Environmental Health Risk Management Plan (EHRMP)

TTK Healthcare Limited

Proposal entitled: Pilot Clinical Investigation of Rigid Tilting disc TTK Chitra -Titanium Heart Valve Model TC2 - the next version of the highly successful TTK-Chitra Heart Valve, Model TC1

1. Institutional Arrangements

i) Brief description of the proposed activity: Manufacturing of TC2 Heart Valves

The device comprises of three components, frame, disc and the sewing ring. The frame is manufactured using conventional CNC machining techniques from Haynes 25 alloy rods. The disc are fabricated by solid state compaction process from machined Ultrahigh Molecular Weight Polyethylene rods. The suture ring is hand fabricated from knitted polyester cloth. These components are assembled in environment controlled clean room. The devices are packed in custom designed packaging containers and sterilised using ethylene oxide.

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

The manufacturing facility located at Trivandrum operates under the Kerala State Pollution Control Board with the integrated consent number PCB/TVM-DO/ICO(R)/HRT/623/2017 issued on 31/08/2017 (File number PCB/TVM-DO/CO/1775/2006).

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		Factory Manager is responsible to ensure EHS compliance supported by the Maintenance team to identify issues and rectify them in a time-bound manner.	The Factory Manager will be responsible for compliance with Environment Health and Safety policies.
2.	Does the EHS staff handle the following?			Detail documentation is not available	Detailed documentation covering the policies, procedures and records will be prepared
	a) Occupational Health and Safety	Yes			
	b) Waste Management	Yes			
	c) List of consents and regulatory clearances	Yes			
	d) Record keeping of accidents and procedures	Yes			
	e) EHS trainings for staff	Yes			
	f) Environment Management Framework compliance for Innovate in India Project		No		Plan with suitable procedures will be initiated and implemented before the start of the project as per the requirement of Innovate in India project
3.	Is there a reporting	Yes		Covered in ISO 13485 Quality	Review and updates will be

	structure in place regarding EHS issues?			Management Systems documents	done in the existing structure as appropriate.
4.	Are regular EHS trainings provided to staff?	Yes		Training reports as part of QMS. Frequency : Annual training	Detailed SOP for training will be prepared before the start of the project
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		Policy is covered in ISO 13485 QMS.	Detailed SOPs will be prepared before the start of the project
6.	Are the following in place?			All required safety measures are in place to handle occupational health hazards in the heart valve factory.	Proper equipment in place with stock will be made available as per the Organisation'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?			All items are stored in an easily identifiable and secure method under lock and key. Appropriate signs displayed at all places as relevant.	Will be included and audited regularly during internal audit as per ISO 13485 QMS.
	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 preventers, etc. in place and regularly maintained?		No	As per the current factory rules and inspections carried out this was not indicated as being essential However basic fire and safety measures including the fire extinguishers are available inside the factory as per the Factory act.	These would be regularly maintained and audited

				The facility is being regulary audited by the fire and safety department of Govt. of Kerala	
9.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		Clean areas have air handling system as per the clean room requirements. High efficiency particulate air filters are installed in the air handling units of clean rooms to control bioburden in the clean work space. Temp controllers are provided as required for the clean rooms.	This facility at the factory will be monitored periodically and any upgradation/ renovation addressed as appropriate.
10.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Factory manager Frequency (type): Annual	Fire drills will be conducted annually
11.	Are staffs provided with OHS training?	Yes		Factory manager. Annual health checkup is provided for all staff.	Any upgradation in the OHS training required for the factory will be studied and implemented.
Biomedical Waste (BMW)					
12.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?		No	No Biomedical waste is generated as part of this project or from the existing manufacturing facility	
13.	Is there trained staff to handle biomedical waste in the grantee?		No	No Biomedical waste is generated in the facility	Qualified personnel will be consulted as and when required.
14.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		No	since the factory doesnot generates biomedical waste.this section is not applicable	The guidances of SPCB will be reviewed regularly and corrective actions if any will be taken appropriately.
15.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?		No	Yellow: Red White Blue	Since no biomedical waste is generated as part of this project this is not applicable. Will be done accordingly as and when the need arises.
16.	Is the bar code system for the segregated waste in place?		No	Not Applicable in the factory as no biomedical waste is generated.	If any biomedical waste is to be sent out of the premises, a bar code system will be established

