

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

Proposal entitled: “A low cost multipowered multifunctional neonatal breathing support device for low resource settings”

i) Brief description of the proposed activity:

InnAccel is a research and development organization. Manufacturing is done with a contract manufacturer Kayens Technologies Pvt Ltd. Bangalore. Our relationship is driven by contact and quality agreements. Manufacturing partner meets all the EHRMP related to the manufacturing facility relevant to the project. We have audited them and relevant information will be produced on request.

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

Our manufacturing partner Kaynes Technologies has following approvals and certification in place:

OHSAS 18001

ISO 13485

ISO 14001

Karnataka State Pollution Control Board

Factory Inspector Clearance (Factory license)

ROR (Register of regulations) is maintained

These certifications will be maintained over the duration of this project.

Responses below are for our manufacturing site (with contract manufacturer), where appropriate.

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Y		We have designated person for health and safety issue	The concerned staff will be trained on the Environment Health and Safety (EHS) . We will comply to Environment Management Framework compliance for Innovate in India Project
2.	Does the EHS staff handle the following?	Y			
	Occupational Health and Safety	Y			
	Waste Management	Y			
	List of consents and regulatory clearances	Y			
	Record keeping of accidents and procedures	Y			
	EHS trainings for staff	Y			
	Environment Management Framework compliance for Innovate in India Project	Y		There is a reporting structure in place regarding EHS issues	This will be regularly followed by ensuring adherence to the requirements.
3.	Is there a reporting structure in place regarding EHS issues?	Y			
4.	Are regular EHS trainings provided to staff?	Y			

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

General Occupational Health and Safety					
5.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Y		Standard Operating Procedures are in place	Display of Procedures at prominent places in the site will be ensured.
6.	Are the following in place?			Shower station not required for assembly of Saans system, as no exposure to hazardous substances Remaining are in place	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		No		
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
7.	Are proper signage and storage system in place?	Yes		Systems are 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			
8.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	Yes		System is in place	These would be regularly maintained.
9.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		Control measures are in place	

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

10.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency	This facility will be prepared and schedule mock drills will be monitored by an appointed officer.
11.	Are staff provided with OHS training?	Yes		Staff are being trained on OHS	We will provide such training for all staff recruited in the project annually.
Biomedical Waste (BMW)					
12.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?		No	We do not generate biomedical waste.	Any BMW generated will be treated adhering to Bio-Medical Waste Management Rules, 2016.
13.	Is there trained staff to handle biomedical waste in the grantee?		No	If No, provide a list of all waste produced in the facility. 1.Food Waste and 2.Electrial plastic waste	Will plan for the training as and when needed during the ongoing Project.
14.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		No		Will keep updating about the status and seek approvals of the necessary authorities as and when required.
15.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?		No		
16.	Is the bar code system for the segregated waste in place?		No		
17.	Is the biomedical waste being sent to an authorized common BMW facility?		No		Will propose a plan and provide a facility if needed during the Project.
18.	Does the grantee have an in-house BMW treatment facility?		No		
	Is the treatment facility own (individual)?		No		
	Is the treatment facility a shared facility in an industrial park?		No		
19.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?		No	We do not generate biomedical waste.	Will ensure compliance of the BMW, 2016 Regulations as and when required.

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

20.	Is the liquid waste checked for active cells before sending to treatment plant?		No		Will ensure to have a proper mechanism in place in case need arises.
21.	Are necessary waste pre-treatment equipment in place?		No		Will ensure to have a proper mechanism in place in case need arises.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?		No		Will adhere to the prescribed norms by State Pollution Control Board wherever required.
22.	Are non-chlorinated plastic gloves and bags phased out in the grantee?		No	We do not deal with or use these items.	
23.	Are grantee's personnel involved in handling BMW provided with regular training?		No	We do not generate biomedical waste.	
24.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		No	We do not generate biomedical waste.	Will ensure that this is being provided to the person responsible for handling the BMW as and when employed during the Project.
25.	Is a daily register for biomedical waste maintained, including accident reporting record?		No	We do not generate biomedical waste.	In case the need arises, we will maintain the record.
26.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	We do not generate biomedical waste.	Will adhere to the requirement of SPCB if needed in future.
Hazardous Waste (HW)					
27.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		All of our components and materials used in Saans devices are ROHS compliant-assembly process generates limited HW (solid plastics) authorization from SPCB for hazardous waste is available	This training shall be given to the respective staff specifically appointed to carry out this activity. In case any hazardous waste authorization if needed in future will be obtained and renewed
28.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			
29.	Does the grantee have authorization from SPCB for hazardous waste?	Yes			
30.	Is there a secure location for storage of HW with proper signage?	Yes			
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

