

Ref. No.: OSSPL/SU2/2025/02/05

Date: 03/02/2025

To,

The Regional Environment Officer
Karnataka State Pollution Control Board,
Regional Office-Doddaballapura,
Urban Eco Park, 100 Ft. Road,
III Phase, Peenya Industrial Area,
Bangalore-560058.

Sub: Submission of Biomedical waste annual returns in Form IV.

Ref: Authorisation No: PCB/WMC-2/306/BMW/2022/170, Dated: 10/04/2023

Dear Sir,

With reference to the above-mentioned subject, we are here by submitting Biomedical waste annual returns in Form-IV for the period from January 2024 to December 2024.

Hence, we request you to accept our returns and acknowledge the same.

Thanking you,

Yours faithfully,

For M/s. OneSource Specialty Pharma Limited,

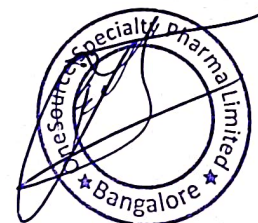

Authorized Signatory

Encl.:

1. Annual Report Form IV Copy.
2. Biomedical Waste Annual Disposal Report January 2024 to December 2024.
3. Agreement with Biomedical waste disposal facility.
4. Biomedical waste authorization copy
5. Biomedical Waste Storage Facility

Annexure-1

**BIOMEDICAL WASTE ANNUAL REPORT
(January 2024 to December 2024)**



Form – IV
(See rule13)
ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)].

M/s. OneSource Specialty Pharma Limited.

At

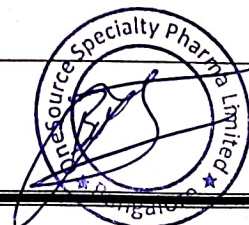
Sy. No. 14/2, 14/3, 14/4, 15/1, 15/2, 15/3, 15/4, 15/5, 16, 17/1, 17/2, 17/3, 17/4 & 17/5 of Plot No. 2-D1, KIADB Industrial Area, Phase 3 of Obadenhalli Village, Doddaballapur Taluk, Bengaluru Rural District- 561203

Facility Photo:



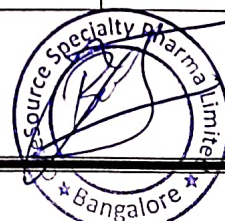
Form – IV
(See rule13)
ANNUAL REPORT

SL. No.	Particulars		
1.	Particulars of the Occupier		
	(i) Name of the authorised person (occupier or operator of facility)	:	Dr. Kameswara Rao A V
	(ii) Name of HCF or CBMWTF:	:	M/s OneSource Specialty Pharma Limited
	(iii) Address for Correspondence:	:	Sy. No. 14/2, 14/3, 14/4, 15/1, 15/2, 15/3, 15/4, 15/5, 16, 17/1, 17/2, 17/3, 17/4 & 17/5, Obadenahalli, Doddaballapura Industrial area, 3 rd Phase, Doddaballapura, Bangalore Rural district - 561203
	(iv) Address of Facility	:	M/s OneSource Specialty Pharma Limited Sy. No. 14/2, 14/3, 14/4, 15/1, 15/2, 15/3, 15/4, 15/5, 16, 17/1, 17/2, 17/3, 17/4 & 17/5, Obadenahalli, Doddaballapura Industrial area, 3 rd Phase, Doddaballapura, Bangalore Rural district - 561203
	(v) Tel. No, Fax. No	:	08022027300
	(vi) E-mail ID	:	KameswaraRao.AV@onesourcecdmo.com
	(vii) URL of Website	:	http://www.Onesourcecdmo.com
	(viii) GPS coordinates of HCF or CBMWTF	:	13°16'48.28"
	(ix) Ownership of HCF or CBMWTF	:	Private Company
	(x). Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules	:	Authorisation No.: PCB/WMC-2/306/BMW/2022/170 Valid up to: 30.06.2027
	(xi). Status of Consents under Water Act and Air Act	:	Authorisation No.: AW-335536 Valid up to: 30.06.2027



