

Draft

Haryana Medical Devices Manufacturing Policy, 2024



**Department of Industries
& Commerce,
Government of Haryana**



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List of Acronyms

CAGR	Compounded Annual Growth Rate
CGTMSE	Credit Guarantee Fund Trust for Micro and Small Enterprises
CLU	Change of Land Use
CoE	Center of Excellence
EDC	External Development Charges
EEC	Empowered Executive Committee
ETP	Effluent Treatment Plant
EU	European Union
FCI	Fixed Capital Investment
FDI	Foreign Direct Investment
GoHR	Government of Haryana
GoI	Government of India
GST	Goods & Services Tax
HEEP	Haryana Enterprises and Employment Policy
HEPB	Haryana Enterprises Promotion Board
HEPC	Haryana Enterprise Promotion Centre
IIT	Indian Institute of Technology
IMT	Industrial Model Township
INR	Indian Rupee
ITC	Input Tax Credit
IVD	In-Vitro Diagnostic
MDR	Medical Device Rules
MSME	Micro, Small and Medium Enterprises
MSMED	Micro, Small and Medium Enterprises Development Act
OEM	Original Equipment Manufacturer
PLI	Production Linked Incentive
R & D	Research and Development
SGST	State Goods & Services Tax
USD	United States Dollar



1. Preamble

Public health is of paramount importance for any economy to tread the fast-paced growth trajectory and hence, it is imperative to create a whole ecosystem that protects people's health & well-being. The medical devices sector is the core component of healthcare landscape. This sector continually advances medical technology, improving patient care and enhancing the quality of life. It not only generates employment opportunities but also fosters research & development, bolstering economic growth and securing its place as a critical industry for regions seeking global market competitiveness.

The state government recognizes the need to harness this potential, leveraging its existing industrial capabilities to nurture a thriving medical device manufacturing ecosystem. By doing so, Haryana aims to enhance its own economic prosperity while contributing significantly to the nation's healthcare infrastructure. Currently, India's medical device sector is dominated by international companies, which is evident from the fact that about 80% of the overall sales are generated by imported medical devices. Hence, there is a desperate need for government to intervene to support and promote manufacturing of medical devices domestically, and the Government of Haryana intends to support the manufacturing of medical devices in the state.

The new Haryana Medical Devices Manufacturing Policy 2024 aims to create an enabling environment for the growth of the medical devices manufacturing sector in Haryana. By streamlining regulations, supporting innovation, and incentivizing domestic production, this policy seeks to propel Haryana into a leading role in the national medical device landscape. It encourages investment, fosters research and development collaborations, and promotes indigenous manufacturing. Through this policy, Haryana envisions a healthier, economically vibrant, and technologically advanced future, firmly establishing itself as a beacon of progress in the medical device manufacturing sector.



2. Definitions

2.1 **Medical Device:** All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

- Disease diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices

This sector is regulated under The Medical Device Rules, 2017 (“MDR”), issued under the Drugs and Cosmetics Act, 1940 (“DCA”) or as amended from time to time.

2.2 **Medical Device Park:** A cluster of medical devices manufacturing units to be developed over a minimum area of 15 to 50 acres as per the norms of Town and Country Planning, Haryana, and or as amended from time to time. The Park Developer should ensure basic amenities such as internal roads, power distribution system, communication facilities, storage facilities, etc for smooth functioning and technological infrastructure like optic fiber connectivity/ broadband connectivity, Wi-Fi access, video conferencing facilities etc. The park may include common social infrastructure such as housing facilities, medical and sports facilities, banks, dormitories, recreational activities etc. and other enabling infrastructure such as CoE, Research & Development Centre, testing labs etc. as per Haryana TCP Norms (as amended from time to time).

2.3 **Common infrastructure facilities:** Some of the indicative activities under the Common facilities/centres are:

- Component Testing Centre/ ESDM/ PCB/ Sensors facility
- Electra-magnetic interference & Electra Magnetic Compatibility Centre
- Biomaterial / Biocompatibility / Accelerated Aging testing centre
- Medical grade moulding/milling/injection moulding/machining/tooling centre
- 3D designing and printing for medical grade products.
- Sterilization/ETO/Gamma Centre
- Animal Lab and Toxicity testing centre
- Radiation testing centre, etc.
- Radiology Tube/Flat Panel Detectors/MRI Magnets/ Piezo electrical
- Crystals/power electronics facility
- Solid waste management/ETP/STP/Electronic Waste management unit



- Common Warehouse & Logistics (Clearing and Forwarding, Insurance, Transportation, Weighbridges, etc.) Centre
- Emergency Response Centre/Safety/Hazardous Operations audit centre
- Centre of Excellence/Technology incubator/ Training Centres/ R&D Centre etc.

