

Environmental and Health Risk Management Plan (EHRMP)

Carenow Medical Private Limited

Proposal entitled: Theruptor Advanced Wound Care using patented Microbicidal Composite Material

i) Brief description of the proposed activity:

Theruptor, an active wound care system achieves infection control by continuously inhibiting growth of pathogen without depletion of kill mechanism. It provides both, barrier for pathogens and sanitizes the wound by actively killing the pathogens.

Intended to be used for indications such as

- 1) minor wounds
- 2) surgical wounds
- 3) trauma wounds
- 4) venous ulcers
- 5) Pressure ulcers
- 6) diabetic ulcers
- 7) chronic vascular ulcers

ii) List of environments related regulatory clearances required for the activity.

1.	Tamilnadu Pollution Control Board	Order No.: 1807218556975, Dated: 01/12/2018
2.	Ministry of Commerce and Industry (Petroleum & Explosives Safety Organisation)	No. P/SC/TN/16/224(P375244)
3.	Department of Public Health & Preventive Medicine (Sanitary Certificate)	R. No:6872/A1/2019, Dated:30/11/2019
4.	Tamilnadu Fire-Rescue Services (Fire Service License)	License No.:2071/2019 K. Dis: 15997/D1/2019

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		Mr. Kathiresan Designated full time staff for Environment Health and Safety (EHS) is available.	The concerned staff will be trained on the Environment Health and Safety (EHS) and will comply with the norms and requirements of the Pollution Control Committee.
2.	Does the EHS staff handle the following?			EHS staff handle all the mentioned responsibilities	The concerned staff will be trained as per the Environment Health and Safety (EHS) Rules. We will comply to Environment Management Framework compliance for Innovate in India Project

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	Occupational Health and Safety	Yes		
	Waste Management	Yes		
	List of consents and regulatory clearances	Yes		
	Record keeping of accidents and procedures	Yes		
	EHS trainings for staff	Yes		
	Environment Management Framework compliance for Innovate in India Project	Yes		
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Reporting structure in place regarding EHS issues Register with any and all the updates will be done in the register maintained by the Management.
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: New hire training Retraining when: (1) changes in the workplace render previous training obsolete. (2) changes in the types of PPE to be used render previous training obsolete. (3) inadequacies in worker knowledge or use of assigned PPE indicate that the worker has not retained the requisite understanding or skill EHS trainings programs will be conducted by the Company annually.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		
6.	Ethics Committee (EC)	Yes		
General Occupational Health and Safety				
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		Standard Operating Procedures are in place. Will be incorporated in the SOPs as part of QMS plan. Employees will be trained on the SOP Display of Procedures at prominent places in the site will

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					be ensured.
8.	Are the following in place?			Mentioned equipment's & systems are in place	Compliance with relevant items be ensured as and when required for any hazardous chemicals produced during the project. Proper equipment will be in place and stock will be maintained as per the Institute's guidelines for Environment Health and Safety (EHS).
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
9.	Are proper signage and storage system in place?	Yes		All the mentioned Systems are available and in place	These would be regularly updated/ replaced while carrying out maintenance.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			
10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	Yes		Smoke detectors, fire alarms, automatic safety/shut off systems are in place and regularly maintained.	Facilities will be upgraded with the activities increased.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		We are having control measures for VOC, air emission are present.	This would be reviewed periodically.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Once in 06 Months	This will be followed as per the schedule prepared by the regulating department/office.

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13.	Are staff provided with OHS training?	Yes		Describe: OHS training is compulsory for all new joined staffs and we are conducting a periodic training for the staff.	Training will be provided to all staff recruited in the project which would be included in the annual plan.
Biomedical Waste (BMW)					
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		List of Bio Medical waste Microbiological Wastes (Microbial Cultures, Medium) Chemical Waste (Production/ Formulation Wastes) Chemical Liquid Waste	We will update the list of Bio waste periodically BMW generated will be treated adhering to Bio-Medical Waste Management Rules, 2016.
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes			Trained Staff available to handle biomedical waste. EHS trainings programs will be conducted by the Company annually.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		From Tamilnadu Pollution Control Board, Order No.: 1807218556975, Dated: 01/12/2018)	Authorization will be renewed from time to time
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Biomedical waste segregated	Register with any and all the updates will be done in the register maintained by the Management.
18.	Is the bar code system for the segregated waste in place?		No		We plan to implement the bar code system for the segregated waste
19.	Is the biomedical waste being sent to an authorized common BMW facility?		No	Pre-treat to sterilize with non-chlorinated chemicals and Autoclave (Decontamination) in on-site	Will send to authorized common BMW facility if required
20.	Does the grantee have an in-house BMW treatment facility?	Yes		In-House procedure for BMW disposal as per Bio Medical Waste Management Rule 2016	Continue the standard practice of BMW management as per SOP.
	Is the treatment facility own (individual)?	Yes			
	Is the treatment facility a shared facility in an industrial park?		No		
21.	Are lab waste, microbiological waste and chemical liquid	Yes		Pre-treat to sterilize with non-chlorinated chemicals and	Register with any and all the updates will be done in the

