Zonal Office:
Karnataka State Pollution Control Board
Parisara Bhavana, Block No. 23 & 24, 1st Floor,
4th Cross, Near ESI Hospital, Industrial Area,
Baikampady, Mangaluru - 575 011
Tel.: 0824-2408420
e-mail: seomangala@kspcb.gov.in

ವಿಭಾಗೀಯ ಕಛೇರಿ:
"ಪರಿಸರ ಭವನ", ಬ್ಲಾಕ್ ನಂ. 23&24,
1ನೇ ಮಹಡಿ, 4ನೇ ಅಡ್ಡ ರಸ್ತೆ,
ಇ.ಎಸ್.ಐ. ಆಸ್ಪತ್ರೆ ಹತ್ತಿರ
ಕೈಗಾರಿಕಾ ಪ್ರದೇಶ, ಬೈಕಂಪಾಡಿ,
ಮಂಗಳೂರು – 575 011

ಕರ್ನಾಟಕ ರಾಜ್ಯ
ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿ

towards a cleaner Karnataka

FORM –III
(See rule 10)
AUTHORISATION

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

1. File number of authorisation and date of issue **NO.KPSCB/SEO (MNG)/UIN NO – /Reg.No.185395/2021-22/**...120..... **dated:** 21/01/2022

2. **Sr. Dr. Janardhan Kamath** of **M/s Tara Hospital** located at **Plot No. 146 P & 148 P, Kasaba Bazar, Ganapathi High School Road, Mangaluru, D.K.District.** is hereby granted an authorisation for;

Activity	Please tick
Generation, segregation	✓
Collection,	✓
Storage	✓
Packaging	--
Reception	✓
Transportation	--
Treatment or processing or conversion	--
Recycling	--
Disposal or destruction	--
Use	--
offering for sale, transfer	--
Any other form of handling	--

3. **M/s Tara Hospital, Plot No. 146 P & 148 P, Kasaba Bazar,Ganapathi High School Road, Mangaluru, D.K.District** is hereby authorized for handling of biomedical waste as per the capacity given below;

(i) Number of beds of HCF: **50**

Type of Waste Category		Quantity permitted for Handling:
Yellow	Human Anatomical Waste	07 Kg
	Soiled Waste	
	Chemical Soiled Waste	
	Expired or Discarded Medicines	
	Chemical Liquid Waste	
	Discarded linen mattresses, beddings contaminated with blood or body fluid	
Red	Contaminated waste (Recyclable)	3.7 Kg
White (Translucent)	Waste Sharps including metals	0.45 Kg
Blue	Glassware	2.26 Kg
	Metallic body implants	

Senior Environmental Officer,

5. This authorisation shall be in force for a period up to **30.09.2031** from the date of issue.
6. This authorisation is subject to 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.
7. The occupier of the HCE shall comply to all the terms and conditions enclosed herewith and submit compliance report regularly.

Date : 21/01/2022
Place: Mangaluru

for

Senior Environmental Officer,

To,
Sr. Dr. Janardhan Kamath
M/s Tara Hospital,
Plot No. 146 P & 148 P,
Kasaba Bazar, Ganapathi High School Road,
Mangaluru, D.K.District.

M/s **Tara Hospital, Mangaluru**

TERMS AND CONDITIONS

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 authorised by the prescribed authority.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
5. The applicant shall 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 applicant shall immunise 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 Immunisation Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time.
7. **In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II for modification of the conditions of authorisation.**

Duties of the Occupier:-It shall be the duty of every occupier to-

1. 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 these rules;
2. 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 these 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;
3. Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags throughdisinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;
4. Phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of these rules;
5. 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;
6. Not to give treated bio-medical waste with municipal solid waste;
7. 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;

8. 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;
9. Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);
10. 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;
11. 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;
12. 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;
13. 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;
14. 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;

Treatment and disposal:-

1. Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards provided in Schedule-II by the health care facilities and common bio-medical waste treatment facility.
2. Occupier 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.
3. No occupier shall establish on-site treatment and disposal facility, if a service of ` common biomedical waste treatment facility is available at a distance of seventy-five kilometer.
4. In cases where service of the common bio-medical waste treatment facility is not available, the Occupiers shall set up requisite biomedical waste treatment equipment like incinerator, autoclave or microwave, shredder prior to commencement of its operation, as per the authorisation given by the prescribed authority.
5. Any person including an occupier or operator of a common bio medical waste treatment facility, 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.
6. On receipt of a request referred to in sub-rule (5), the Central Government may determine thestandards and operating parameters for new technology which may be published in Gazette by the Central Government.
7. The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.

