MAHARASHTRA POLLUTION CONTROL BOARD

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LETTER OF BIO-MEDICAL WASTE AUTHORISATION

[Authorisation for of Bio-Medical Wastes under See Rule 10]

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transport and disposal of biomedical waste)

I. File number of authorisation and date of issue
MPC/SRN-I/BMW/2006000130 **Dtd:- 12/06/2020**

II. **M/s. Shantimohan Hospital** is hereby granted an authorisation for generation of biomedical waste on the premises situated **at Poorvi Enterprises, 1st floor, Opp. Saraf Chamber, Sadar, Nagpur., DIST-NAGPUR.**

III. This authorisation shall be in force for a **period up to 31/03/2023**. an application shall be made by the occupier/operator for renewal **3 months** before expiry of earlier authorisation.

IV. This authorisation is issued subject to compliance of the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Environment (Protection) Act, 1986.

V. No of Beds: **25 beds.**

Maharashtra Pollution Control Board Sub Regional Office-I NAGPUR

Terms and Conditions of authorisation

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.

2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorized by the prescribed authority.

3. The personal authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.

4. Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorization.

5. It is the duty of the authorized person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.

6. The authorisation is granted for generation of Bio-Medical Waste (BMW) in waste categories and quantities listed here in below :

Sr. No.	Category	Type of Waste	Quantity Generated or Collected, Kg/Day	Method of Treatment and Disposal (Refer Schedule-I)
1	Yellow	a) Human Anatomical Waste	15	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
		b) Animal Anatomical Waste	--	
		c) Soiled Waste		
		d) Expired or Discarded Medicines	--	
		e) Chemical Solid Waste	60	
		f) Chemical Liquid Waste	70	
		g) Discarded Linen, Mattresses, beddings contaminated with blood or body fluid.	1	
		h) Microbiology, Biotechnology and other clinical laboratory waste		
2	Red	Contaminated Waste (Recyclable)	--	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
3	White (Translucent)	Waste Sharps including Metals	16	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
4	Blue	Glassware	---	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
		Metallic Body Implants		

7. The liquid/solid waste generated from the treatment activity (from laboratory and washing, cleaning, housekeeping and disinfecting activities) shall be treated suitably by providing effluent treatment facility to conform the standards prescribed in Schedule II of said Rules and the Environment (Protection) Act, 1986.
8. (i) BMW shall be treated and disposed of in accordance with Schedule I and in compliance with the standards prescribed in Schedule II of said Rules.

(ii) You shall setup requisite BMW, treatment facilities like incinerator, autoclave / Microwave, shredder etc., at the disposal side in accordance with the BMW rules 2016. You shall disposed of the duly treated BMW and incineration ash in secured land fill site at your own premises / at MSW secured land fill site of Municipal Council authorized by MPCB and duly earmarked for disposal of treated BMW / at common H.W. treatment & disposal facility setup as per the Hazardous Waste (M.&.TM) Rules, 2016 as amended and authorized by MPCB.

9. (i) BMW shall not be mixed with other wastes or reused, recycled or sold in any form.

(ii) BMW shall be segregated into containers / bags at the point of generation in accordance with Schedule-I prior to storage, treatment and disposal. The containers shall be labeled according to Schedule IV- Part-A.

(iii) If a container containing BMW is to be transported from the premises where BMW is generated to any waste treatment facility outside the premises, the container shall, apart from the Label prescribed in Schedule IX, also carry information prescribed in Schedule IV Part B and shall be transported by authorized Transporter only.

(iv) Notwithstanding anything contained in the Motor Vehicles Act, 1988 or Rules there under, BMW shall be transported only in such vehicle as may be authorized for the purpose by the competent authority as specified by the Government.

(v) Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty- eight hours.

Provided that in case for any reason it becomes necessary to store such waste beyond such a period, the occupier shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and inform the prescribed authority along with the reasons for doing so.

(vi) Microbiology waste and all other clinical laboratory waste shall be pre-treated by sterilisation to Log 6 or disinfection to Log 4, as per the World Health Organisation guidelines before packing and sending to the common bio-medical waste treatment facility.

