

MAHARASHTRA POLLUTION CONTROL BOARD

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LETTER OF BIO-MEDICAL WASTE AUTHORISATION [Authorization for of Bio-Medical Wastes under See Rule 10]

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

I. File number of authorization and date of issue

RO-NASHIK/BMW_AUTH/200100430

Date: -22/01/2020

- II. M/s. Rainbow Mother and Child Care Unit Pvt Ltd is hereby granted an authorization for generation of biomedical waste on the premises situated at St. No.615/32, Plot no.105-A, Shree Hari Kute Marg, Behind Kalika Mandir, Mumbai Naka, Nashik
- III. This authorization shall be in force for a period from 31.03.2021. 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: 30 beds. (As per NOC submitted by Nashik Municipal Corporation)

Terms and Conditions of authorization

1. The "authorized Person" Dr. Pratima Tarun Kanade of M/s. Rainbow Mother and Child Care Unit Pvt Ltd, shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.
2. The authorization 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 authorization is granted for generation of Bio-Medical Waste (BMW) in waste categories and quantities listed here in below :

Pratima Kanade



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	50.0 Kg/Month	Bio-medical Waste shall be sent to CBMWTSDF authorized by MPCB
		b) Animal Anatomical Waste	--	
		c) Soiled Waste	50.0 Kg/Month	
		d) Expired or Discarded Medicines	10.0 Kg/Month	
		e) Chemical Solid Waste	---	
		f) Chemical Liquid Waste	---	
		g) Discarded Linen, Mattresses, beddings contaminated with blood or body fluid.	---	
		h) Microbiology, Biotechnology and other clinical laboratory waste	---	
2	Red	Contaminated Waste (Recyclable)	--	Bio-medical Waste shall be sent to CBMWTSDF authorized by MPCB
3	White (Translucent)	Waste Sharps including Metals	10.0 Kg/Month	Bio-medical Waste shall be sent to CBMWTSDF authorized by MPCB
4	Blue	Glassware	---	Bio-medical Waste shall be sent to CBMWTSDF authorized 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 & Other Wastes (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 sterilization to Log 6 or disinfection to Log 4, as per the World Health Organization 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 1×10^4 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. This authorization is issued subject to condition as mentioned below.
 - i) You shall submit compliance of authorization conditions every six months to Sub-Regional Office Nashik.
 - ii) You shall provide Annual report in Form-II duly certified by facility operator.
 - iii) You shall obtain Consent to Operate from Board under Water (P &CP) Act, 1974 and Air (P &CP) Act, 1981, forthwith.
 - iv) The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.
 - v) The Hospital shall not carry any expansion, change, Addition, Modification, and Modernization in the existing set up till to obtain prior permission from the Board.
15. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.
16. The Hospital Authority shall furnish Bank Guarantee of ₹. 50000/- towards BMW segregation and Handling as per BMW Rules & towards O & M of ETP to achieve prescribed discharge Standards having validity for 1 year period drawn in favor of Regional Officer, MPCB, Nashik shall be furnished within 15 days from date of issuance of the Authorization.
17. The Hospital Authority shall furnish Bank Guarantee of Rs.75,000/- having validity up to 30.06.2021 drawn in favor of Regional Officer, MPCB, Nashik towards compliance of conditions of authorization within 15 days from date of issuance of the authorization as per Circular of MPCB, HQ, Mumbai vide letter.No.MPCB/PSO/BMW/B-1825. dtd.10.04.2013.

For and on behalf of the
Maharashtra Pollution Control Board


(Dr. J.B. Sangewar)

Regional Officer, Nashik.

To
M/s. Rainbow Mother and Child Care Unit Pvt Ltd,
Sr. No.615/32, Plot no.105-A,
Shree Hari Kute Marg, Behind Kalika Mandir, Mumbai Naka, Nashik

Authorization Fees Received:-

Sr. No.	Amount	Transaction No.	Transaction Date
1	7500/-	TXN2001000201	02.01.2020