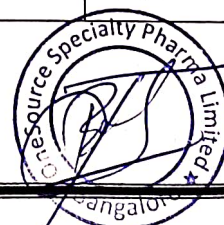
Form – IV
(See rule13)
ANNUAL REPORT

2	Type of Health Care Facility						
	(i) Bedded Hospital	:	No. of Beds: Not applicable				
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	Not applicable				
	(iii) License number and its date of expiry	:	Not applicable				
3	Details of CBMWTF		:	M/S Medicare Environmental Management Pvt. Ltd., Ramkey House, Site No. 25 – 30, 2 nd Cross Raghavendra Nagar, Hennuru Ring road, Kalyana Nagar Post, Bangalore - 560043.			
	(i) Number healthcare facilities covered by: CBMWTF	:	Not applicable				
	(ii) No of beds covered by CBMWTF	:	Not applicable				
	(iii) Installed treatment and disposal capacity of CBMWTF:	:	10000 Kg per day as per authorization				
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	10000 Kg per day as per authorization				
4	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)		:	Yellow Category: 10721.1 Kg/Annum			
:			Red Category: Nil				
:			White: 93 Kg/Annum				
:			Blue Category: 3307.6 Kg/Annum				
:			General Solid waste: Nil				
5	Details of the Storage, treatment, transportation, processing and Disposal Facility						
	(i) Details of the Onsite storage facility/ disposal facilities	:	Size: Not applicable				
		:	Capacity: Not applicable				
		:	Provision of on-site storage: (cold storage or any other provision): Not applicable				
		:	Type of treatment	No of	Capacity Kg/ day	Quantity treated	



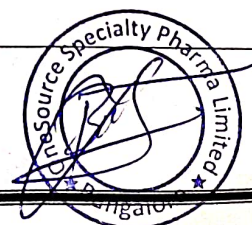
Form – IV
(See rule13)
ANNUAL REPORT

			equipment	Units		or disposed in kg per annum			
			Incinerators	NA	NA	NA			
			Plasma						
			Pyrolysis						
			Autoclaves						
			Microwave						
			Hydroclave						
			Shredder						
			Needle tip cutter or destroyer						
			Sharps, encapsulation or concrete pit						
			Deep burial pits						
			Chemical disinfection						
			Any other treatment equipment						
	(iii) Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.	:	Not applicable						
	(iv) No of vehicles used for collection and transportation of biomedical waste	:	01						
	(v) Details of incineration ash and ETP sludge generated and disposed during	:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;"></td> <td style="width: 20%;">Quantity</td> <td style="width: 20%;">Where</td> </tr> </table>					Quantity	Where
	Quantity	Where							



Form – IV
(See rule13)
ANNUAL REPORT

	the treatment of wastes in Kg per annum				generated	disposed
				Incineration	Nil	Nil
				Ash		
				ETP Sludge	Nil	Nil
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	:	M/S Medicare Environmental Management Pvt. Ltd. Ramkey House, Site No. 25 – 30, 2 nd Cross Raghavendra Nagar, Hennuru Ring road, kalyana nagar Post, Banagalore - 560043.			
	(vii) List of member HCF not handed over bio-medical waste.	:	Not applicable			
6	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period	:	Yes			
7	Details trainings conducted on BMW					
	(i) Number of trainings conducted on BMW Management.	:	10 Nos.			
	(ii) number of personnel trained	:	450 Nos.			
	(iii) number of personnel trained at the time of induction	:	200 Nos.			
	(iv) number of personnel not undergone any training so far	:	Nil			
	(v) whether standard manual for training is available?	:	Yes			
	(vi) any other information	:	Not applicable			
8	Details of the accident occurred during the year					
	(i) Number of Accidents occurred	:	Nil			
	(ii) Number of the persons affected	:	Nil			
	(iii) Remedial Action taken (Please	:	Nil			
	(iv) Any Fatality occurred, details.	:	Nil			
9	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?	:	Yes			
	Details of Continuous online emission	:	Not applicable			



Form – IV
(See rule13)
ANNUAL REPORT

	monitoring systems installed		
10	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?	:	Yes Nil
11	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?	:	Not applicable
12	Any other relevant information		Not applicable

Certified that the above report is for the period from January-2024 to December-2024

