MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 25802272
Fax : 25805398
Email : srothane2@mpcb.gov.in
Visit At : http://mpcb.gov.in

Sub-Regional Office, Thane-I
5th Floor, Office Complex
Bldg., Near Mulund Check
Naka, Wagale Estate,
Thane-400 604

LETTER OF BIO-MEDICAL WASTE AUTHORISATION

[Authorization for Generation of Bio-Medical Wastes under Rule 7(4)]

I. File number of authorization and date of issue
MPCB/SRO-THANE I/BMW_ Ren. AUTH/2207000140 Date : 08/07/2022

II. M/S SANTATI TEST TUBE BABY AND FERTILITY CENTRE is hereby granted an authorization for generation of biomedical waste on the premises situated at. Dev Corpora, 1st floor, B-wing, Office No. 110 & 111, 1st Floor, A-wing, office No. 103, Cadbury Junction, Thane (W).

III. This authorization shall be in force for a period up to **31/08/2025**. An application shall be made by the occupier/operator for renewal **3 Months** before expiry of earlier authorization.

IV. This authorization 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: **04**

Terms and Conditions of authorization

1. The authorized Person shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.
2. The authorization shall be produced for inspection at the request of an officer authorized by the prescribed authority.
3. i) The authorized person shall not rent, lend or sell the biomedical waste or facility.

   ii) The authorized person can transfer the BMW generated at above premises to the "Transporter" or "Operator of Facility" authorized by MPCB under Bio-Medical Waste (Management and Handling) Rules, 2016 for collection, transportation, treatment and/or disposal of BMW generated.
4. Any unauthorized change in 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.

Maharashtra Pollution Control Board S.R.O. THANE I

08/07/2022

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 Kg/M	Treatment & Disposal
1	Yellow	a. Human Anatomical Waste	03	Bio medical waste shall be sent to Common BMW Treatment & Disposal facility authorized by MPCB.
		b. Animal Anatomical Waste	--	
		c. Soiled Waste Items contaminated with Blood, body fluids like dressings plaster casts cotton swabs	02	
		Solid Waste	1	
		d. Expired of Discarded medicines	01	
		e. Chemicals waste	--	
		f. Chemical Liquid Waste	300 Lit/M	
		g. Discarded Linen, Mattresses, bedding contaminated with blood or body fluid	--	
		h. Microbiology, Biotechnology and other Clinical Laboratory Waste	--	
2	Red	Contaminated Waste (Recyclable) tubing, Bottle, IV etc.	--	
3	White (Translucent)	Waste Sharps including metals	01	
4	Blue	Glassware	--	
		Metallic Body Parts	--	

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 V 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 V 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. 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 & H) 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.

disposal facility setup as per the Hazardous Waste (M & H) 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-II prior to storage, treatment and disposal. The containers shall be labeled according to Schedule III.

(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 III, also carry information prescribed in Schedule IV 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) No untreated BMW shall be kept stored beyond a period of 48 hours.

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.

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-II 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 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. When any accident occurs at any institution or facility or any other site where BMW is handled or during transportation of such waste, the authorized person shall report the accident in Form III to the prescribed authority forthwith.

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

15. The authorization is issue as a generator by joint CBMWTDF at Thane and subject to condition that the BMW is send to Common facility regular.

16. The Hospital authority shall obtain Certificate of registration from Corporation under section - IV of the Bombay Nursing Home Registration Act, 1949, Amendment 2006.

17. This is issued with the pursuant to the office order issued vide No. MPCB/PSO/B-881 dtd. 01.03.2014.

18. The applicant shall obtain consent under the provision of Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Pollution) Act, 1981.

19. The applicant shall obtain & submit permission/ NOC from Central Ground Water Authority (CGWA) Government of India for Abstraction/ Use of Ground Water.

20. The applicant shall comply with the provision of E-Waste Management Rules, 2016.

21. HCEs shall preferably handover Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc. to the Pharmaceutical industry/ Biotechnology firms for production of drugs, reagent chemicals, markers, etc., if any such Pharmaceutical

21. HCEs shall preferably handover Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc. to the Pharmaceutical industry/ Biotechnology firms for production of drugs, reagent chemicals, markers, etc., if any such Pharmaceutical industry/ Biotechnology firms approached then for the same. If there are any difficulties in the matter, the same may be communicates to such firm and copied to the Board also.

22. HCEs shall strictly follow the procedure for packaging & transportation of Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc. to the Pharmaceutical industry/ Biotechnology firms as per the guidelines of CPCB published in Feb-2019 for "Handling of BMW for utilization".

23. HCEs shall submit the report to the Board office about type, quantity and frequency of handling over such BMW on yearly basis.

24. Industry to enter into legal agreement with HCE's and inform the MPC Board and competent authority of State Public Health Department about such collection of BMW along with quantity and type of waste collected.

25. In case of any technical difficulty towards handing over the required BMW then, you shall inform to the Board accordingly.

26. HCEs shall properly dispose & handover the waste to authorized user/ facilities having valid consent to operate from MPCB.

27. **This BMW Authorization is issued with condition to submit New CTF (MWML) & Annual report form IV within a month from date of issue of authorization.**

For and on behalf of the
Maharashtra Pollution Control Board

Maharashtra Pollution Control Board S.R.O. THANE I

08/07/2022

(Shakil Shaikh)
Sub Regional Officer, Thane-I

To,
M/S SANTATI TEST TUBE BABY AND FERTILITY CENTRE,
at. Dev Corpora, 1st floor, B-wing, Office No. 110 & 111,
1st Floor, A-wing, office No. 103,
Cadbury Junction, Thane (W).

Authorization Fees Received:-

Sr. No.	Amount	DR No. / Transaction No.	Date	Bank Name
1	--	--	--	--

Copy submitted to:

1. Chief Accounts Officer, MPCB, Sion, Mumbai
2. Regional Officer, M.P.C. Board, Thane

Copy to : Master file- 2022