2.4 Existing Enterprise/ Unit: It means any enterprise/ unit existing and in operation prior to notification of this policy.

2.5 New Enterprise/ Unit: It means an enterprise established and commencing commercial production during the operative period of this policy. The existing enterprise undertaking expansion/ diversification/ modernization during the operative period of this policy shall also be considered as a New Enterprise.

2.6 Fixed Capital Investment (FCI): The new investment in land, building, plant, machinery, hardware & software made after the notification of this policy and before the commencement of commercial production shall be considered as FCI. However, the entire fixed capital investment made before going into commercial production and within 1 year thereon shall be considered while calculating eligible fixed capital investment for capping of benefit.

2.7 Eligible Capital Expenditure: The eligible capital expenditure shall include, building, plant, machinery, hardware & software (excluding land).

2.8 Ultra-Mega Project: Iconic Projects having minimum Fixed Capital Investment of INR 6000 Cr. in A Blocks, INR 4,500 Cr. in "B" category blocks, INR 3,000 Cr. in "C" category blocks and INR 1,500 Cr. in "D" category blocks (or as amended in HEEP 2020 from time to time and/or any future Haryana's Flagship Industrial Policy (if and when released)).

2.9 Mega Project: Projects having minimum Fixed Capital Investment (FCI) of INR 200 Cr. in B Blocks, FCI of over INR 100 Cr. in C Blocks and FCI of over INR 75 Cr. in D Blocks. The projects undertaking expansion/ diversification and the identified services with same criteria of investment shall also be treated as Mega Project (or as amended in HEEP 2020 from time to time and/or any future Haryana's Flagship Industrial Policy (if and when released)).

2.10 Large Enterprises: Investment in Plant and Machinery more than INR 50 Cr. and turnover greater than INR 250 Cr. (over and above of limit of medium units defined by GoI under the MSMED Act, 2006, or as amended by GoI from time to time).

2.11 Medium Enterprise: Investment in Plant and Machinery or Equipment does not exceed INR 50 Cr. and turnover does not exceed INR 250 Cr. or as amended by GoI under the MSMED Act, 2006 from time to time.

2.12 Small Enterprise: Investment in Plant and Machinery or Equipment does not exceed INR 10 Cr. and turnover does not exceed INR 50 Cr. or as amended by GoI under the MSMED Act, 2006 from time to time.

2.13 Micro Enterprise: Investment in Plant and Machinery or Equipment does not exceed INR 1 Cr. and turnover does not exceed INR 5 Cr. or as amended by GoI under the MSMED Act, 2006 from time to time.



2.14 Net SGST: Net SGST to be considered for reimbursement means that the eligible unit will be entitled to get reimbursement of SGST amount paid through cash ledger against the output liability of SGST on sale of eligible products. The eligible unit shall first have to utilize all the eligible Input Tax Credit (ITC) including eligible ITC of IGST available in its Credit Ledger, against the SGST output liability, before adjusting the SGST amount through Cash Ledger.

2.15 Local Employee: An employee who is a permanent resident of the state of Haryana (having Haryana Bonafide domicile certificate) shall be considered a Local employee for the purpose of this policy.

2.16 Categorization of Blocks: For promoting the geographical dispersal of industry, the State has been divided into 4 categories of Development Blocks viz. A, B, C and D based on the level of industrialization, level of socio-economic development, locational advantage (connectivity), state of infrastructure development and level of skill development. For this policy, the block category is as defined in Haryana Enterprises and Employment Policy (HEEP), 2020 or as amended from time to time and/or any future Haryana's Flagship Industrial Policy (if and when released).

2.17 Eligible Startup - Any entity shall be considered a startup if it meets the latest definition of startups as per the Haryana State Startup Policy 2022 and is registered with the Industries and Commerce Department, Haryana.

