MAHARASHTRA POLLUTION CONTROL BOARD

Sub-Regional Office KALYAN-III

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LETTER OF BIO-MEDICAL WASTE AUTHORISATION

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

I. File number of authorization and date of issue
SRO-KALYAN III//BMW_AUTH/ 2007000418 **Dtd.** 25/06/2021

II. SHREE CLINICAL LAB MURBAD is hereby granted an authorization for generation of biomedical waste on the premises situated 06/GR FLOOR- B -Wing Sri Vishwa Apt. OPP-GOV Rest House Mhasa Road, Tal. Murbad, Dist. Thane. This authorization shall be in force for a period up to **28.02.2023** An application shall be made by the occupier/operator for renewal **3 Months** before expiry of earlier authorization.

III. 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 and **Bio-Medical Waste Management Rules, 2016 vide Notification dated 28 March, 2016.**

IV. No of Beds: 1

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, 1998 for collection, transportation, treatment and/or disposal of BMW generated.

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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.

6. The authorization 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 Kg/M	Type of Bag or Container to be used	Treatment & Disposal option
1	Yellow	(a) **Human Anatomical Waste:** Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).	9	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial* Or Bio medical Waste shall be sent to CBMWTSDF authorized by MPCB.
2	Yellow	(b)**Animal Anatomical Waste :** Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.	-	Yellow coloured non-chlorinated plastic bags	
3	Yellow	(c)**Microbiology, Biotechnology and other clinical laboratory waste:** Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.	-	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organization or World Health Organization guidelines thereafter for Incineration. Or Bio medical Waste shall be sent to CBMWTSDF authorized by MPCB.
4	White	**Waste sharps including Metals:** Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or	12	Puncture proof, Leak proof, tamper	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete;

		any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps		proof containers	combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit. Or Bio medical Waste shall be sent to CBMWTSDF authorized by MPCB.
5	Yellow	(d) **Expired or Discarded Medicines**: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	-	Yellow coloured non-chlorinated plastic bags or containers	Expired `cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration. Or Bio medical Waste shall be sent to CBMWTSDF authorized by MPCB.
6	Yellow	(c) **Soiled Waste**: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components.	12	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery. Or

					Bio medical Waste shall be sent to CBMWTSDF authorized by MPCB.
7	Yellow	(f) **Chemical Liquid Waste:** Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	1.5	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III. Or Bio medical Waste shall be sent to CBMWTSDF authorized by MPCB.

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 incompliance 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, 1989 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) Not with standing 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.

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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 than 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 issued subject to HCE shall renew the membership of CBMWTSDF & Certificate under Bombay Nursing Act time to time.

For and on behalf of the
Maharashtra Pollution Control Board

25.6.21

(Devidas Koparkar)
(Sub-Regional Officer, Kalyan III)

To,
SHREE CLINICAL LAB MURBAD
06/GR FLOOR- B -Wing Sri Vishwa Apt.,
OPP-GOV Rest House, Mhasa Road,
Tal. Murbad, Dist. Thane.

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Authorization Fees Received:-

Sr. No.	Amount	Transation number	Transation date	Drawn On
....	....	....	....	....

Copy Submitted to:-
1. Chief Accounts Officer, MPCB Board Mumbai
2. Regional Officer (HQ), MPCB, Sion Mumbai.