Environmental Health Risk Management Plan (EHRMP)

Vasmed Health Sciences Pvt. Ltd

Proposal entitled: Application for commercialisation of Vision FFR System with 0.014 pressure/IBP wire

1. Institutional Arrangements

i) Brief description of the proposed activity:

Vasmed Health Sciences Pvt. Ltd. is engaged in design, development, manufacture of medical devices. Currently we are in process of CDSCO approval for the facility as the Guidewires are controlled medical devices. No products are commercially released and no revenue is recorded by the company. Following processes are done internally

- Design of PCBA, Assembly of PCBAs
- Design of Guidewires
- Processing of guidewires from raw material to finished product.
- PTFE coating
- Cleanroom processing of finished product
- Sterilisation of the final product
- Our microbiology lab

Subcontracted work

- PCB Fabrication and Assembly
- Microbiology testing including EO Residual and Sterility
  (Internal microbiology lab is under construction and is planned to be completed in 6 months)

No Pharmaceutical ingredients, genome. Molecular materials including DNA, RNA or body liquids, contaminated products, hospital used products, blood products, or blood derivatives are handled at the factory.

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

As per Government requirements, Karnataka state Pollution control board (KSPCB) consent for operations is required once CDSCO approval is completed.

Application for CFO is under process..

KSPCB the consent to establish (CTE) from 2016 is available

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		No	Quality manager act as EHS manager	QC officer will support for EHS issues
2.	Does the EHS staff handle the			QM acts as EHS Manager	Additional team

	following?				members to be trained prior to September 2020
	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		To be implemented	EMF to be implemented prior to 30th June 2020
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Available A documented reporting structure implemented for EHS as a part of QMS.	Vasmed will comply with Environment, Health and Safety policy.
4.	Are regular EHS trainings provided to staff?	Yes		Available Frequency: Annual (or as induction training for new staff) Training provided for all staff on environment health and safety.	EHS trainings programs will be conducted by Vasmed on regular basis.
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.)?	Yes		Available SOP's are implemented for hazards and other emergencies as per QMS	SOPs and protocols will be maintained for any new activity included in the work
6.	Are the following in place?			Goggles, Gloves, breathing masks provided for employees for working special medical coating areas. Face wash, Shower stations, First Aid Kit, Fire Extinguishers, register of accidents and injuries are placed in respective areas	Chemical spill kits, and Eye wash Bowel with a RO water Bottle will be implemented in chemical coating area by 30th May 2020
	Chemical spill kits		No		
	Eye wash		No		
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
7.	Are proper signage and storage system in place?			Available at Vasmed	MSDS Signages and its's storage system will be reviewed monthly basis. Emergency Contact numbers will be reviewed 3 months
	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			once
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			Signages across the facility will be monitored monthly
8.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	Yes		Risk areas like sterilization is provided with Gas detection system.	Gas detection system will be checked before the sterilization of each batch.
9.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No	Only for specialized areas like sterilization, coating area provided with temperature monitoring. Cleanroom is temperature controlled.	Air Emission ducting will be implemented in Sterilization area, VOC (Volatile organic compounds) not applicable
10.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Annual Fire safety drills	External trained safety staff will conduct mock drills once in a year
11.	Are staff provided with OHS training?	Yes		Training part of QMS training.	During induction training
Biomedical Waste (BMW)					
12.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?				Microbiology lab is under construction and to be completed in 6 months time. BMW is applicable only with commissioning of the microbiology plan
		Yes		Laboratory chemicals Growth Media Disposables as Laboratory aprons Hand gloves Face mask Chemical containers Lab tissue papers Shoe covers Head caps Glassware	To be implemented with lab commissioning, Review on monthly basis will be done during Waste disposable collection
13.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Qualified Microbiologist is available inhouse.	Yearly review will be done as per company appraisal

14.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Consent To Establishment from KSPCB	Consent for Operations is under process and will be procured within time.
15.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		To implement Segregating at point of generation and storing in containers Yellow: Lab media Red: Not Applicable White: Not Applicable Blue: Broken Glassware	Review and Report will be generated during disposal of biomedical waste monthly
16.	Is the bar code system for the segregated waste in place?		No	To be implemented	Barcode system for segregated biomedical waste as mentioned will be implemented by December 2020, recording will be done during waste disposal
17.	Is the biomedical waste being sent to an **authorized** common BMW facility?	Yes		Name and address of CBMWF: Century Eco Solution India Pvt Ltd , #161 B and C, KIADB 1st Phase , Vasanthnarasapura Industrial Area, Taluk: Tumkur, District: Tumkur , District : Tumkur Distance from facility: 60KM Frequency and Mode of transport: Monthly Who transports? Supplier	Review done yearly once. Will continue this throughout the Project.
18.	Does the grantee have an in-house BMW treatment facility?		No	Reason: Authorization: Distance of nearest CBWM from facility: Types of treatment:	All growth media will be sterilized by autoclave prior to disposal.
	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	Yes		Types of treatment: All chemical liquid is autoclaved prior to	Autoclave of chemical liquids will be done each batch prior to