2.18 Centre of Excellence (CoE): Center of Excellence is a dedicated unit that focuses on developing and maintaining expertise in a specific area of Medical Devices. The CoE may explore emerging areas like Artificial Intelligence, Internet of Things, and Nanotechnology in the field of Medical Devices. These COEs are intended to oversee all stages of medical device development, from designing and prototyping, to development and safety testing, or other specialized fields related to Medical Devices. The primary objective of a CoE is to promote excellence, innovation, research, and development in a particular area of Medical Devices. This is achieved by bringing together a team of highly skilled and experienced professionals who work together to develop and implement best practices, standards, and processes related to their area of expertise.

2.19 Developer: Developer means an individual, company, association, firm or a limited liability partnership, designated through a collaboration/development agreement with the owner for making an application for grant of licence and for completion of formalities required on behalf of such owner to develop a colony. as per Haryana TCP Norms (as amended from time to time).

2.20 Owner: Owner refers to a person/ entity in whose favour a lease of land has been granted in Haryana for a period of not less than ninety-nine years or the title of ownership is in the name of the person/ entity. as per Haryana TCP Norms (as amended from time to time).

Policy Overview



3. Industry Overview

The global medical devices market displayed a notable performance by reaching a valuation of approximately USD 562.6 billion in 2022. Projections indicate a sustained growth trajectory, with an anticipated CAGR of 6.2% during the forecast period spanning from 2023 to 2031. This growth is expected to culminate in a market worth approximately USD 965.2 billion by 2031. The growing prevalence of chronic diseases and increasing emphasis of healthcare agencies towards early diagnosis and treatment are leading to an increasing number of patients undergoing diagnostic and surgical procedures leading to rising demand for medical devices equipment and consumables globally. This is further augmented by increasing investments from leading market players in the research and development for the manufacturing of technologically advanced equipment.

The current market size of the medical devices industry in India is estimated at USD 12 billion in FY21. Medical devices market is one of the fastest growing sector India, amongst the emerging markets, expected to grow at a CAGR of 15% to reach a market value of USD 50 billion in FY31. India's import of medical devices is staggering at almost 80% (USD 9 billion), and the country is highly dependent on foreign suppliers, particularly for high-end equipment such as cancer diagnostics, medical imaging, ultrasonic scans, and polymerase chain reaction technologies. However, Export from India stood merely at USD 2.53 billion in FY21. The Indian medical device market is driven by 75-80% imports from countries such as the US, China and Germany. Thus, it becomes imperative to encourage and promote manufacturing of medical devices in India, attract investments in this sector and reduce import dependency transitioning to self-sufficient India.

The Indian medical device industry is thriving due to various key factors. Increasing life expectancy, growing demand for healthcare devices in light of global health challenges like the COVID-19 pandemic, a rising burden of non-communicable diseases, and changing healthcare preferences are driving the demand for medical devices. Additionally, the affordability of medical care in India and the growth in disposable income have led to a flourishing medical tourism industry, contributing significantly to the sector's annual growth rate of 22-25%. These factors have created a favorable environment for growth and innovation in the Indian medical device industry.

Haryana is one of India's industrial powerhouses, contributing significantly to the country's economy. The state's industrial growth rate was around 8-9% in the years leading up to 2022. With a robust infrastructure, strategic location, and a skilled workforce, Haryana has become an attractive destination for manufacturers. Hence, the Haryana Medical Devices Manufacturing Policy, 2024 will provide the requisite impetus to the medical devices manufacturing industry.



4. Vision

“To transform Haryana as a global leading hub for the manufacturing of medical devices by developing a thriving ecosystem.”

5. Mission

- i. Create a conducive environment for the manufacturing of medical devices in the State.
- ii. Promote the 'Make in India' campaign by tapping into the entire value-chain of the healthcare domain and reduce dependence on imports and indigenize the manufacturing of medical devices.
- iii. Promote continuous innovation, encouraging the development of advanced and cost-effective medical solutions, and maintaining stringent quality control.
- iv. Fostering an ecosystem of continuous improvement and innovation.

6. Objectives

- i. Attract investments of INR 3000 Cr. in Medical Device manufacturing.
- ii. Create at least 20,000 employment opportunities within the state.
- iii. Promote exports from Haryana by equipping companies with pre-requisites necessary for access to global market.
- iv. Foster innovation, research, and development to bridge the technological gaps in the medical device sector.

7. Validity of the Policy

This policy will be valid for a period of 05 years from the date of notification of this policy or the date of any new policy/amendment, introduced by the Government of Haryana, whichever is earlier.

