

**FORM III**

(See Rule 10)

**AUTHORISATION No: 24BAZ57899103 Dated 17/05/2024**

**Proceeding No: JCEE-M/VLZ/TNPCB/F.0329VLR/BWA/RS/VLR/2024 dated 17/05/2024**

**Sub:** Tamil Nadu Pollution Control Board – Bio-Medical Waste Authorization - Renewal-  
CBMWTF- M/s.KEN BIO LINKS PVT LTD, S.F.No.351/1A,1B,1C,352/5B [ PART],353/3M, KANDIPEDU village, KATPADI Taluk, Vellore District -  
Authorization under Rule 10 of the Bio-Medical Waste Management Rules, 2016 enacted  
under Environment (Protection) Act, 1986 – Issued- Reg. (Industry User ID-  
R15VLR882534)

**Ref:** 1. OCMMS Application No: 57899103 dated 06-03-2024 and resubmitted on 29.04.2024  
2. BMW-IR.No: F.0329VLR/BWA/RS/DEE/VLR/2024 dated 13/05/2024

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**AUTHORISATION FOR OPERATING A FACILITY FOR GENERATION, COLLECTION, RECEPTION, TREATMENT, STORAGE, TRANSPORT AND DISPOSAL OF BIO-MEDICAL WASTES**

1. File number of authorization: 24BAZ57899103 and date of issue: 17/05/2024
2. The Director of M/s. KEN BIO LINKS PVT LTD, an occupier or operator of the facility located at S.F.No.351/1A,1B,1C,352/5B [ PART],353/3M, KANDIPEDU Village, KATPADI Taluk, Vellore District is hereby granted an Authorisation for Collection, Reception, Transportation, Treatment or Processing or Conversion, Recycling, Disposal or destruction use, Offering for sale, Transfer of Bio-Medical Waste
3. M/s. KEN BIO LINKS PVT LTD is hereby authorized for handling of Bio-Medical waste as per the capacity given below.

i)	Number of HCFs covered by the CBMWTF	1799	Nos
ii)	Installed treatment and disposal capacity of CBMWTF	9600	Kg/day
iii)	Jurisdictional area and distance covered by the CBMWTF	Ranipet-Vellore-Thiruvanamalai- Thirupathur - 130 Sq.Kms	

iv) Quantity of Bio-Medical Waste handled, treated or disposed				
	Category	Type of Waste	Quantity permitted for handling	Unit
	Yellow	a) Human Anatomical Waste	3250	Kg/day
		b) Animal Anatomical Waste	95	Kg/day
		c) Soiled Waste	2550	Kg/day
		d) Expired or Discarded Medicines	10	Kg/day
		e) Chemical Solid Waste	5	Kg/day
		f) Chemical Liquid Waste in KLD	1	KLD
		g) Discarded linen, mattresses, beddings contaminated with blood or body fluid routine mask and gown	75	Kg/day
		h) Microbiology, Biotechnology and other clinical laboratory waste	15	Kg/day
	Red	Contaminated waste (Recyclable)	3450	Kg/day
	White(Translucent)	Waste sharps including Metals	50	Kg/day
	Blue	Glassware	75	Kg/day
		Glassware Metallic Body Implants	25	Kg/day

4. The authorization shall be in force for a period up to 31/03/2029
5. The authorization is issued 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.

**Joint Chief Environmental Engineer-Monitoring  
Tamil Nadu Pollution Control Board  
Vellore**

#### **TERMS AND CONDITIONS OF AUTHORIZATION**

1. The authorization 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 Tamil Nadu State Pollution Control Board.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the Bio-Medical wastes without obtaining prior permission of Tamil Nadu State Pollution Control 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 this authorization.

5. It is the duty of the authorized person to take prior permission of the Tamil Nadu Pollution Control Board to close down the facility and such other terms and conditions may be stipulated by Tamil Nadu Pollution Control Board.
6. Any other conditions for compliance as per the Guidelines issued by the MoEF&CC or CPCB from time to time.