Yours faithfully,

For M/s. OneSource Specialty Pharma Limited,


Authorized Signatory

Annexure-2

Biomedical Waste Annual Disposal Report January-2024 to December-2024

SL.No.	Date	Disposed Waste	Vendor Name	Yellow Bag in Kg	Blue Bag in Kg	Red Bag in Kg	White Bag in Kg	Quantity in Kg's
1	08-01-2024	Biomedical waste	Medicare Environmental	1440.00	407.00	0	0.00	1847
2	17-01-2024	Biomedical waste	Medicare Environmental	2327.00	560.00	0	20.00	2907
3	07-02-2024	Biomedical waste	Medicare Environmental	278.80	0.00	0	0.00	278.8
4	27-02-2024	Biomedical waste	Medicare Environmental	0.00	0.00	0	0.00	0
5	28-02-2024	Biomedical waste	Medicare Environmental	494.00	120.00	0	0.00	614
6	20-03-2024	Biomedical waste	Medicare Environmental	516.00	184.00	0	12.00	712
7	25-03-2024	Biomedical waste	Medicare Environmental	0.00	0.00	0	0.00	0
8	08-05-2024	Biomedical waste	Medicare Environmental	1780.00	243.60	0	36.00	2059.6
9	14-06-2024	Biomedical waste	Medicare Environmental	454.00	0.00	0	0.00	454
10	17-06-2024	Biomedical waste	Medicare Environmental	0.00	0.00	0	0.00	0
11	05-07-2024	Biomedical waste	Medicare Environmental	300.00	98.00	0	0.00	398
12	19-07-2024	Biomedical waste	Medicare Environmental	650.00	410.00	0	0.00	1060
13	12-08-2024	Biomedical waste	Medicare Environmental	820.00	470.00	0	0.00	1290
14	19-08-2024	Biomedical waste	Medicare Environmental	141.30	0.00	0	0.00	141.3
15	21-10-2024	Biomedical waste	Medicare Environmental	520.00	360.00	0	0.00	880
16	09-11-2024	Biomedical waste	Medicare Environmental	580.00	372.00	0	25.00	977
17	15-12-2024	Biomedical waste	Medicare Environmental	0.00	0.00	0	0.00	0
18	16-12-2024	Biomedical waste	Medicare Environmental	420.00	83.00	0	0.00	503
Generated quantity per Annum				10721.1	3307.6	0	93	14121.7
Generated quantity per month				893	276	0	7.75	NA
Authorised quantity as per Consent				385 Kg/day	70 Kg/day	NA	5	NA
Authorised quantity per month as per Consent				11550	2100	NA	150	NA

Yours faithfully,
For M/s. OneSource Specialty Pharma Limited,

Authorized signatory
OneSource Specialty Pharma Limited
Bangalore

Annexure-03

MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING is made and executed at Bangalore on this the 25th day of July 2024 and deemed to be effective from 1st April 2024 by and between

ONESOURCE SPECIALTY PHARMA LIMITED ("formerly known as Stelis Biopharma Limited"), a company incorporated as per the laws of India and having its registered office at Star 1, Opp IIM Bangalore, Bilekahalli, Bannerghatta Road, Bengaluru – 560 076 (hereinafter referred to as "Onesource" which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean in include its successors-in-interests and permitted assigns) of the **FIRST PART**

AND

MEDICARE ENVIRONMENTAL MANAGEMENT PRIVATE LIMITED, having its registered Office at Level 11, Aurobindo Galaxy, Hyderabad Knowledge City, Hitech City Road, Hyderabad – 500081 and having branch office at No: 25-30, 2nd Cross, Raghavendra Nagar, Hennur Ring Road, Kalyan Nagar (post), Bangalore-560043 (hereinafter referred to as "Medicare Environmental Management Pvt Ltd", which expression shall mean and include unless excluded by or repugnant to the context, its successors in interest and assigns) of the **SECOND PART**.