8. Eligibility Criteria

- 8.1 Any unit manufacturing medical devices as covered under the Medical Device Rules 2017 (issued under the Drugs and Cosmetics Act, 1940) by the Ministry of Health & Family Welfare, Govt. of India or any other schemes/policies relating to medical device sector issued by GoI from time to time will be eligible under the policy. An Indicative list of products is provided in **Annexure - I**.
- 8.2 The new units which will commence commercial production/operations post the date of the notification of this policy shall be eligible for availing benefits as enlisted under this policy.
- 8.3 This policy is also applicable to new and existing Medical Devices Manufacturing units in Haryana undertaking expansion/diversification, subject to compliance of the following conditions:
 - (a) Units undertaking expansion / diversification anywhere in 'A', 'B', 'C', and 'D' blocks on land parcels with valid CLU permission under commercial or industrial category or in Government approved Industrial Estates / IMTs; and



- (b) Units undertaking an expansion/diversification, with an additional investment of at least 50% of FCI and commencing commercial production/ operations of said expansion/diversification during the operative period of the policy.
- (c) Units undertaking expansion/ diversification will be eligible for availing incentives only once during the policy period.

8.4 Units are not eligible to avail incentives under the same head in this policy if it has been availed/applied under 'HEEP 2020' or any other policy issued by the Government of Haryana.

8.5 The cumulative incentives for Medical Device Unit or Park shall be subject to a ceiling of 125% of Fixed Capital Investment (FCI).

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Fiscal Incentives



9. Fiscal Incentives for Medical Devices Manufacturing Units

Fiscal incentives under this policy have been provisioned to reduce the burden pertaining to capital and operational expenditures on manufacturing units and assist businesses in developing their competitiveness as a world class manufacturer. In the long-term, these initiatives are aimed at creating a mature value chain within this sector and developing a more favorable industrial ecosystem, within the state.

9.1 Fiscal Incentives for Ultra-Mega units

Ultra-Mega Projects shall be offered customized package of incentives by Haryana Enterprise Promotion Board (HEPB) throughout the State.

9.2 Special Package of Incentives

Special Package of incentives for Mega units in 'B', 'C' and 'D' Category blocks having potential of ancillarisation shall be decided by HEPB over and above standard package of incentives based on Cost Benefit Analysis as per HEEP 2020 (as amended from time to time) and/ or any future Haryana's Flagship Industrial Policy (if and when released).

Special Package of incentives in 'A' Category Block having potential of ancillarisation shall be decided by HEPB over and above standard package of incentives based on Cost Benefit (CB) Model. Capping of custom incentives for 'A' Category block will be at par with 'B' Category block as per the approved CB Model by HEPB.

9.3 Fiscal Incentives for Mega & Large Units

The incentives under this section are applicable only for the eligible Large and Mega Medical Device Manufacturing units.

9.3.1 Investment Subsidy

There are 3 options for availing the subsidy, out of which, the enterprise will have to choose any one of the following options:

a) Net SGST Reimbursement

Units can avail 50% reimbursement on Net SGST paid to state government, for 5 years for units in A block & 10 years for units in B, C & D blocks; subject to a ceiling of 100% FCI or INR 300 Cr., whichever is less;

Or

b) Capital Subsidy

Units are eligible to avail reimbursement of eligible capital expenditure depending on investment size and location/block ('A', 'B', 'C', 'D') as per the criteria & proportions, as specified below:



#	Eligible Reimbursement under Capital Subsidy for 10years	
Block	Large	Mega
D	20% of eligible capital expenditure	25% of eligible capital expenditure
C	15% of eligible capital expenditure	20% of eligible capital expenditure
B	10% of eligible capital expenditure	15% of eligible capital expenditure
A	05% of eligible capital expenditure	10% of eligible capital expenditure

Capital subsidy shall be limited to INR 300 Cr. and shall be reimbursed in annual equal installments in 10 years.

Or

c) State Production Linked Incentive (PLI):

Units can avail production linked incentive depending on the location of the project. The incentive will be in proportion to the incremental turnover achieved annually by the firm:

#	State Production Linked Incentive		
Block	C&D	B	A
PLI (%)	1.6%	1.3%	1%

Production linked incentive will be applicable for 10 years and limited to 100% of FCI or INR 300 Cr, whichever is less.

