be signed by full time Director / CEO / MD of the company / firm duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

FORMAT-A

1. Whereas, the applicant namely *(name of company with address)* has submitted an application under Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices to Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, Government of India seeking incentives for the application pertaining to manufacturing……(Eligible Product) at… (location(s)).

2. Now, therefore, the applicant including its officers / representatives commits and undertakes that he / she will take all measures necessary to prevent corruption. He / She commits to observe the following principles during his / her association / engagement with DoP or its agencies or its consultants engaged with the process of appraisal and verification of application for the approval of application and disbursement of incentives under PLI.

2.1. The PLI applicant will not directly or through any other person or firm, offer, promise or give to any of the DoP's officer(s) or consultant or agency representative (appraisal or / and verification agency appointed by DoP to handle the application) involved in the process of dealing with application or to any third person any material or other benefit which he / she is not legally entitled to in order to obtain in exchange any advantage of any kind whatsoever before or during or after the process of the application for grant of approval or disbursement of incentives under PLI.

2.2. The PLI applicant will not commit any offence under the relevant IPC / PC Act; Further, the applicant will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the DoP.

2.3. The PLI applicant shall disclose the name and address of the duly authorized Agents/ Representatives who will be dealing with DoP or its agencies and the remuneration of these agents or representatives shall not include any hidden amount or component to get the work done in undue manner or causing inducement of whatsoever nature whether in cash or kind to influence the normal process or practice of work.

2.4. The PLI applicant will disclose any and all payments he / she has made, is committed to or intends to make to agents, brokers or any other intermediaries, other than regular employees or officials of the applicant, in connection with the grant of approval or / and disbursement of incentives.

2.5. The applicant will not offer any illicit gratification to obtain unfair advantage.

2.6. The applicant will not collude with other parties to impair transparency and fairness.

2.7. The applicant will not give any advantage to anyone in exchange for unprofessional behavior.

3. The applicant declares that no pervious transgressions occurred in the last 3 years with any other Company in any country conforming to the anti-corruption approach or with any other Public Sector Enterprises / Central or State Government or its any instrumentality in India.

4. The applicant agrees that if it is found that the applicant has made any incorrect statement on this subject, the application will be closed or rejected and DoP reserve the right to initiate legal action of whatsoever nature. In case if DoP has disbursed the incentives under PLI, the amount disbursed to applicant be recoverable along with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually besides blacklisting of the applicant and initiation of legal action of whatsoever nature at the discretion of DoP.

The contents of the above undertaking have been gone through and after understanding the same is being executed / given on……day of .....(month / year)

Signature

(Name & designation with address) Director / CEO / MD

Subject: Performa for Integrity compliance to be furnished by PLI Applicants before release of incentive

(To be signed by full time Director / CEO / MD of the company / firm duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

FORMAT– B

1. Whereas, the applicant namely *(name of company with address)* has submitted an application under Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices to Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, Government of India seeking incentives for the application pertaining to manufacturing .....(Eligible Product) at… ..... (location(s)).

2. And Whereas, the applicant has submitted an undertaking for observance and commitment for Integrity vide Undertaking dated……given under the signatures / authority of applicants ..... (name and designation) to DoP in respect of aforesaid application.

3. And whereas, the applicant including its officers / representatives gives commitment and undertake that he / she will take all measures necessary to prevent corruption and that he / she will not directly or through any other person or firm, offer, promise or give to any of the DoP's officer(s) or consultant or agency representative (appraisal or / and verification agency appointed by DoP to handle the application) involved in the process of dealing with application or to any third person any material or other benefit which he / she is not legally entitled to in order to obtain in exchange any advantage of any kind whatsoever before or during or after the process of the application for grant of approval or disbursement of incentives under PLI.

4. And whereas, the application submitted by the applicant has been given the approval by DoP vide its communication no……dated……...

5. And whereas, the applicant has submitted a claim for disbursement of incentive dated ....to the PMA for claiming incentives of INR…….

6. And whereas, the PMA has considered the claim for disbursement of incentive and is in the process of disbursement / release of incentives on the claim dated…….

7. Now, therefore, I / We hereby confirm the compliance thereof with the Integrity Undertaking submitted to DoP duly certifying that there is no breach to the same and requests that eligible incentives under PLI be released to applicant and the amount of incentives be credited in the bank account of applicant.

The contents of the above Undertaking have been gone through and after duly understanding the same, is being executed / given on……. day of……. (month / year).

Signature

(Name & designation with address) Director / CEO