- A. Medicare Environmental Management Pvt Ltd with consent from Karnataka State Pollution Control Board is having a common treatment facility for Managing Bio-Medical Waste in Bangalore rural district at Dabaspeth 40 Km on NH4. The facility is having a state of art Autoclave system along with the shredder and incinerator.
- B. Onesource gives its bio-medical waste, properly packed in color-coded bags as per pollution control Board regulations for treatment and final disposal to Medicare Environmental Management Pvt Ltd. The waste should be given at one single point by the Onesource at given time of Medicare Environmental Management Pvt Ltd Vehicle.
- C. Medicare Environmental Management Pvt Ltd will charge a price of Rs. 11500/- (Rupees Eleven thousand five hundred only) per month exclusive of all applicable taxes amended from time to time (Up to 200 Kgs per month, if it exceeds Rs 55/- per Kg will be charged extra) as agreed for collection, transportation, treatment, and final disposal of biomedical waste. This price will be fixed for a period of one (1) year from date of this MOU and thereafter there will be 10% (Ten percent) escalations in the price for every one-year on existing rate.
- D. However, if the service is not satisfactory, the Onesource can terminate this MOU and can enter MOU with other parties.
- E. Onesource is assuring that payment should be made through Account Payee Cheque/ NEFT/RTGS in favor of Medicare Environmental Management Pvt Ltd on or before 5th of every month.
- F. In case of non-receipt of payment on the agreed date from Onesource, Medicare Environmental Management Pvt Ltd will stop the collection of waste by serving thirty (30) days written notice.
- G. Medicare Environmental Management Pvt Ltd will collect medical waste as per your declaration in the application form regularly and treat the waste as per the regulations. Medicare Environmental Management Pvt Ltd will not collect any waste that is not segregated or not properly packed. Medicare Environmental Management Pvt Ltd WILL NOT COLLECT GENERAL GARBAGE.
- H. Medicare Environmental Management Pvt Ltd will issue a proof of waste collection to Onesource through registered email id. This will help the individual industry for getting compliance with the

Neesha Sharma

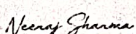
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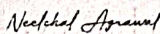
Neelesh Agrawal

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State Pollution Board. The individual industry can take their Authorization from the pollution control board by informing the board that Medicare Environmental Management Pvt Ltd treats their waste (The same has to be mentioned in the Authorization Form).

- I. In case any industry finds any irregularities in collection of waste, they can send a notice in writing to Medicare Environmental Management Pvt Ltd for immediate action. And Spillage of any during the transit is responsibility of Medicare Environmental Management Pvt Ltd.
- J. Medicare Environmental Management Pvt Ltd will maintain their plant in good running condition all the time and ensure continuity of service as per your declaration in application form.
- K. The term of this Memorandum of Understanding is 5 (five) from the effective date of this MOU.
- L. This Memorandum of Understanding is entered into on the express understanding that Medicare Environmental Management Pvt Ltd will maintain and run the facilities and collect transport and treat the waste at their plant strictly in accordance with the consent of the Karnataka State Pollution Control Board and it shall be the responsibility to obtain the consent and keep the same always current.
- M. This MOU shall be governed by and construed in accordance with the laws of India. Any dispute that may arise in connection with the interpretation or implementation of this MOU shall be submitted exclusively to the courts of Bangalore.
- N. This MOU shall be deemed to have come into effective from 1st April 2024 and shall remain in full force and effect for a period of 12 months from the date hereof and shall expire automatically upon the expiry of the said period, unless extended for such further period, and on such terms and conditions, as may be mutually agreed to in writing between the Parties.
- O. Either Party may terminate this MOU in case the other Party has committed a breach of any of the terms of this MOU and has not cured such breach within in a period of thirty (30) days from the date of the receipt of the notice from the aggrieved Party requesting it to so cure such breach.
- P. Either Party may immediately terminate this MOU by giving written notice, in the following circumstances:
 - a. the other Party makes an assignment for the benefit of its creditors; or
 - b. the other Party goes into liquidation, or a winding up order is made against it, or it suffers the appointment of a receiver, trustee or similar officer of the whole or part of its business or assets, or it files a petition seeking reorganization, composition or a similar relief, or it takes any action under any law regarding insolvency;
 - c. the representations and warranties made by the other Party are false or misleading;
- Q. Onesource reserves the right to terminate this MOU without any notice if there are any continuous irregularities on the part of Medicare Environmental Management Pvt Ltd on the above terms & conditions of this MOU.
- R. Medicare Environmental Management Pvt Ltd shall indemnify and keep indemnified Onesource against any claim that its workmen may make against Onesource, or any claim made against Onesource any other party arising out of negligence or any wrongful act on the part of the Medicare Environmental Management Pvt Ltd or any of its workmen. Medicare Environmental Management Pvt Ltd hereby undertakes to indemnify and make good any claim made against