17.	Is the biomedical waste being sent to an authorized common BMW facility?		No	Not applicable as no biomedical waste is generated in the facility as part of this project	
18.	Does the grantee have an in-house BMW treatment facility?		No	Not applicable as no biomedical waste is generated in the facility as part of this project	
	Is the treatment facility own (individual)?				
	Is the treatment facility a shared facility in an industrial park?				
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?	Yes		Selective bacterial culture media like Sabouraud dextrose agar and Soyabean casein are prepared in our microbiology lab for clean room air monitoring and product sterility testing. After testing a dedicated system is used for disinfecting the microbiological waste before disposal.	These practices will be monitored during the internal audits and will be followed throughout the project
20.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		A dedicated system is used for disinfecting the microbiological waste before disposal/incineration.	These practices will be monitored during the internal audits and will be followed throughout the project.
21.	Are necessary waste pre-treatment equipment in place?	Yes		Decontamination in microbiology lab is done by autoclaving	All the decontamination practices will be monitored during the internal audits twice annually
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?				
22.	Arechlorinated plastic gloves and bags phased out in the grantee?	Yes		Only latex and nitrile rubber gloves are used in the fatory or laboratory.	These practices will be monitored during the internal audits twice annually
23.	Are grantee's personnel involved in handling BMW provided with regular training?		No	Not Applicable as no biomedical waste is generated in the factory	This policy will be reviewed during management reviews and changes made as appropriate
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	Not Applicable as no biomedical waste is generated in the factory	This policy will be reviewed during management reviews and changes made as appropriate

25.	Is a daily register for biomedical waste maintained including accident reporting record?		No	Not Applicable as no biomedical waste is generated in the factory	This policy will be reviewed during management reviews and changes made as appropriate
26.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	Not Applicable as no biomedical waste is generated in the factory	This policy will be reviewed during management reviews and changes made as appropriate
Hazardous Waste (HW)					
27.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	No		No Hazardous waste is generated as a result of the project or from the manufacturing facility. List of waste produced at the manufacturing facility: 1. Plastic waste: Sold to authorized dealer suggested by the KINFRA authority (Industrial Park authority). 2. Carton & Paper waste of material packing: Sold to authorized dealer suggested by KINFRA. 3. Gaseous Waste: EO & DG Set emission- Stack provided as per the requirements of SPCB. 4. Battery: Returned back to the supplier for recycling at the time of new purchase as per the Manufacturer's policy (Exide). 5. E- waste- Returned back to the Head office at Chennai DG Oil - Collected and is given for recycling though the scrap collector.	No hazardous waste is generated as part of this project. The policy of waste disposal will be reviewed during management reviews and appropriate changes affected.
28.	Is there trained staff in the facility to identify and handle hazardous waste?		No	No Hazardous waste is generated	The policy of waste disposal will be reviewed during management reviews and appropriate changes affected.
29.	Does the grantee have authorization from SPCB for		No	No Hazardous waste is generated	The policy of waste disposal will be reviewed during

	hazardous waste?				management reviews and appropriate changes affected.
30.	Is there a secure location for storage of HW with proper signage?		No	No Hazardous waste is generated	The policy of waste disposal will be reviewed during management reviews and appropriate changes affected.
	Are hazardous waste stored for more than 90 days in the grantee's premises?				
31.	Is the hazardous being sending to an **authorized** disposal facility or user?		No	No Hazardous waste is generated	The policy of waste disposal will be reviewed during management reviews and appropriate changes affected.
	Is the disposal facility in house?				
	Is the disposal facility external/outsourced?				
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?		No	No Hazardous waste is generated	The policy of waste disposal will be reviewed during management reviews and appropriate changes affected.
E-Waste and Batteries					
33.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		Minimal e waste from office use only like laptops and desktops. These are sent back to Central System Dept at HO, Chennai. No electrical or electronic equipment or batteries are manufactured in the facility.	This process of disposing the minimal e-waste generated will be regularly followed throughout the Project.
34.	Has the grantee obtained SPCB authorization on e-waste?		No	Not Applicable as the e-waste generation is minimal and whatever is generated is processed through the organizations centralized e-waste processing	This policy process will be monitored and reviewed throughout the Project with appropriate corrections.
35.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?	Yes		Processed through the organizations centralized e-waste processing	This process will be followed throughout the Project.
36.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Not Applicable as the e-waste generation is minimal	Not Applicable as the e-waste generation is minimal