#### **ADDITIONAL CONDITIONS**

1. The Common Bio-medical Waste Treatment and Disposal Facility (CBMWTF) shall comply with the provisions of the Bio Medical Waste Management Rules, 2016.
2. The CBMWTF shall maintain the records of collection, reception, storage, transportation, treatment and disposal and or any form of handling bio medical waste in accordance with the rules and records shall be subject to inspection and verification by the Board at any time.
3. The CBMWTF shall take all necessary steps to ensure that the bio-medical waste collected from the HCFs is transported, handled, stored, treated and disposed of, without any adverse effect to the human health and the environment, in accordance with these rules and guidelines issued by the Central Government from time to time.
4. The CBMWTF shall ensure timely collection of bio-medical waste from the HCFs as prescribed under these rules that in no case the waste shall be kept in the health care facility beyond 48 Hours and also ensure collection of biomedical waste on holidays.
5. The operator of CBMWTF shall transport the bio-medical waste from the premises of HCFs to any off-site bio-medical waste treatment facility only in the vehicles having label as provided in part 'A' of the Schedule IV along with necessary information as specified in part 'B' of the Schedule IV.
6. 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.
7. The CBMWTF shall maintain a log book for each of its treatment equipment according to weight of batch; categories of waste treated; time, date and duration of treatment cycle and total hours of operation.
8. The CBMWTF shall dispose the Non-hazardous solid wastes like Autoclaved plastic bags to Authorized recycler having valid consent orders under the Water and Air Acts then and there without any accumulation.
9. The CBMWTF shall operate and maintain the automatic computer recording arrangements in autoclave to monitor the pressure and temperature.
10. The CBMWTF shall maintain all record for operation of incineration, autoclaving, shredding etc for a period of five years and made available for inspecting officer at all time.
11. The CBMWTF shall maintain the details such as quantity of bio-medical waste collected from HCF in various categories, treated in the facility, quantity of generation of recyclable wastes, agency to

whom disposed, quantity of generation of HWs & disposal of the same and provide in the web site and report regularly to TNPCB.

12. The CBMWTDF shall operate and maintain the ETP effectively and continuously so that the treated water is recycling to process.

13. The CBMWTDF shall store the incineration ash & ETP sludge in an impervious room under closed shed immediately and ensure disposal of accumulated wastes through TSDF located in Tamilnadu and furnish the status report every month to the Board..

14. The CBMWTDF shall ensure that the incinerator achieves the standards for retention time (2 seconds) in secondary chamber to attain the desired level of emission control with respect to volatile organic compounds, especially dioxins and furans.

15. The emissions from incinerator shall comply with standards prescribed for PM (50 mg/Nm<sup>3</sup>), NO<sub>2</sub> (400 mg/Nm<sup>3</sup>), HCL (50 mg/Nm<sup>3</sup>), Total Dioxins and Furans (0.1ngTEQ/Nm<sup>3</sup> (at 11%O<sub>2</sub>) and Hg & its compounds (0.05 mg/Nm<sup>3</sup>).

16. The CBMWTDF shall provide non-chlorinated plastic bags to HCFs, so as to phase out the use of chlorinated plastic bags and gloves.

17. The CBMWTDF shall ensure continuous transmission of data of emission parameters (PM, NO<sub>x</sub>, HCL, CO, CO<sub>2</sub>, O<sub>2</sub>, and Temperature) from stack of incinerator to CAC of TNPCB without any interruption. It shall be explored the possibility of connectivity of GPS tracking system to CAC, TNPCB with the help of service providers.

18. The CBMWTDF shall maintain continuous emission monitoring systems (OCEMS) and ensure that the data is transmitted to both the state Board website and CPCB.

19. The CBMWTDF shall display details of authorization, treatment of bio medical waste, annual report etc on its web-site.

20. The operator of CBMWTDF shall submit an annual report to the prescribed authority in Form-IV, on or before the 30th June of every year.

21. The operator of CBMWTDF shall follow good housekeeping practices within the premises of the facility.

22. The operator of CBMWTDF shall apply for revised/fresh authorization under BWM Rules, 2016 when there is an increase in the quantity of bio-medical waste handling against the present authorized quantity.