31.	Is the hazardous being send to an authorized disposal facility or user?	Yes		Register is being maintained	Timely renewals of the existing contract with the agency will be done.
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?	Yes			
32.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?	Yes			
E-Waste and Batteries					
33.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		Faulty components, rejected PCBs, etc.	If any permission required in this will be obtained
34.	Has the grantee obtained SPCB authorization on e-waste?	Yes		authorization from SPCB for electronic waste is available	
35.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		channelize the e-waste to authorized recycling or disposal facility	
36.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Safe disposal instructions are provided to customer in user manual.	
37.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	Yes		Our components and products are all ROHS compliant.	Extended Producer Responsibility system and EPR-authorization will be followed if required
38.	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?	Yes		We provide ROHS declaration	Will continue to maintain and follow this throughout the Project.
39.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		We maintain a record	This is an ongoing process and will be carried on throughout the Project.
40.	Does the grantee submit annual reports on e-waste to SPCB?	Yes		We submit annual report to SPCB	
41.	Is there accident reporting and	Yes		We have register to	Accident reporting

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

	records in place?			record accidental events	and recording mechanism will be reviewed and maintained.
42	Are PPEs available to staff?	Yes		Safety glasses, caps, gloves, and coveralls available	
43	Is the grantee involved in manufacture of batteries?		No	We are not manufacturing any batteries so this is not applicable	
44	Does the grantee generate battery waste?	Yes		We procure batteries for Saans system-some of them may be rejected and have to be disposed.	
45	Does the grantee deposit the battery waste to a registered recycler/dealer/manufacturer/reconditioner/collection center?	Yes		Sent the batteries to authorized recycler	
46	In case of manufacturing, does the grantee comply with Battery Management Rules 2000 and ensure collection of old batteries?	Yes			Will comply with Battery Management Rules 2000 and ensure collection of old batteries
Others					
47.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		No	We don't have any radioactive materials in our activity	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	We don't have any radioactive materials in our activity	
	Are radioactive warning signs in place?		No	We don't have any radioactive materials in our activity	
48.	Is the lab/room air regularly checked for microbial contamination?		No	No biologics are being used so not being done	
49	Are there any odor control measures in place?	Yes		odor control measures in place	Proper measures will be put in place with Periodic cleaning and maintenance as and when required.

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

50.	Are fume hoods and exhausts regularly checked and maintained?		No	We do not have fume hood and exhausts, as our activities do not generate fumes.	
51.	Does the grantee use DG set > 15 KVA?	Yes		emissions from boilers and DG sets regularly monitored to be within the prescribed norms	Will ensure maintenance of the DG sets used by the Company during the Project.
	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			
52.	Does the grantee have a proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?	Yes		disposal process of solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016	Will be maintained and monitored throughout the Project.
53.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		wastewater is being treated	Periodic checks will be done and the treatment plant shall be maintained
	Are there sludge management and cut off drains in place for wastewater?	Yes		System is in place	Will ensure that they are maintained throughout to treat the wastewater.
54.	Are necessary provisions for noise cancellation in place?	Yes		Necessary equipment's has been provided to designated staff and workers employed in this area.	Will keep reviewing the noise generated and cap them according to the existing cancellation provisions.
55.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	No Eco-sensitive areas near the factory premises	
56.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Since facility is on a public road, there is direct access to fire vehicles from outside the premises	Will ensure that the premise is well equipped with these essential services.

Environmental and Health Risk Management Plan (EHRMP)

Innaccel Technologies Private Limited

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.