

ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿ
ಪ್ರಾದೇಶಿಕ ಕಛೇರಿ: ಬೆಂಗಳೂರು ನಗರ ವಿಭಾಗ-ದಕ್ಷಿಣ
ನಿಸರ್ಗ ಭವನ, 1ನೇ ಮಹಡಿ, 7ನೇ ಮುಖ್ಯ ರಸ್ತೆ
ಪುಷ್ಪಾಂಜಲಿ ಚಿತ್ರಮಂದಿರದ ಮುಂಭಾಗ
ಶಿವನಹಳ್ಳಿ, ತಿಮ್ಮಯ್ಯ ಮುಖ್ಯರಸ್ತೆ,
ಬೆಂಗಳೂರು-560010, ಕರ್ನಾಟಕ, ಭಾರತ
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Karnataka State Pollution Control Board

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(This document contain 07 pages)

Auth. No: KSPCB/RO: B.C. South/BMW/EO/DEO/AEO/2021-22/556

Date: 16 MAR 2022

FORM -III (See rule 10)

(AUTHORIZATION FOR OPERATING A FACILITY FOR GENERATION, COLLECTION, RECEPTION, TREATMENT, STORAGE, TRANSPORT AND DISPOSAL OF BIO-MEDICAL WASTES)

- Ref: 1. Board office Memo vide No: PCB/WMC/BMW/4/2021/5953, Dtd: 07.02.2022.
2. Application submitted vide Consent Module Regn. No.183366 Dt: 21.09.2021.

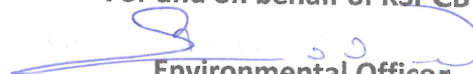
1. The Authorized Signatory, **M/s. Norwich Clinical Service Pvt. Ltd**, is hereby granted an authorization for the activity of Generation, Segregation, Collection, Storage, Packaging, Disposal or destruction, of Bio Medical Wastes.
2. **M/s. Norwich Clinical Service Pvt. Ltd, No. 147/F, 8th Main, 3rd Block, Koramangala, Bangalore-560034** is hereby authorized for handling of Bio-Medical Waste generating from **Bio-equivalence studies both clinical and Bio analytical. Drawing the blood samples from donors for Clinical Research Activity Health Care Facility.**
3. The Bio medical wastes categories- segregation, collection, quantity, handling, treatment and disposal shall be as follows as specified in Part- I of Schedule – I [See rules 3 (e), 4(b), 7(1), 7(2), 7(5), 7 (6) and 8(2).

Categ ory	Type of Wastes	Quantity permitted in Kg/Day	Type of Bags or containers to be used	Treatment and disposal options
1	2	3	4	5
Yellow	a) Human Anatomical Waste:	15 .00	Yellow Coloured non-chlorinated plastic bags	Shall be disposed to the operator of Common Bio Medical Wastes treatment facility (CBMWTF)
	(b)Animal Anatomical Waste :			
	c) Soiled Waste:			
	d) Expired or Discarded Medicines:			
	e) Chemical Waste:		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 Annexure.
	f) Chemical Liquid Waste :			
	g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.		Non-chlorinated yellow plastic bags or suitable packing material	Shall be disposed to the operator of Common Bio Medical Wastes treatment facility (CBMWTF)

	(h) Microbiology, Biotechnology and other clinical laboratory waste:		Autoclave safe plastic bags or containers	Shall be disposed to the operator of Common Bio Medical Wastes treatment facility (CBMWTF)
Red	Contaminated Waste (Recyclable)	7.5	Red coloured non-chlorinated plastic bags or containers	Shall be disposed to the operator of Common Bio Medical Wastes treatment facility (CBMWTF)
White (Translucent)	Waste sharps including Metals	01	Puncture proof, Leak proof, tamper proof containers	Shall be disposed to the operator of Common Bio Medical Wastes treatment facility (CBMWTF)
Blue	a) Glassware	--	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or shall be disposed to operator of CBMWTF
	b) Metallic body implants			

- The Bio-Medical Wastes generated above shall be disposed to operator of **CBMWTF-M/s. Maridi Bio Industries Pvt. Ltd** as per MOU submitted with the application.
- This authorization shall be in force **from 01.10.2021 to 30.06.2023** subject to cancelation/ suspension, impose/reimpose conditions, revoke and time to time review from the Board.