9.3.2 Additional support to Large and Mega units utilizing GoI Schemes

For beneficiaries under PLI:

For units availing subsidy/incentive under upcoming GoI's PLI schemes associated with medical device sector (announced after the notification of this policy) shall be eligible for additional 50% top-up on production linked incentive.

- Financial support, under this category will be limited to:

Additional Top-up incentive under Production Linked Incentive (PLI)	
Large and Mega Units	INR 300 Cr. or 100% of FCI whichever is lesser
MSME	INR 50 Cr. or 100% of FCI whichever is lesser

- Large and Mega units availing top-up on PLI will be eligible only for capital subsidy or SGST reimbursement under 'Asset development subsidy' category. In such case, the overall incentive for 'top-up on PLI' combined with 'Asset development subsidy' will be capped to 150% FCI or INR 300 Cr., whichever is lesser.



9.4 Fiscal Incentives for All Eligible (Mega, Large, and MSME) Medical Devices Manufacturing Units

The incentives in this section are applicable for all categories of eligible Medical Device Manufacturing units as specified below:

9.4.1 Electricity Duty Reimbursement

100% electricity duty reimbursement for 20 years in 'D' category blocks, for 15 years in 'C' category blocks and for 10 years in 'B' category blocks.

9.4.2 Stamp Duty Reimbursement

100% reimbursement of stamp duty in 'C' and 'D' category blocks; 80% in 'B' category blocks after commencement of commercial production within 5 years from the date of purchase of land.

9.4.3 External Development Charges Reimbursement

100% reimbursement from External Development Charges in 'D' category blocks, 75% in 'C' category blocks and 60% in 'B' category blocks.

9.4.4 Reimbursement of ETP Cost

One-time reimbursement up to 50% of the expenditure for setting up ETP, subject to a ceiling of INR 50 lakh.

9.4.5 Reimbursement of Quality Certification Cost

75% reimbursement of the total expenditure incurred for obtaining certification and logistics charges thereof subject to a maximum of INR 5 lakhs per certification for obtaining ISO/ HACCP/ BSI/ WHO-GMP/ ZED/ TS/ Hallmark certifications and INR 10 lakhs per certification for other country specific certifications and would be in addition to the support being provided by Government of India.

9.4.6 Employment Generation Subsidy

The units shall be eligible for employment generation subsidy of INR 48,000 per year per employee (only in case of direct employment on payroll with valid ESI/PF Number and total monthly remuneration of up to INR 40,000) for a period of 10 years for capacity building of persons (skilled/semi-skilled/un-skilled) having Haryana Bonafide Resident Certificate.

9.4.7 Reimbursement of Freight Charges

With the aim to reduce logistic costs, the Government of Haryana will be providing the following incentives on freight charges:



- a) **Exports:** 1% of Free on Board (FOB) value or actual freight excluding government fee and taxes on transportation of goods from place of manufacture to the seaport/ air cargo/ by road up to international border, whichever is less and maximum up to INR 10 lakh in 'C' and 'D' category blocks and INR 5 lakh in 'A' and 'B' category blocks per annum.
- b) **Imports:** 1% of Free on Board (FOB) value or actual freight excluding government fee and taxes on transportation of goods from place of manufacture to the seaport/ air cargo/ by road up to international border, whichever is less and maximum up to INR 10 lakh in 'C' and 'D' category blocks and INR 5 lakh in 'A' and 'B' category blocks during the operative period of the policy. Only those raw materials imported will be eligible under this for which customs duty has been exempted by the Ministry of Finance (GoI), as per the notification no. 02/2023-Customs to 12/2023-Customs dated 19th Feb 2023 or as amended from time to time or any other relevant guidelines/ acts/ rules/ circulars notified by the Government of India.

9.5 Additional Incentives for eligible MSME units

The incentives in this section are applicable for eligible new MSME Units as well as eligible existing units undertaking expansion. The MSME units will be eligible for the incentives over and above as per the HEEP-2020 (Annexure-4, Section-4) and other incentives under MSME Policy 2019 or any other policy, as amended from time to time.

9.5.1 Net SGST Reimbursement

Units can avail 50% Net SGST Reimbursement first 10 years, 35% for next 3 years with cap of 150% of FCI in 'D' Block, 50% for first 7 years, 35% for next 3 years with a cap of 125% of FCI in 'C' Block, 50% for first 5 years, 25% for next 3 years with a cap of 100% of FCI, 50% for 5 years in 'A' Block.