37.	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 as no electrical or electronic equipments or components are manufactured in the facility.	Not Applicable as no electrical or electronic equipments or components are manufactured in the facility
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?		No	Not Applicable as no electrical or electronic equipments or components are manufactured in the facility.	Not Applicable as no electrical or electronic equipments or components are manufactured in the facility.
39.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	Very limited number of computers and lap tops used for the office administration purposes Sent back to Central System Dept at HO, Chennai. Records of these transfers are maintained.	This practice will be regularly followed throughout the Project.
40	Does the grantee submit annual reports on e-waste to SPCB?		No	Not Applicable as the e-waste generation is minimal and its processing at the Central System Dept at HO	This practice will be regularly followed throughout the Project
41	Is there accident reporting and records in place?	Yes		A form for reporting accidents and associated follow up actions is in place confirming to ISO 13485 Quality Management System	The adequacy of this procedure will be monitored during the Quality Management reviews and corrections incorporated as appropriate
42	Are PPEs available to staff?	Yes		PPEs are provided as part of ISO 13485 Quality Management System	Any change required in the PPEs will be reviewed and corrections incorporated as appropriate.
43	Is the grantee involved in manufacture of batteries?		No	Grantee NOT involved in the manufacture of batteries.	- Disposal of minimal battery waste will be regularly monitored when required during the project
44	Does the grantee generate battery waste?	Yes		Batteries used for inverters and generator are Exchanged at the time of purchase of new batteries.	Disposal of minimal battery waste will be regularly monitored when required during the project
45	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/	Yes		Exchanged at the time of purchase of new battery from registered dealer.	This policy will be reviewed periodically and any changes required will be incorporated

	reconditioned/collection center?				
46	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	Not Applicable as the grantee not involved in the manufacture of batteries	Disposal of minimal battery waste will be regularly monitored when required during the project
Others					
47.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		No	No radioactive materials are used in the factory.	Grantee is NOT using any radioactive materials in the factory. Hence no monitoring mandated
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	No radioactive materials are used	Since no radioactive materials are used in the factory monitoring is not mandated
	Are radioactive warning signs in place?		No	No radioactive materials are used in the factory. Hence, not applicable.	Since no radioactive materials are used in the factory this is not applicable
48.	Is the lab/room air regularly checked for microbial contamination?	Yes		Microbial count is checked on a weekly basis in clean rooms and laminar flow benches.	Control charts will be maintained for clean rooms and laminar flow benches. Corrective actions will be initiated based on the control level of microbial contamination. Disinfection and fumigation are the routine measures used for decontamination
49	Are there any odour control measures in place?		No	No odour generating chemicals are employed in the factory.	Will put up proper measures in place as and when the need arises.
50.	Are fume hoods and exhausts regularly checked and maintained?		No	No fume hoods are used. Laminar Flow Bench in microbiology lab and clean rooms are regularly checked and maintained under a preventive maintenance protocol	The Preventive Maintenance activities will be monitored during the course of the project.
51.	Does the grantee use DG set > 15 KVA?	Yes		Covered under pollution control board certificate. DG set is covered under AMC through the manufacturer	The consent shall be maintained through proper renewal application made within timeline
	Does the grantee have consent for DG > 15 KVA?	Yes			
	Are emissions from boilers and DG sets regularly monitored to be within the	Yes			

	prescribed norms?				
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		Sorted disposal management system maintained & disposed through authorized person	Periodic inspection is performed on handling and disposal of solid plastic waste is made part of the internal audit
53.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Microbiological lab waste comprising of media for microbes (specified in point no.19) is disposed after disinfecting the used media.	All the decontamination practices will be monitored during the internal audits twice annually
	Are there sludge management and cut off drains in place for wastewater?	Yes		Sewage system maintained as per regulatory guidelines by the KINFRA industrial park authorities.	Regular verification of the system for any maintenance/repair will be carried out during the project period
54.	Are necessary provisions for noise cancellation in place?	Yes		The noise cancellation systems are installed for the electric power generators. No other major noise generating equipments are installed in the factory	Will put up proper measures in place as and when the need arises.
55.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	The factory is located inside in an industrial park zone. Project implementation will not cause any adverse destruction /alteration in surrounding ecosystem	No Eco-sensitive areas near the factory premises hence monitoring is not mandated
56.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Buffer zones and fire vehicle routes are maintained in the industrial zone of KINFRA and within the premises of the factory	The existing fire vehicle routes will be monitored for free access.

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.