23. The operator of CBMWTF shall be liable for all the damages caused to the environment or the public due to improper handling of bio- medical waste and shall be liable for action under section 5 and section 15 of the EP Act, in case of any violation.

24. The CBMWTF shall carry out third party evaluation done by reputed institutions and furnish the report once in every year.

25. The CBMWTF shall operate and maintain the surveillance cameras (CCTV) in the vulnerable location of the facilities (Waste storage, waste feeding, PLC attached with the treatment equipment (incinerator and autoclave).

26. The CBMWTF shall maintain good housekeeping with no odour nuisance.

27. The CBMWTF shall continue to develop green belt within the premises of the unit.

28. The CBMWTF shall not install additional treatment equipments and shall not go for any expansion more than the existing installed capacity without obtaining EC under EIA Notification amendment dated 17.04.2015.

<b>SPECIAL CONDITIONS - CBMWTF</b>	
1	All the provisions of the Biomedical Waste Management Rules, 2016 must be complied with.
2	The CBMWTF shall take all necessary steps to ensure that the bio-medical wastes collected from the HCF occupiers are transported, handled, stored, treated and disposed of without any adverse effect to the human health and the environment, in accordance with the BMW Management Rules, 2016 and guidelines issued by the Central Government or as the case may be, the Central Pollution Control Board from time to time.
3	The CBMWTF shall ensure timely collection of bio-medical waste from the HCF - occupiers as prescribed under the BMW Management Rules, 2016.
4	The CBMWTF shall ensure the collection of biomedical waste on holidays also.
5	The CBMWTF shall inform to TNPCB immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with the BMW Management Rules, 2016.
6	The CBMWTF shall supply non-chlorinated plastic coloured bags to the HCF - occupiers on chargeable basis (if required) for proper collection & storage of bio-medical wastes at source.
7	All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.
8	The CBMWTF shall establish bar coding and global positioning system for handling of bio-medical waste within one year.
9	The operator of common bio-medical waste treatment facility shall transport the bio-medical waste from the premises of an occupier to any off-site bio-medical waste treatment facility only in the vehicles having label as provided in part 'A' of the Schedule IV along with necessary information as specified in part 'B' of the Schedule IV of BMW Management Rules, 2016.

10	The vehicles used for transportation of bio-medical waste shall comply with the conditions if any stipulated by the State Pollution Control Board or Pollution Control Committee in addition to the requirement contained in the Motor Vehicles Act, 1988 (59 of 1988), if any or the rules made there under for transportation of such infectious waste.
11	Bio-medical wastes shall be treated and disposed of in accordance with Schedule I and in compliance with the standards provided in Schedule-II of the BMW Management Rules, 2016 by the health care facilities (HCFs) and common bio-medical waste treatment facility (CBMWTF).
12	The CBMWTF after ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from the treated bio-medical wastes such as plastics and glass, shall be given to recyclers having valid consent or authorisation or registration from TNPCB.
13	The Operator of a common bio-medical waste treatment facility 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 TNPCB as part of its annual report. The record shall be open for inspection by TNPCB.
14	The CBMWTF shall maintain all record for operation of incineration, hydro or autoclaving for a period of five years. The CBMWTF shall upgrade existing incinerators to achieve the standards for retention time in secondary chamber and Dioxin and Furans within two years from the date of the Notification of BMW Management Rules, 2016.
15	The CBMWTF shall maintain a log book for each of its treatment equipment according to weight of batch; categories of waste treated; time, date and duration of treatment cycle and total hours of operation.
16	The CBMWTF shall submit an Annual Report to TNPCB in Form-IV, on or before the 30th June of every year for the period from January to December of the preceding year.
17	The CBMWTF shall make available the annual report on its web-site within a period of two years from the date of publication of Bio-Medical Waste Management(Amendment) Rules,2018
18	The CBMWTF shall display details of authorisation, treatment, annual report etc on its web-site.
19	The CBMWTF shall allow occupier, who are giving waste for treatment to the operator to see whether the treatment is carried out as per the BMW Management Rules, 2016.
20	In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to TNPCB about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I.
21	Information regarding all other accidents and remedial steps taken shall be provided in the annual report in accordance with Rule 13 by the occupier.
22	In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorization was earlier granted, the occupier or operator of HCF shall intimate to TNPCB about the change or variation in the activity and shall submit a fresh application in Form II for modification of the conditions of Authorization.
23	The CBMWTF shall adopt the following treatment and disposal methods as described in the BMW Management Rules, 2016 <ul style="list-style-type: none"> <li>i. Chemical treatment using at least 1% to 2% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log104 reduction efficiency for microorganisms as given in Schedule- III.</li> <li>ii. Mutilation or shredding must be to an extent to prevent unauthorized reuse.</li> <li>iii. There will be no chemical pretreatment before incineration, except for microbiological, lab and highly infectious waste.</li> <li>iv. Incineration ash (ash from incineration of any bio-medical waste) shall be disposed through hazardous waste treatment, storage and disposal facility, if toxic or hazardous constituents are present beyond the prescribed limits as given in the Hazardous and Other Wastes (Management &amp; Transboundary Movement) Rules, 2016 or as revised from time to time.</li> </ul>

