IntEssence Solutions Private Limited

Proposal entitled: Enable the advancement of novel dental implant system to a market leading product offering

- i) Brief description of the proposed activity:
 Manufacturing of Dental implants as approved by CDSCO
- ii) List of environments related regulatory clearances required for the activity.
 - -Industry and type of operation is considered under 'White' category, by Karnataka pollution control board. This category does not require a clearance on consent for manufacture from the board.

		Yes	No	Details	Proposed Plan			
	Institutional Arrangement							
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	X		One of the directors, takes charge of this profile	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? Occupational Health and Safety Waste Management List of consents and regulatory	X X X		EHS staff handle all the mentioned responsibilities	The concerned staff will be trained as per the Environment Health and Safety (EHS) Rules.			
	clearances Record keeping of accidents and procedures EHS trainings for staff	X X		_	We will comply to Environment Management Framework			
	Environment Management Framework compliance for Innovate in India Project	X			compliance for Innovate in India Project			
3.	Is there a reporting structure in place regarding EHS issues?	X		Reporting structure in place regarding EHS issues Reports to Management	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?		X		Will be incorporated in the training plan with frequency.			
5.	Institutional Bio-Safety Committee (IBSC)		X	The company is not engaged in the field of use of Genetically Modified Organisms (GMOs) and products thereof in research and application to the users as well as to the environment				
6.	Ethics Committee (EC)		X	The company on its own does not engage in medical experimentation and human	Whenever there is a need for medical experimentation and human subject research, the			

					Ethics committee of the respective institutes will be approached and necessary approvals taken
Gene	eral 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.)?		X		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 be ensured.
8.	Are the following in place?			No hazardous chemical used	Compliance with relevant
	Chemical spill kits		X	and hence no need for	items be ensured as and
	Eye wash		X	_chemical spill kits, eye wash	
	Shower stations		X		hazardous chemicals
	First Aid Kit	X			produced during the project.
	Fire Extinguishers	X		_	
	Register of accidents and injuries	X			Proper equipment will be in place and stock will be maintained as per the Institute's guidelines for Environment Health and Safety (EHS).
9.	Are proper signage and storage system in place?			•	These would be regularly updated/ replaced while
	Display of Material Safety Data	X			carrying out maintenance.
	Sheet (MSDS) where relevant	1			carrying out mamienance.
		X			Display of emergency numbers and procedures
	critical places				will be ensured.
	Signage across the facility (labs, storage, hazardous areas, etc.)	X			
	Are flammable materials appropriately stored to prevent fire hazards?	X			
10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?		X	causes substantial fire	We will establish fire safety equipment's as per the requirement of the project
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	X		Thermostats and temperature indicators in dryers and cleaning station	This would be reviewed periodically.
12.	Are regular mock drills conducted for emergency preparedness and safety?		X		Will be incorporated in the SOP
13.	Are staff provided with OHS training?		X		Will be incorporated in the training plan
					rraining nian

14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	X	facility	
15.	Is there trained staff to handle biomedical waste in the grantee?	X	We don't generate bio	Will plan for the training as and when needed during the ongoing Project.
	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		Not Applicable as there is no generation of effluents and the applicable medical device industry comes under white category	Authorization will be obtained if required
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	X	We don't generate bio medical waste in our activity	Will follow if Bio medical waste generated
18.	Is the bar code system for the segregated waste in place?	X	We don't generate bio medical waste in our activity	Will follow if Bio medical waste generated
19.	Is the biomedical waste being sent to an authorized common BMW facility?	X	We don't generate bio medical waste in our activity	Will propose a plan and provide a facility if needed during the Project.

20	Doog the greates have an in house	W	Wa dan't can and - 1-:-	1
20.	Does the grantee have an in-house	X	We don't generate bio	
	BMW treatment facility?		medical waste in our	
	Is the treatment facility own	X	activity	
	(individual)?		_	
	Is the treatment facility a shared	X		
	facility in an industrial park?			
21	A 11	**	XX7 1 24 4 1 :	XX'11 C 11 'C D' ''
21.	Are lab waste, microbiological waste and	X	We don't generate bio	Will follow if Bio medical
	chemical liquid waste pre-treated before		medical waste in our	waste generated
	storing and sending to treatment facilities		activity	
	according to guidelines prescribed in			
22	BWM, 2016 regulations? Is the liquid waste checked for active cells	X	We don't generate bio	Will follow if Bio medical
22.	before sending to treatment plant?	Λ	medical waste in our	waste generated
	before sending to treatment plant:		activity	waste generated
23.	Are necessary waste pre-treatment	X	We don't generate bio	Will follow if Bio medical
25.	equipment in place?	,	medical waste in our	waste generated
	-qu-p-ment in place.		_activity	, aste generated
	Do the equipment adhere to prescribed	X		
	norms by State Pollution Control Board			
	(SPCB)?			
24.	Are chlorinated plastic gloves and bags	X	We don't generate bio	Will follow if Bio medical
	phased out in the grantee?		medical waste in our	waste generated
			activity	
25.	Are grantee's personnel involved in	X	We don't generate bio	Will follow if Bio medical
	handling BMW provided with regular		medical waste in our	waste generated
	training?		activity	
26.	Are medical examination provided to	X	We don't generate bio	Will follow if Bio medical
	personnel involved in BMW waste		medical waste in our	waste generated
	handling and are they provided		activity	
	with relevant immunization like Hepatitis			
27	B and Tetanus? Is a doily register for biomedical yeasts	X	Wa dan't ganamta hia	Will follow if Bio medical
27.	Is a daily register for biomedical waste maintained including accident reporting	A	We don't generate bio medical waste in our	
	record?		activity	waste generated
28.	Are annual reports on BWM submitted to	X	We don't generate bio	Will follow if Bio medical
۷٥.	SPCB as per required form (see Bio-		medical waste in our	waste generated
	Medical Waste Rules 2016)?		activity	wasie generated
H279	ardous Waste (HW)		µCH VILY	
29.	Is there generation of hazardous waste (as	X	If No, provide a list of	In future, if any of the
	per Hazardous Waste Rules, 2016) in the	,	all waste produced in the	activities need
	grantee?		facility	Environmental policies or
			List of all waste produced	permissions, it will be done
			in the facility:	by approaching the
			1) Housekeeping wastes-	concerned authorities and
			rags, paper, plastics,	guidelines.
			disinfectants	
			2) Packaging- paper,	
			cardboard, plastic,	
			wraps, foam, wood 3) Cleaning medium-	
			3) Cleaning medium- Detergent based: After	
		1	Detergent based: After	