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Onesource by any statutory authorities for the non-fulfilment of the obligations of the Medicare Environmental Management Pvt Ltd. Onesource shall be entitled to recover such claims from the charges payable to the Medicare Environmental Management Pvt Ltd.

- S. Neither Party shall be liable for any failure or delay on its part in performing under this MOU if such failure or delay is due to "Force Majeure" conditions in whole or in part such as strikes or other labour troubles, damages to the vehicle, direct or indirect acts, regulations or orders including restrictions and other licenses imposed by the governments, wars, riots, fire, floods, earthquakes, and other acts of God or of the Public enemy, and any other causes beyond the control of such Party.

The Party affected by such Force Majeure condition shall forthwith notify the other Party of the nature and extent thereof and shall make best efforts to mitigate such condition. The performance under this MOU shall be suspended for the period during which the Force Majeure conditions continue. However, if the Force Majeure condition in question prevails for a continuous period of **7 (Days)** days, the Parties shall enter into bona fide discussion with a view of alleviating its effect on this MOU by such alternative arrangement as may be fair and reasonable.

- T. Both the Parties shall hold or cause to be held, in strict confidence any and all information received by it from other Party for the purpose of carrying out the activities under this MOU. This confidentiality obligation shall not apply to information, which is now or hereafter becomes, generally known to the public through no act or fault of other.


Both Parties shall use utmost care to maintain confidential the information provided by the other Party and limit its disclosure only to such of its employees, who would be working on this assignment and shall advise such employees and representatives of the existence and terms of this MOU and of the obligations of confidentiality herein.

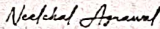
Further, unless prior written consent of the other Party is obtained, such Party shall not use the information provided by the other for any purpose other than the purpose contemplated under this MOU.

Information shall not be duplicated or reproduced by either Party in any manner.

This Clause shall survive for a further period of one (1) years from the expiration or termination of this MOU.

- U. Nothing in this MOU is to be construed to make Onesource and Medicare Environmental Management Pvt Ltd a partner, an agent or legal representative of the other for any purpose. Neither Party has any right or authority to accept any service of process or to receive any notices on behalf of the other Party or to enter into any commitments, undertakings, or MOU purporting to obligate such other Party in any way, or to amend, modify or vary any existing MOU to which such other Party may be a party. Each Party will be solely responsible for compliance with any laws, decrees, regulations or orders affecting the agents, representatives, employees or workers of such Party, and will hold the other Party harmless from any claims whatsoever arising in connection therewith.


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IN WITNESS WHEREOF, the parties hereto have executed this MOU on the day, month and year first herein above written.

FOR ONESOURCE SPECIALTY PHARMA LIMITED

**FOR MEDICARE ENVIRONMENTAL
MANAGEMENT PRIVATE LIMITED**

Name: Neeraj Sharma
Title: Authorised Signatory
(e-signed)

Name: Neelchal Agrawal
Title: Project Head
(e-signed)

Neeraj Sharma
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Neelchal Agrawal
27 Jul 2024 11:35:17 AM (UTC+05:30)
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Certificate Of Signature Completion

Document Details

Document ID: **66a2311e16de3312b1514134**
Document name: **MOU Onesource Medicare**
Signature algorithm: **SHA-256 With RSA**

Signer details

Neeraj Sharma

neeraj.sharma@steri-science.com (OTP : 985923)

eSign Service Type: **electronic**

Signature method & algorithm

Electronic Signature by SignDesk.com
SHA-256 With RSA

Signed time & IP

25 Jul 2024 08:58 PM
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Consent and Consent ID

I understand that by clicking the "Sign Now" button I would be electronically signing the said document. I have read and understood the said document. I agree to electronically sign all the pages of the said document and agree to be bound by them.