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	waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?			Autoclave (Decontamination)	register maintained by the Management.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		Enumeration and Bioburden techniques	Will monitor this during the Project and if needed will propose a plan of treating the same as per BWM Regulations.
23.	Are necessary waste pre-treatment equipment in place?	Yes			Facilities will be upgraded with the activities increased.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		Using Nitrite Examination Gloves	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes			Training will be provided to all staff recruited in the project which would be included in the annual plan.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		medical examination provided to personnel involved in BMW waste handling	Register with any and all the updates will be done in the register maintained by the Management.
27.	Is a daily register for biomedical waste maintained including accident reporting record?		No		We plan to implement the daily register for BMW
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No		Will submit the reports if required as per BMW rules
Hazardous Waste (HW)					
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		List of Hazardous waste Process Residues and Wastes - Production Waste - Empty barrels/containers/liners/ contained with hazardous chemicals/wastes - other cleaning wastes	We will update the list of waste periodically. The collection, treatment and disposal of these hazardous waste generated will comply with the Hazardous Waste Rules 2016.

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				- Oil sludge and Emulsion	
30.	Is there trained staff in the facility to identify and handle hazardous waste?	yes			Training will be provided if required
31.	Does the grantee have authorization from SPCB for hazardous waste?		No		Necessary Authorization will be taken if required
32.	Is there a secure location for storage of HW with proper signage?	Yes			Facilities will be upgraded with the activities increased.
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being send to an authorized disposal facility or user?		No		Proper maintenance and
	Is the disposal facility in house?	Yes			
	Is the disposal facility external/outsourced?		No		
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?		No		Facilities will be upgraded with the activities increased. Register will be maintained if required
E-Waste and Batteries					
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016. Plant setup is new and till date no waste generating activities are acquired. However, there is separate area mark for E-waste to be collected for the periodically handled and disposed as per E-waste Management Rules 2016.	Will ensure proper the e-waste as and when generated are treated as per E-waste management Rules, 2016.
36.	Has the grantee obtained SPCB authorization on e-waste?		No		Necessary Authorization will be taken if required.

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37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure proper the e-waste as and when generated are treated as per E-waste management Rules, 2016.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure proper the e-waste as and when generated are treated as per E-waste management Rules, 2016.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure proper the e-waste as and when generated are treated as per E-waste management Rules, 2016.
40.	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure proper the e-waste as and when generated are treated as per E-waste management Rules, 2016.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure proper the e-waste as and when generated are treated as per E-waste management Rules, 2016.
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure proper the e-waste as and when generated are treated as per E-waste management Rules, 2016.
43.	Is there accident reporting and records in place?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure this facility is in place as and when applicable during the Project.
44.	Are PPEs available to staff?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Will ensure proper provisions of these as and when required during the Project.
45.	Is the grantee involved in manufacture of batteries?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management	

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				Rules 2016	
46.	Does the grantee generate battery waste?		No	Not Applicable- There is one generator, and one battery is available in premises. For Re-circulation we will purchase the new batteries form vendor. E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	Re-circulation will be done by purchase of new batteries form vendor. E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	Not Applicable- E-waste and lead acid Batteries are not available in our premises as per E-waste Management Rules 2016	
Community Health and Safety and risk mitigation					
49.	Safety Transportation Management System (for transport of hazardous material)	Yes		Hazardous waste being sent to through authorized vehicle.	Will follow the same for the project activities.
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		On site emergency plan is in place.	The local community health workers and community leaders will be informed about any issues that can affect the community. The Emergency Preparedness plan will be executed as per the SOP in place.
Others					
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		No	We are not using any radioactive materials	We do not have any plan to use radioactive material in the near future
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	We are not using any radioactive materials	We do not have any plan to use radioactive material in the near future
	Are radioactive warning signs in place?		No	We are not using any radioactive materials	We do not have any plan to use radioactive material in the near future hence not required to put signage

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52.	Is the lab/room air regularly checked for microbial contamination?	Yes		lab/room air regularly checked	Register with any and all the updates will be done in the register maintained by the Management.
53.	Are there any odor control measures in place?	Yes		odor control measures in place	Register with any and all the updates will be done in the register maintained by the Management.
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		fume hoods and exhausts regularly checked	Register with any and all the updates will be done in the register maintained by the Management.
55.	Does the grantee use DG set > 15 KVA?	Yes			DG sets are regularly monitored and maintained as per norms
	Does the grantee have consent for DG > 15 KVA?	Yes			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes			
56.	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?	Yes		solid and plastic waste is disposed as per rules	Register with any and all the updates will be done in the register maintained by the Management.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Medium, cultures and Microbiological waste are disposed by Autoclave. We segregate solid waste and plastic waste in separated area. We can handed over to the Municipals waste collection with its periodically as per solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016.	Register with any and all the updates will be done in the register maintained by the Management.
	Are there sludge management and cut off drains in place for wastewater?	yes			These will be periodically checked and maintained to ensure their proper functioning.
58.	Are necessary provisions for noise cancellation in place?		No	Not Applicable-The ambient noise level is not exceeded in the limit of 75dB	

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59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	Yes			Local Self Government Body of the region and other government departments shall be involved in such instances
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Fire vehicle movement routes are available	Will ensure that the site premises are well equipped with these essential facilities

Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.