24 The CBMWTF shall comply with the following standards for treatment and disposal of Bio-Medical wastes as prescribed in Schedule-II of BMW Management Rules, 2016.

**I. STANDARDS FOR INCINERATION**

All incinerators shall meet the following operating and emission standards.

**A. Operating Standards**

i). Combustion efficiency (CE) shall be at least 99.00%.

ii). The Combustion efficiency is computed as follows:

$$\text{C.E.} = \frac{\% \text{CO}_2}{\% \text{CO}_2 + \% \text{CO}} \times 100$$

iii) The temperature of the primary chamber shall be a minimum of 800<sup>0</sup>C and the secondary chamber shall be minimum of 1050<sup>0</sup>C + or - 50<sup>0</sup>C.

iv). The secondary chamber gas residence time shall be at least two seconds.

**B. Emission Standards**

SI NO	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg/Nm <sup>3</sup> unless stated	Sampling Duration in minutes, unless stated
1.	Particulate matter	50	30 or 1Nm <sup>3</sup> of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO <sub>2</sub> expressed as NO <sub>2</sub>	400	30 for online sampling or grab sample
3.	HCl	50	30 or 1Nm <sup>3</sup> of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1ngTEQ/Nm <sup>3</sup> (at 11% O <sub>2</sub> )	8 hours or 5Nm <sup>3</sup> of sample volume, whichever is more
5.	Hg and its compounds	0.05	2 hours or 1Nm <sup>3</sup> of sample volume, whichever is more

C. Stack Height: Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

Note:

- a) The existing incinerators shall comply with the above within a period of two years from the date of the notification.
- b) The existing incinerators shall comply with the standards for Dioxins and Furans of  $0.1 \text{ ngTEQ/Nm}^3$  as given below within two years from the date of commencement of these rules.
- c) All upcoming common bio-medical waste treatment facilities having incineration facility or captive incinerator shall comply with standards for Dioxins and Furans.
- d) The existing secondary combustion chambers of the incinerator and the pollution control devices shall be suitably retrofitted, if necessary, to achieve the emission limits.
- e) Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- f) Ash from incineration of biomedical waste shall be disposed of at common hazardous waste treatment and disposal facility. However, it may be disposed of in municipal landfill, if the toxic metals in incineration ash are within the regulatory quantities as defined under the Hazardous and Other Wastes (Management & Transboundary Movement) Rules, 2016 or as amended from time to time.
- g) Only low Sulphur fuel like Light Diesel Oil or Low Sulphur Heavy Stock or Diesel, Compressed Natural Gas, Liquefied Natural Gas or Liquefied Petroleum Gas shall be used as fuel in the incinerator.
- h) The occupier or operator of a common bio-medical waste treatment facility shall monitor the stack gaseous emissions (under optimum capacity of the incinerator) once in three months through a laboratory approved under the Environment (Protection) Act, 1986 and record of such analysis results shall be maintained and submitted to TNPCB. In case of dioxins and furans, monitoring should be done once in a year.
- i) The occupier or operator of the common bio-medical waste treatment facility shall install continuous emission monitoring system for the parameters as stipulated by TNPCB in authorisation and transmit the data real time to the servers at TNPCB.
- j) All monitored values shall be corrected to 11% Oxygen on dry basis.
- k) Incinerators (combustion chambers) shall be operated with such temperature, retention time and turbulence, as to achieve Total Organic Carbon content in the slag and bottom ashes less than 3% or their loss on ignition shall be less than 5% of the dry weight.
- l) The occupier or operator of a common bio-medical waste incinerator shall use combustion gas analyzer to measure  $\text{CO}_2$ , CO and  $\text{O}_2$