For and on behalf of KSPCB



Environmental Officer

Bengaluru City-South

To,
Dr. Saral Thangam,
M/s. Norwich Clinical Service Pvt. Ltd,
No. 147/F, 8th Main, 3rd Block, Koramangala,
Bangalore - 560034.

TERMS AND CONDITIONS OF AUTHORIZATION

1. The applicant 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 Board.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the Board.
4. Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of his authorization.
5. It is the duty of the authorized person to take prior permission of the Board to close down the facility and such other terms and conditions may be stipulated by the Board.
6. The applicant shall submit Annual report in **Form – IV** on or before **30th June** every year for the period from January to December of the preceding year
7. The applicant shall take all necessary steps to ensure that Bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with rules.
8. The applicant shall make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in **Schedule - I**, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I.
9. The applicant shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilization on-site in the manner as prescribed by the World Health Organization (WHO) or National AIDs Control Organization (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;
10. The applicant shall phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of these rules;
11. The applicant shall dispose of solid waste other than bio-medical waste in accordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time
12. The applicant shall provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report.
13. The applicant shall immunize all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste, in the manner as prescribed in the National Immunization Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time.
14. The applicant shall establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of these rules;



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15. The applicant shall ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralization prior to mixing with other effluent generated from health care facilities;
16. The applicant shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974)
17. The applicant shall ensure occupational safety of all its health care workers and others involved in handling of biomedical waste by providing appropriate and adequate personal protective equipments;
18. The applicant Shall conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;
19. The applicant shall maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I;
20. The applicant shall report major accidents including accidents caused by fire hazards, blasts during handling of biomedical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report to Regional Office, Bengaluru City South.
21. The applicant shall make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of these rules.
22. The applicant shall establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months and the record of the minutes of the meetings of this committee shall be submitted along with the annual report to the prescribed authority and the healthcare establishments having less than thirty beds shall designate a qualified person to review and monitor the activities relating to bio-medical waste management within that establishment and submit the annual report;
23. The applicant shall inform the prescribed authority immediately in case the operator of a facility does not collect the bio-medical waste within the intended time or as per the agreed time;

GENERAL CONDITIONS:

I. TREATMENT AND DISPOSAL:

- a. The applicant shall ensure that the Bio-medical waste shall be treated and disposed of in accordance with **Schedule I**, and in compliance with the standards provided in **Schedule-II**
- b. The applicant shall hand over segregated waste as per the **Schedule-I** to common bio-medical waste treatment facility for treatment, processing and final disposal: Provided that the lab and highly infectious bio-medical waste generated shall be pre-treated by equipment like autoclave or microwave.
- c. The applicant intending to use new technologies for treatment of bio medical waste other than those listed in **Schedule I** shall request the Central Government for laying down the standards or operating parameters.


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- d. The applicant shall phase out use of non-chlorinated plastic bags within two years from the date of publication of these rules and after two years from such publication of these rules, the chlorinated plastic bags shall not be used for storing and transporting of bio-medical waste and the occupier shall not dispose of such plastics by incineration and the bags used for storing and transporting biomedical waste shall be in compliance with the **Bureau of Indian Standards**. Till the Standards are published, the carry bags shall be as per the Plastic Waste Management Rules, 2011.
- e. The applicant shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.
- f. The applicant shall handle and dispose all the Mercury and lead wastes in accordance with the respective rules and regulations.