30.	3	X		neutralizing. IPA for disinfection that is either reclaimed or naturally evaporated 4) used abrasive 5) Gloves, masks, hair and shoe covers, used in clean room for product assembly/ packing 6) Scrap components and consumables-Metallic-Titanium, Steel Non Metallic: Plastics-PC, TPE, Silicone, PSU, PET, PVC, etc. Coated paper, paper, labels, stickers 7) Used batteries/ wire/ plastic parts from laptops/ desktops Director responsible for	Will train staff if Hazardous
	identify and handle hazardous waste?			EHS will oversee the identification	waste generated
31.	Does the grantee have authorization from SPCB for hazardous waste?		X	We don't generate Hazardous waste in our activity	Authorization will be obtained if required
32.	Is there a secure location for storage of HW with proper signage?		X	We don't generate Hazardous waste in our	Will follow if Hazardous waste generated
	Are hazardous waste stored for more than 90 days in the grantee's premises?		X	- activity	
33.	Is the hazardous being send to an authorized disposal facility or user? Is the disposal facility in house?		X X	We don't generate Hazardous waste in our activity	Will dispose hazardous wastes to authorized disposal facility if generated
	Is the disposal facility external/outsourced?		X		
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?		X	We don't generate Hazardous waste in our activity	We will maintain the register if hazardous wastes generated
	aste and Batteries	T			
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	X		Used computers/ printers/ batteries	
36.	Has the grantee obtained SPCB authorization on e-waste?		X		Necessary Authorizations will be taken if required

37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	X		Used computers/ printers/ batteries are given to authorized recyclers	
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		X		Will follow if required
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		X		Will follow if required
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?		X		Will follow if required
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		X		Will follow if required
42.	Does the grantee submit annual reports on e-waste to SPCB?		X		Will follow if required
43.	Is there accident reporting and records in place?		X		Will follow if required
44.	Are PPEs available to staff?	X			The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		X	Manufacturing of batteries is not in our activity	
46.	Does the grantee generate battery waste?	X		Used batteries are generated	
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditione r/collection center?				Will give the used batteries to recyclers when ever generated
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		X		Will follow if required
Com	munity Health and Safety and risk mitig	ation			
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)		X		Will propose a plan and provide an arrangement if needed during the Project.
50.	Emergency preparedness and participation of local authorities and potentially affected communities		X		Emergency preparedness plan will be made and this topic will be inserted in the plan
<u> </u>			1		Employees will be trained a

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			T		per plan			
Othe	Others							
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		X		we don't use radioactive material			
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		X		If we use, then we will arrange for proper storage and disposal			
	Are radioactive warning signs in place?		X		Will be implemented if required			
52.	Is the lab/room air regularly checked for microbial contamination?	X		Monitored at regular intervals as per SOP and reaction plan exists	Periodic checks will be done			
53.	Are there any odor control measures in place?	X			Periodic cleaning will be done			
54.	Are fume hoods and exhausts regularly checked and maintained?	X		Maintained as per maintenance schedule	Periodic cleaning of exhausts will be done			
55.	Does the grantee use DG set > 15 KVA?		X	Not applicable since there is no Gen set in the premises				
	Does the grantee have consent for DG > 15 KVA?		X					
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		X					
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?	X		of local municipality	It will be ensured that segregation rules are followed. This will be maintained and monitored by an authorized Committee.			
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	X		for cleaning that is mixed with water is brought down to PH 8 prior to disposal	Periodic checks will be done and the treatment plant shall be maintained			
	Are there sludge management and cut off drains in place for wastewater?		X		Will be implemented when needed			
58.	Are necessary provisions for noise cancellation in place?		X	Not applicable. Since DB is less than permissible levels of 80				
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		X		Since, no water bodies or cultivable land nearby, no environmental risk.			
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	X			In future, if required, fire tender movement route will be defined whenever required.			

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.