9.5.2 Reimbursement of Guarantee Fee under CGTMSE

100% guarantee fee to be reimbursed to MSMEs subject to a maximum of INR 2 lakh per year for 5 years, from the date of commercial production.

9.5.3 Reimbursement of Credit Rating Expenses

Reimbursement of the expenses incurred towards the credit rating to the extent of 75% or a maximum of INR 2 lakh for MSMEs carried out by SEBI accredited credit rating agencies, i.e. CRISIL, ICRA, CARE, SMERA, Fitch India, and Brickwork Ratings, etc. or any other credit rating agencies empanelled by SIDBI. Units shall be eligible for reimbursement once during the validity period of the policy.

9.5.4 Reimbursement of Quality Testing/ Certification Cost

50% Reimbursement of the expenses incurred towards quality testing/certification from government accredited test centres/laboratory with a ceiling of INR 10 lakh per annum.



9.5.5 Testing Equipment Assistance

In order to ensure 'Zero Defect' in the quality of products to make globally competitive, Financial support of 50% as subsidy or maximum of INR20 lakh per year for the purchase of testing equipment shall be provided.

9.5.6 Assistance for Technology Acquisition

75% of cost for acquiring technology from premier National/International Institutes/Patented Technology from domestic/foreign companies, max. of INR 50 lakh.

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10. Infrastructure Augmentation

10.1 Fiscal Incentives to Medical Devices Park

There is a need to develop a complete eco-system wherein the players in the value chain would be coherently working towards manufacturing high-end medical devices. Thus, the Government of Haryana envisages to facilitate establishment of medical device parks, by providing support in creating world-class infrastructure.

Financial assistance for developers will be applicable if the park/ cluster is setup as per the following norms:

S.No.	Zone as prescribed in Haryana Development & Regulation of Urban Areas Act, 1975 (as amended from time to time)	Minimum Area (Acres)	Minimum Units	Minimum Investment (excluding land) (in INR Cr.)
1.	Hyper/ High Potential Zone	50	20	60
2.	Medium Potential Zone	25	10	30
3.	Low Potential Zone	15	5	15

10.1.1 Capital Investment Subsidy

25% reimbursement of the eligible capital expenditure, subject to a ceiling of INR 20 Cr., in the 'B', 'C' and 'D' category blocks only.

Disbursement of CAPEX assistance will be based on stages of construction and occupancy.

Instalment	Criteria	Grant Tranche
First Instalment	50% development of Park with requisite amenities as per approved development plan.	25% of Eligible Incentive
Second Instalment	Development of remaining 50% of Park with requisite amenities as per approved development plan and, Proof of operation of at least 25% of total permissible area earmarked for setting up units as per approved development plan.	35% of Eligible Incentive
Third Instalment	Proof of operation of at least 75% of total permissible area earmarked for setting up units as per approved development plan.	25% of Eligible Incentive
Last Instalment	Proof of operation of at least 100% of total permissible area earmarked for setting up units as per approved development plan.	15% of Eligible Incentive

10.1.2 Stamp Duty Reimbursement

100% Stamp duty reimbursement in the 'D' category block, 75% in 'C' category block, 50% in the 'B' category block.



11. Human Resource Development

11.1 Reimbursement of Technical Course Fees

Reimbursement of 50% of course fees up to INR 20,000 per employee for a maximum of 10 employees shall be provided to units once during the policy period for supporting Haryana domicile employees on completion of professional courses such as Quality Management Systems (as per the Indian and International Standards), Medical Device Risk Management, Medical Device Regulatory Affairs, Medical Device Software Certifications etc.

11.2 Development of Specialized Courses

In consultation with leading industry players, sector skill councils and academic institutions, focused specialized skill development courses will be offered in state skilling institution, Government/ ITI/ Polytechnics of Haryana to ensure skilled ready workforce for the industry.

The State Government shall also encourage skill development and training programmes for youth as per National Skill Development Corporation Guidelines released by Government of India from time to time.

A special training programme will be designed and organized for faculty development to be equipped with the know-how in order to cultivate entrepreneurial intellect.



12. Incubation Center for MedTech Startups

12.1 Financial Assistance for MedTech Incubation Center

Financial support subject to a ceiling of INR 4 Cr. to any Government Departments or any Government entities in collaboration with relevant industry association(s) for establishment of MedTech Incubation Center in the state for the purpose of furnishing and equipping (Medical Devices Infra., Testing Facilities etc.) the bare shell space and INR 1 Cr. yearly for 3 years recurring expenditure support at potential locations.