II. SEGREGATION, PACKAGING, TRANSPORTATION AND STORAGE:

- a. The applicant shall ensure that they shall not be mixing of untreated bio-medical waste with other wastes and the bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with **Schedule I** prior to its storage, transportation, treatment and disposal.
- b. The containers or bags referred to in sub-rule (2) shall be labeled as specified in **Schedule IV** and the Bar code and global positioning system shall be added by the applicant within one year time.
- c. The applicant shall not store Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology wastes beyond forty –eight hours: provided that in case for any reason it becomes necessary to store such waste beyond such a period, the applicant shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and inform the Board along with the reasons for doing so.
- d. The applicant shall pre-treat the Microbiology waste, and all other clinical laboratory waste 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.
- e. The applicant in case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorization was earlier granted, shall intimate to the Board about the change or variation in the activity and shall submit a fresh application in **Form - II** for modification of the conditions of authorization.
- f. The applicant shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for a period of five years, in accordance with these rules and guidelines issued by the Central Government or the Central Pollution Control Board or the Board as the case may be & all records shall be subject to inspection and verification by the Board or the Ministry of Environment, Forest and Climate Change at any time.
- g. The applicant shall be liable for all the damages caused to the environment or the public due to improper handling of bio- medical wastes and also liable for penal action under section 5 and section 15 of the Act, in case of any violation.
- h. The applicant shall ensure that all plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.


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- i. The applicant shall ensure that chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate $\text{Log}_{10}4$ reduction efficiency for microorganisms as given in **Schedule- III**.
- j. The mutilation or shredding must be to an extent to prevent unauthorized reuse and there shall not be any chemical pretreatment before incineration, except for microbiological, lab and highly infectious waste.
- k. The applicant shall ensure that dead fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or health care establishment.
- l. The applicant shall ensure that the cytotoxic drug vials shall not be handed over to unauthorized person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature $>1200^{\circ}\text{C}$.
- m. The applicant shall ensure that residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
- n. The applicant shall ensure that on-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organization or National AIDS Control Organization and then given to the common bio-medical waste treatment and disposal facility.
- o. The applicant shall ensure that syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage. Wherever the occupier is not linked to a disposal facility it shall be the responsibility of the occupier to sterilize and dispose in the manner prescribed.
- p. The bedded health care facility applicants shall apply and obtain renewal of authorization one month in advance prior to expiry of the previous authorization validity period by filing prescribed authorization application in **Form-II**.

Note: Conditions Nos. 9, 15, 16, II (K) and II (P) are not applicable.


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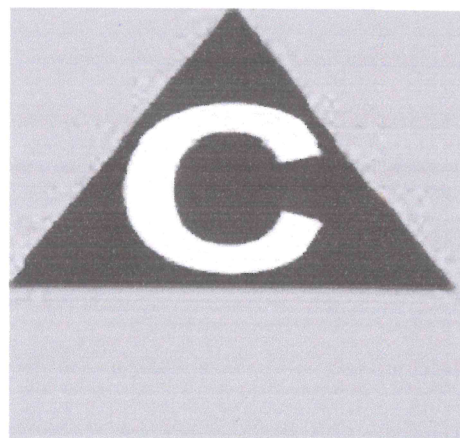
SCHEDULE- IV
[See rule 8(3) and (5)]

Part A

LABEL FOR BIO-MEDICAL WASTE CONTAINERS/BAGS

BIOHAZARD SYMBOL

CYTOTOXIC HAZARD SYMBOL



HANDLE WITH CARE

HANDLE WITH CARE

Note: Label shall be non-washable and prominently visible.

Part B

LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

Day-	Month-	Year-	
Date of generation			
Waste category Number			
Waste quantity			
Sender's Name and Address along with Phone Number & Fax Number		Receiver's Name and Address along with Phone Number & Fax Number	
Contact Person		Contact Person	
In case of emergency please contact Name and Address, phone no.			

Note :Label shall be non-washable and prominently visible.


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