ID: 5e25847f109eee1bec6320fd

Neelchal Agrawal

neelchal.agrawal@resustainability.com (OTP : 271125)

eSign Service Type: **electronic**

Signature method & algorithm

Electronic Signature by SignDesk.com
SHA-256 With RSA

Signed time & IP

27 Jul 2024 11:35 AM
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Consent and Consent ID

I understand that by clicking the "Sign Now" button I would be electronically signing the said document. I have read and understood the said document. I agree to electronically sign all the pages of the said document and agree to be bound by them.

ID: 5e25847f109eee1bec6320fd

History

Document created	Dhanya Sastha	25 Jul 2024 04:33 PM IST (UTC+05:30)
Signer invited	Neeraj Sharma neeraj.sharma@steri-science.com	25 Jul 2024 04:35 PM IST (UTC+05:30)
Signer invited	Neelchal Agrawal neelchal.agrawal@resustainability.com	25 Jul 2024 04:35 PM IST (UTC+05:30)
Document signed	Neeraj Sharma neeraj.sharma@steri-science.com	25 Jul 2024 08:58 PM IST (UTC+05:30)
Document signed	Neelchal Agrawal neelchal.agrawal@resustainability.com	27 Jul 2024 11:35 AM IST (UTC+05:30)

Annexure-4

ಫ್ಯಾಕ್ಸ್/Fax : 080-25586321
 ಈಮೇಲ್/E-mail : ho@kspcb.gov.in
 ವೆಬ್‌ಸೈಟ್/Website : http://kspcb.gov.in



25581383, 25589112
 25588151, 25588270
 25588142, 25586520

ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿ Karnataka State Pollution Control Board

"ಪರಿಸರ ಭವನ", 1 ರಿಂದ 5ನೇ ಮಹಡಿಗಳು, ನಂ. 49, ಚರ್ಚ್ ಸ್ಟ್ರೀಟ್, ಬೆಂಗಳೂರು - 560 001, ಕರ್ನಾಟಕ, ಭಾರತ
 "Parisara Bhavana", 1st to 5th Floor, # 49, Church Street, Bengaluru - 560 001, Karnataka, INDIA

FORM -III

(See rule 10)

AUTHORISATION

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transportation & disposal of bio medical waste)

1. File number of authorisation and date of issue

NO. PCB/WMC-2/306/BMW/2022/ 170 dt: 10 APR 2023

2. M/s. Stelis Biopharma Pvt Ltd., Plot No. 2D1, DB Pura 3rd Phase, Industrial Area Doddaballapura Taluk , Bengaluru Rural-561203-reg, 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. Stelis Biopharma Pvt Ltd., Plot No. 2D1, DB Pura 3rd Phase, Industrial Area Doddaballapura Taluk , Bengaluru Rural-561203-reg, is hereby authorized for handling of biomedical waste generated during quality control operation of bio pharmaceutical as per the capacity given below;

Category	Bio- Medical Waste generated	Quantity Kg/day	Treatment method
1.Yellow	a. Human Anatomical Waste	--	Solid waste shall be handed over to Common Bio Medical Waste Treatment Facility (CBMWTF).
	b. Animal Anatomical Waste	--	
	c. Soiled Waste	15 Kg/day	
	d. Expired or Discarded Medicines	10 Kg/day	

AVOID USE OF PLASTICS-BE 'ECO' FRIENDLY

	e. Chemical Solid Waste	10 Kg/day	
	f. Discarded linen, mattresses, beddings contaminated with blood or body fluid.	--	
	g. Microbiology, Biotechnology and other clinical laboratory waste	350 Kg/day	
	h. Chemical Liquid Waste	--	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 of the biomedical Waste Management Rules, 2016.
2. Red	Contaminated Waste (Recyclable)	--	Shall be Handed over to CBMWTF
3. White	Waste Sharps including metals	5 Kg/day	Shall be Handed over to CBMWTF
4. Blue	Glassware	70 Kg/day	Shall be Handed over to CBMWTF
	Metallic body implants	--	

4. This authorisation shall be in force for a period from **01.07.2022 to 30.06.2027**.
5. 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.