Segregation, packaging, transportation and storage:-

1. No untreated bio-medical waste shall be mixed with other wastes.
2. 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.
3. The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV.
4. 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.

5. 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.

Annual report:-

Every occupier or operator of common bio-medical waste treatment facility shall submit an annual report to the prescribed authority in Form-IV, on or before the 30th June of every year.

Maintenance of records:-

1. Every authorised person shall maintain records related to thegeneration, collection, reception, storage, transportation, treatment, disposal or any other form ofhandling of bio-medical waste, for a period of five years, in accordance with these rules andguidelines issued by the Central Government or the Central Pollution Control Board or theprescribed authority as the case may be.
2. All records shall be subject to inspection and verification by the prescribed authority or the Ministry of Environment, Forest and Climate Change at any time.

Standards for Deep Burial:-

1. A pit or trench should be dug about two meters deep.It should be half filled with waste, then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil.
2. It must be ensured that animals do not have any access to burial sites. Covers of galvanized ironor wire meshes may be used.
3. On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.
4. Burial must be performed under close and dedicated supervision.
5. The deep burial site should be relatively impermeable and no shallow well should be close to thesite.
6. The pits should be distant from habitation, and located so as to ensure that no contamination occurs to surface water or ground water. The area should not be prone to flooding or erosion.
7. The location of the deep burial site shall be authorised by the prescribed authority.
8. The institution shall maintain a record of all pits used for deep burial.
9. The ground water table level should be a minimum of six meters below the lower level of deepburial pit.

Standards for Efficacy of Chemical Disinfection:-

Microbial inactivation efficacy is equated to "Log10 kill" which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for Bacillus Subtilis (ATCC19659) in chemical treatment systems.

Standards for Liquid Waste:-

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

PARAMETERS	PERMISSIBLE LIMITS
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l
Bio-assay test	90% survival of fish after 96 hours in 100% effluent.

M/s **Tara Hospital, Mangaluru**

Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options

Category	Type of waste	Type of Bag or Container to be used	Treatment and Disposal options
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.		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.
	(d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs alongwith 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 ^{0}C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200^{0}C Or Encapsulation or Plasma Pyrolysis at >1200^{0}C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.
	(f) Chemical Liquid Waste : Liquid waste generated due to use of chemicals in production of biological and used ordiscarded disinfectants, Silver X-ray film developing liquid,discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.	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.
	(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plazma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plazma Pyrolysis.

Red	**Contaminated Waste (Recyclable)** (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and *fixed needlesyringes*) and vaccutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Transluce nt)	**Waste sharps including Metals:** Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades,or any other contaminated sharpobject that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; 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.
Blue	**(a) Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated withcytotoxic wastes.	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.
	(b) Metallic Body Implants	Cardboard boxes with blue colored marking	

Disposal by deep burial is permitted only in rural or remote areas where there is no access tocommon bio-medical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Schedule-III. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time.

Part -2

1. All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.
2. Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate $Log_{10}4$ reduction efficiency for microorganisms as given in Schedule- III.
3. Mutilation or shredding must be to an extent to prevent unauthorized reuse.
4. There will be no chemical pretreatment before incineration, except for microbiological, lab and highly infectious waste.
5. Cytotoxic drug vials shall not be handed over to unauthorised 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 a1t common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature >1200 oC.

6. On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags hold be disinfected or sterilized as per the Guidelines of World Health Organisation or National AIDS Control Organisation and then given to the common bio-medical waste treatment and disposal facility.
7. Installation of in-house incinerator is not allowed. However in case there is no common biomedical facility nearby, the same may be installed by the occupier after taking authorization from the State Pollution Control Board.
8. 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.
9. Bio-medical waste generated in households during healthcare activities shall be segregated as per these rules and handed over in separate bags or containers to municipal waste collectors. Urban Local Bodies shall have tie up with the common bio-medical waste treatment and disposal facility to pickup this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal in the manner as prescribed in this Schedule.

Senior Environmental Officer,
KSPCB, Mangaluru