12.2 Financial Assistance for Prototyping

The eligible startups can avail reimbursement of 50% of the cost incurred for developing a prototype of a product subject to a ceiling of INR 10 lakh per year, with an allowance of a maximum of 2 sanctions per year per startup.

12.3 MedTech Pitch-A-thon

The State would organize MedTech based Pitch-A-thon to identify new and disruptive technological innovations for solving the problems/ challenges faced by medical devices industry, for building high-end innovative products and solutions using cutting-edge technologies like Artificial Intelligence, Data Analytics, Machine Learning, Big Data, Internet of Things (IoT), Blockchain etc. This will promote out-of-box thinking and innovation among emerging entrepreneurs.



13. Facilitating R&D and Innovation

Financial reimbursement @ 35% of project cost, subject to a ceiling of INR 2 Cr. to facilitate setting up of R&D Centers/ Laboratories for research and innovation, throughout the State. This financial assistance will only include cost of plant, machinery, and equipment.

Also, a grant of 20% of total operational expenditure, subject to a ceiling of INR 20 lakh per year will be provided, for a period of 3 years. Such grants shall cover expenditures including salaries of scientists, engineers and research staff, cost of participation in conferences & workshops, the fee associated with publication of research papers, and raw materials/consumables/ tools/ components required for the research.

R&D centers recognized by DSIR (Department of Scientific & Industrial Research), Council of Scientific & Industrial Research (CSIR), or any other institute of national/ international importance, or as decided by the Steering Committee shall also be eligible to avail this incentive under the policy.

13.1 Academia Collaboration

The State shall collaborate with Academia/ Educational institutions to foster research and development in the Medical Devices Sector and promote growth and innovation in the industry.



14. Marketing Development

14.1 Linkage with government and digital commerce portals

To facilitate easy access to the market, the Government of Haryana will support businesses in joining GeM (Government e-Marketplace) portal, ONDC (One Network for Digital Commerce) & other e-commerce platforms, through IEC activities and institutional tie-ups.

14.2 Industry Engagement & Outreach

To promote brand Haryana and attract private sector investments, the Government shall organise focused conferences/ business events/ road shows, promotional events at various locations from time to time to facilitate B2B, B2G, G2G interaction and participate in national/ international events, exhibitions, conferences.

14.3 Market Development Assistance

The Government will support eligible units in order to encourage Haryana based Medical Devices units/ Startups to showcase and promote their product/ service offerings at various national and international fairs/ exhibitions/ events, etc. The following shall be reimbursed for participation in the international/ domestic/ exhibitions for one fair in a year.

i. International Fairs/ Events/ Exhibitions, etc.

- a. 75% of the cost towards space charges, shipment of exhibits, cost of product literature, display material, stall/ stand construction/ fabrication/ designing charges or maximum up to INR 4 lakh
- b. Airfare by economy class up to INR 1 lakh (maximum 2 persons)

ii. Domestic Fairs/ Events/ Exhibitions, etc.

- a. 75% of the cost towards space charges, shipment of exhibits, cost of product literature, display material, stall/ stand construction/ fabrication/ designing charges or maximum up to INR 3 lakh
- b. Airfare by economy class up to INR 0.5 lakh per person (maximum 2 persons)
- c. Boarding charges up to INR 5000/- per day per person (maximum 2 persons)

Simplified Regulatory Regime





15. Regulatory Reforms

15.1 Issuance of Licences through Haryana Enterprise Promotion Centre (HEPC)

The Government of Haryana will further strengthen the Single Roof Clearance System for obtaining various regulatory clearances. In addition, the following licences pertaining to Food & Drug Administration, Haryana shall be included under HEPC - Single Window System.

- I. License to manufacture Medical Devices (Class A & B)
- II. License to manufacture Medical Devices (Class A & B) in loan/lease premise.
- III. Licence for wholesale of Medical Devices
- IV. Licence for retail sale of Medical Devices

15.2 Dedicated Single Roof

The Government of Haryana has already constituted Haryana Enterprise Promotion Council (HEPC), which provides one-stop-shop clearances to business entities willing to invest in the State.