Date

Place: Bangalore

Draft Approved
By Member Secretary

MEMBER SECRETARY
KSPCB

To,
M/s. Stelis Biopharma Pvt Ltd.,
Plot No. 2D1, DB Pura 3rd Phase,
Industrial Area Doddaballapura Taluk ,
Bengaluru Rural-561203-reg.

**ADDITIONAL CONDITIONS TO ACCOMPANY CONSENT FOR OPERATION
ORDER OF M/s. STELIS BIOPHARMA PVT LTD., PLOT NO. 2D1, DB PURA 3RD
PHASE, INDUSTRIAL AREA DODDABALLAPURA TALUK, BENGALURU RURAL-
561203-REG.**

M/s. Stelis Biopharma Pvt Ltd., Plot No. 2D1, DB Pura 3rd Phase, Industrial Area
Doddaballapura Taluk , Bengaluru Rural-561203-reg.

The authorities have obtained Consent for Operation issued under the provisions of
the Water Act, 1974 and Air Act, 1981 from the Board Office with vide Consent
Order No.AW-335536,dated: 16.01.2023 for the period upto 30.06.2027.

Now, the authority has applied for the authorisation for operating a facility for
generation, collection, reception, treatment, storage, transportation & disposal of
bio medical waste under Bio – Medical Waste (Management and Handling) Rules,
2016 authorisation for the above said activity for further period from **01.07.2022**
to **30.06.2027**.

Accordingly, authorisation under Bio – Medical Waste (Management and Handling)
Rules, 2016 is hereby issued with following additional conditions.

- 1) This authorisation is issued under Bio – Medical Waste (Management and
Handling) Rules, 2016 for management, segregation and disposal of bio-
medical waste generated during quality control operation of bio
pharmaceutical
- 2) This authorization for M/s. Stelis Biopharma Pvt Ltd., is granted for the
period from **01.07.2022** to **30.06.2027**

A. TERMS AND CONDITIONS:

1. The applicant 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. It is the duty of the authorised 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. 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 these rules.


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7. 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 of the Bio-Medical Waste Management Rules, 2016.
8. Applicant shall 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 the Bio-Medical Waste Management Rules, 2016.
9. Applicant shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection 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;
10. The applicant shall use non- chlorinated plastic bags, gloves and blood bags for disposal of bio-medical waste.
11. Applicant shall dispose 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. Applicant shall not to give treated bio-medical waste with municipal solid waste;
13. 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:
14. 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;
15. 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;
16. Applicant shall ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities.
17. Applicant shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);
18. 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;
19. 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;

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20. 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 the Bio-Medical Waste Management Rules, 2016;
21. 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;
22. Applicant shall make available the annual report on its web-site and all the health care facilities.
23. 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;
24. 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;
25. Applicant shall maintain all record for disposal of biomedical waste for a period of five years.
26. The applicant shall update COVID Bio Medical Waste data in CPCB tracking software at bmw.cpcbcr.com/#/p/login.
27. Application shall follow following guideline
 - a. Guidelines for Management of Healthcare Waste in Health Care Facilities as per Bio Medical Waste Management Rules, 2016.
 - b. Guidelines for Bar code System for Effective Management of Bio-Medical Waste.
 - c. Revised guidelines for Common Bio -Medical Waste Treatment and Disposal Facilities.
 - d. Guidelines for Monitoring Performance of CBMWTFs by SPCB/PCCs
 - e. Guidelines for Handling, treatment and disposal of waste generated during treatment, diagnostics and quarantine of COVID 19 patients.
 - f. Guidelines for "Imposition of Environmental Compensation against HCF's and CBWTF's.
 - g. Guidelines for Verification of Two Seconds Residence time in secondary combustion chamber of the Bio medical Waste Incinerator.
 - h. Guidelines for Handling of biomedical Waste for Utilization.
 - i. Environmentally Sound Management of Mercury Waste Generated from Health Care Facilities.


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ANNEXURE-5

BIOMEDICAL WASTE STORAGE FACILITY