	facilities according to guidelines prescribed in BWM, 2016 regulations?			disposable. Additional method planned.	disposable
20.	Is the liquid waste checked for active cells before sending to treatment plant?		No	No active cells are generated.	
21.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.): - Available autoclave Details of waste pre-treatment: Decontamination with autoclave.	Autoclave equipment will be calibrated once in a year
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
22.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		chlorinated plastic gloves and bags is not planned to be used	
23.	Are grantee's personnel involved in handling BMW provided with regular training?			Frequency: Quarterly Trainer: Internal (QC Officer and Microbiologist)	Will be done during induction training and quarterly training
24.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		Frequency of medical examination: Yearly	(All production, quality staff in contact with products of Vasmed will undergoe annual examination.
25.	Is a daily register for biomedical waste maintained including accident reporting record?		No	To be implemented	Recorded in Biomedical waste segregation register
26.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	To be implemented	Will be submitted as part of Consent for Operation from KSPCB adhering to the timelines.
Hazardous Waste (HW)					
27.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		- Wastes from Sterilization - chemical containers - PTFE chemical residue	During each batch of sterilizer, Chemical Containers and chemical residue will be recorded and monitored as on replacement of new containers.
28.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		Maintenance, Production manager	After undergone training the review will be within 1 to 3 months.
29.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		Consent for Establishment for KSCB	Timely renewals will be done with proper authorization from the concerned regulating

					authorities.
30.	Is there a secure location for storage of HW with proper signage?	Yes		Available	Review will be done on Monthly basis.
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No	Disposable is planned on every month	
31.	Is the hazardous being send to an **authorized** disposal facility or user?	Yes		Hazardous waste is storing and collecting by external authorized party for disposal.	Disposal is planned on Monthly basis which will continue throughout the project.
	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		Register is available and maintained by Vasmed.	Recording and review done during disposal of waste on monthly basis
E-Waste and Batteries					
33.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		Wires and cables PCB components	Recording and review done during disposal of waste on monthly basis
34.	Has the grantee obtained SPCB authorization on e-waste?	Yes		Consent for Establishment from KSPCB	CFO under application. Will ensure timely renewals.
35.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?	Yes		Name and address of disposal facility/recycler: Century Eco Solution India Pvt Ltd, #161 B and C, KIADB 1st Phase, Vasanthnarasapura Industrial Area, Taluk: Tumkur, District: Tumkur In-house or outsourced Facility: Outsourced	Authorized external recycling facility, Recyler agreement will be reviewed on a yearly basis.
36.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Limited generation of E-Waste (except for ESD assembly wastes)	Authorized external recycling facility will be taking care of the E-waste generated.
37.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	Yes		ESD work flow procedure	Review will be done periodically.
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		Product IFU	Hazardous substances/parts are identified in IFU, Provided the disposable methodologies,

					Customer will be trained during product Installation training.
39.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		ESD procedure	During monthly disposable the records will be generated.
40	Does the grantee submit annual reports on e-waste to SPCB?		No		Not implemented, after CFO to be provided.
41	Is there accident reporting and records in place?	Yes		Production Documents	Recorded in Employee Health report as on injury occurrence
42	Are PPEs available to staff?	Yes		Clean room garments with PPE set available	Disposable type PPE's are used by clean room operator's on daily basis. The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
43	Is the grantee involved in manufacture of batteries?		No		Batteries will be procured as on required
44	Does the grantee generate battery waste?		Yes	Limited batteries are used in company. Individual UPS are provided for desktop computers.	Such waste is discarded as a part of E-waste, Disposable of E-waste on monthly basis
45	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/reconditioned/collection center?	Yes		To the Authorized recycling and disposal facility	Disposable of E-waste on monthly basis
46	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No		Not in a scope of Battery manufacturing
Others					
47.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		No		Not in a scope of radioactive materials
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No		Not in a scope of radioactive materials
	Are radioactive warning signs in place?		No		Not in a scope of radioactive materials

48.	Is the lab/room air regularly checked for microbial contamination?	Yes		Fumigation is following as per the SOP for production areas especially Cleanroom and Microbiology Lab when commissioned.	This will be ensured once in a Year and after completion of any civil work for cleanroom For lab, monthly fumigation once commissioned.
49	Are there any odor control measures in place?		No		Not in scope of work under the Project, hence not applicable.
50.	Are fume hoods and exhausts regularly checked and maintained?	Yes		HEPA filter	ISO 7, 8 & 5 clean rooms are maintaining, As per maintenance
51.	Does the grantee use DG set > 15 KVA?		NO		As there is minimal power failures and only single shift of operation DG is not installed there is a Plan to install 150 KVA DG set during the Project.
	Does the grantee have consent for DG > 15 KVA?		No		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		No		
52.	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		Authorized local vendors are collecting the waste	This process will be carried on 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 treated separately	This treatment shall be maintained with proper checks and balances.
	Are there sludge management and cut off drains in place for wastewater?		No		
54.	Are necessary provisions for noise cancellation in place?	Yes		All noises within approved limits	During yearly maintenance of AHU record will be generated
55.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	Factory is an approved Industrial land provided by Karnataka industrial development board, with the industrial area developed by KIADB with adequate buffer zones.	Area is developed by KIADB (Karnataka industrial development board), Only industries are allowed to operate.
56.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		As required by Karnataka industrial development board plan approval and Factory license approval	Provided as per factory layout plan and will be maintained throughout the Project.

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.