15.3 Self-Certification

The Government of Haryana has allowed Self-certification, vide Notification No. 11/12/2018-4Lab dated 03.05.2018 (as amended from time to time), 3rd party verification for Labour related clearances and approvals under 14 acts of the Labour Department in Haryana. Self-certification/3rd Party verification has been allowed for the below-mentioned acts of Labour:

- Factories Act, 1948 and Rules framed thereunder.
- Minimum Wages Act, 1948 and Rules framed thereunder.
- Payment of Wages Act, 1936 and Rules framed thereunder.
- Contract Labour (Regulation & Abolition) Act, 1970 and Rules framed thereunder.
- Payment of Bonus Act, 1965 and Rules framed thereunder.
- Payment of Gratuity Act, 1972 and Rules framed thereunder.
- Maternity Benefit Act, 1961 and Rules framed thereunder.
- Child Labour (Prohibition & Regulation) Act, and Rules framed thereunder.
- Shops & Commercial Establishments Act, 1958 and Rules framed thereunder.
- The Inter-State Migrant Workmen (RECS) Act, 1979 and Rules framed thereunder.
- The Equal Remuneration Act, 1976 and Rules framed thereunder.
- Motor Transport Workers Act, 1961 and Rules framed thereunder.
- Punjab Industrial Establishments (National & Festival Holidays & Casual and Sick Leave) Act, 1965.
- The Building and Other Construction Works (Regulation of Employment and Conditions of Service) Act, 1996



15.4 Online single return for various Acts pertaining to the Department of Labour

The Labour Department has approved the online submission of a unified single return under all labour laws. The Government of Haryana has already implemented online filing of returns for labour compliance using a single application form and have been keeping the labour-related records in electronic form.

15.5 Allowing three shifts and night shifts for Women

Medical Device Manufacturing Units will be permitted for three shift operations with allowing women to be working at night, which is subject to the units taking the necessary precautions in respect of the safety and security of women employees. In addition, the government will implement an auto-renewal system, basis self-certification for such permissions (subject to fulfilling necessary regulatory compliance) and encourage faceless and paperless approval.

15.6 Essential Services

The Government will be declaring the Medical Device Manufacturing Units (as covered under this policy) as an essential service under Haryana Essential Services Maintenance Act, 1974. The eligibility for such units will be decided by the Steering Committee.

15.7 Steering Committee

A Steering Committee constituting Senior officials of Government of Haryana, Industry Experts/ Associations, or any other special invitee, etc. will be formed for deliberation on policy matters and implementation thereof.

Note: All the eligible Medical Device Manufacturing units shall be given the above regulatory benefits in addition to the ones mentioned in HEEP 2020 (as amended from time to time).



Annexure-I Indicative list of Medical Devices Sector and their Components

S.No.	Sector	Medical Device Components
1	Medical Devices	Cardiac stents, Drug eluting stents, Catheters, Intra-ocular lenses, IV cannulae, Heart valves, Scalp vein set, Internal prosthetic replacements, pacemakers, etc.
2	Medical Disposables	Adhesive / non adhesive medical dressings, sutures, blood bags, blood group reagents, Syringes, needles, catheters, cannulae, surgical gloves, medical/surgical sterilizers, Nappies & Hygiene Products, Latex Medical Disposables, etc
3	Medical Implants	Copper T, Orthopaedic implants, Bone cements, hearing aids, artificial joints, artificial teeth, Dental cements/fillings, IOL's, etc.
4	Medical Equipment (Electro Medical Devices)	Electrocardiographs, Pulse Oximeters, Ultrasound apparatus, MRI Apparatus, Scintigraphic apparatus, UV/IR apparatus, ECG and EEG monitors, DC defibrillators, Patient monitoring systems, Radiography equipment, Therapy equipments, Surgical diathermy units, Apnea/respiratory monitors, Colour Doppler ultrasound scanners, CT and MRI systems, Digital subtraction angiography systems, Laser and fibre optic devices such as endoscopes, colonoscopies, laparoscopes, laser lithotripters etc; linear accelerators, Simulators and treatment planning systems, dental drill engines, Ophthalmology equipment etc.
5	Medical X-ray, A, B, C Ray Equipment	Computed tomography apparatus, X ray apparatus for dental/medical/surgical / veterinary use, Medical alpha, beta, gamma ray apparatus, X Ray tubes etc.
6	Medical Furniture and Software	All varieties of medical furniture and software to support the devices and equipment