25	<p><b>STANDARDS FOR AUTOCLAVING OF BIO-MEDICAL WASTE:—</b>  The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste.</p> <p>1) When operating a gravity flow autoclave, medical waste shall be subjected to :</p> <ul style="list-style-type: none"> <li>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</li> <li>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</li> <li>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.</li> </ul> <p>2) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of three pre-vacuum pulse to purge the autoclave of all air. The air removed during the pre-vacuum, cycle should be decontaminated by means of HEPA and activated carbon filtration, steam treatment, or any other method to prevent release of pathogen. The waste shall be subjected to the following:</p> <ul style="list-style-type: none"> <li>i) a temperature of not less than 121°C and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or</li> <li>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.</li> </ul> <p>3) 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.</p>														
26	<p><b>STANDARDS FOR DEEP BURIAL.-</b></p> <ul style="list-style-type: none"> <li>(a) 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.</li> <li>b) It must be ensured that animals do not have any access to burial sites. Covers of galvanised iron or wire meshes may be used.</li> <li>c) On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.</li> <li>d) Burial must be performed under close and dedicated supervision.</li> <li>e) The deep burial site should be relatively impermeable and no shallow well should be close to the site.</li> <li>f) 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.</li> <li>g) The location of the deep burial site shall be authorised by the prescribed authority.</li> <li>h) The institution shall maintain a record of all pits used for deep burial.</li> <li>i) The ground water table level should be a minimum of six meters below the lower level of deep burial pit.</li> </ul>														
27	<p><b>STANDARDS FOR LIQUID WASTE</b></p> <p>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</p> <table border="1" data-bbox="203 1956 1490 2306"> <thead> <tr> <th>PARAMETERS</th> <th>PERMISSIBLE LIMITS</th> </tr> </thead> <tbody> <tr> <td>pH</td> <td>6.5-9.0</td> </tr> <tr> <td>Suspended solids</td> <td>100 mg/l</td> </tr> <tr> <td>Oil and grease</td> <td>10 mg/l</td> </tr> <tr> <td>BOD</td> <td>30 mg/l</td> </tr> <tr> <td>COD</td> <td>250 mg/l</td> </tr> <tr> <td>Bio-assay test</td> <td>90% survival of fish after 96 hours in 100% effluent</td> </tr> </tbody> </table>	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
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	<p>2. Sludge from Effluent Treatment Plant shall be given to common bio-medical waste treatment facility for incineration or to hazardous waste treatment, storage and disposal facility for disposal.</p>														

28	The CBMWTF shall provide training for all its workers involved in handling of bio-medical waste at the time of induction and at least once a year thereafter.
29	The CBMWTF shall ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments.
30	The operator of a common bio-medical waste treatment facility shall be liable for all the damages caused to the environment or the public due to improper handling of bio- medical wastes. The occupier or operator of common bio-medical waste treatment facility shall be liable for action under section 5 and section 15 of the Act, in case of any violation.

**Joint Chief Environmental Engineer-Monitoring  
Tamil Nadu Pollution Control Board  
Vellore**

To

The Director  
KEN BIO LINKS PVT LTD  
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Copy to:

1. Copy submitted to the Member Secretary, Tamil Nadu Pollution Control Board, Chennai for favour of kind information
2. The District Environmental Engineer, Tamil Nadu Pollution Control Board, VELLORE  
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