10. **Standards for waste autoclaving:**

The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste,

(I) When operating a gravity flow autoclave, medical waste shall be Subjected to:

(i) a temperature of not less than 121 C° and pressure of 15 pounds per Square inch (psi) for an autoclave residence time of not less than 60 minutes; or

(ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or

(iii) a temperature of not less than 149 C° and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.

(II) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air. The waste shall be subjected to the following.

(i) a temperature of not less than 121 C° and a pressure of 15 psi for an autoclave residence time of not less than 45 minutes; or

(ii) a temperature of not less than 135 C° and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes; or

(III) Medical waste shall not be considered properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure were reached during the autoclave process. If for any reasons, time temperature or pressure indicates that the required temperature, pressure or residence time was not reached, the entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved.

(IV) *Recording of operational parameters*,- Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.

(V) *Validation test: Spore testing*. – The autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be Bacillus stearothermophilus spores using vials or spore strips, with at least 1x 10^4 spores per milliliter. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 121 C° or a pressure, less than 15 psi.

(VI) Routine Test.—A chemical indicator strip/tape that changes color when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more that one strip over the waste package at different location to ensure that the inner content of the package has been adequately autoclaved.

11. Every 'Authorized Person' shall submit an Annual Report to the prescribed authority in Form-IV by 31st January every year including information about the categories and quantities of BMW handled during the preceding year.

12. (i) Every 'Authorized Person' shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of BMW for period of 5 years in accordance with these Rules and any guidelines issued.

(ii) All records shall be subject to inspection and verification by the prescribed authority at any time.

13. Accident reporting – 1) In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorized person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I.

2) Information regarding all other accidents and remedial steps taken shall be provided in the annual report in accordance with rule 13 by the occupier.

14. You shall submit total Bank Guarantee of Rs. 1,50,000/- valid up to validity of this authorization, in favour of Regional Officer, M.P.C. Board, Nagpur within 15 days. Specific conditions with Bank Guarantees along with time bound programme for compliance as per Board's circular no MPCB/PSO/BMW/B-1825 dtd 10/04/2013 is as follows-

Sr. No.	Activity/Condition to be Complied	Compliance Timeline (Months)	Amount of Bank Guarantee (Rs)
I(A)	**Operation and Maintenance**		
1	To segregate and Handle BMW as per rule	Continuous	25,000
2	Operation and Maintenance of ETP to achieve prescribed discharged standards.	Continuous	25,000
I(B)	**Records**		
1	To Maintain records of BMW and submission of Annual Report in Form-II before 31st January	Continuous	15,000
2	To Maintain records of BMW material received / delivered to authorized party / CBMWTSDF (Transporters only)	Continuous	10,000
II	**Performance**		
1	To provide Separate BMW storage facility	Six	25,000
2	Effluent treatment plant not provided / need up gradation	Six	50,000
		Total	1,50,000/-
	Rupees One Lakh Fifty Thousand only		

15. **You shall submit compliance of each Bank Guarantee conditions every six months to Regional Officer, Nagpur for verification purpose.**

16. **Ensure treatment and disposal of liquid waste in accordance with Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974) and comply Bio-Medical Waste Management Rules 2016.**

17. **Conditions for D.G. Set**

a. Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.

b. Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/ acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards, whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.

c. The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise not less than 55 dB(A) during day time and 45 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.

d. Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper sitting and control measures.

e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.

f. A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use

g. D.G. Set shall be operated only in case of power failure

h. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. set.

18. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.

19. Hospital shall comply Maharashtra plastic and Thermocol Products (Manufacture, Usage, Sale, Transport, Handling and Storage) Notification, 2018.

For and on behalf of the
Maharashtra Pollution Control Board

(Hema Deshpande)
Sub-Regional Officer-I
M.P.C. Board, Nagpur.

Maharashtra Pollution Control Board Sub Regional Office-I NAGPUR

To
DR. SANJAY SHANTILAL JAIN,
M/s. Shantimohan Hospital,
Poorvi enterprises, 1st floo, Opp.
Saraf Chember, Sadar, Nagpur, DIST-NAGPUR.

Sr. No.	Amount	D.D. No.	Date
1.	3750.00	TXN1912001846	20-12-2019