File NO: CLAA/B&BP/KERALA/140/2002-D Government of India Directorate General of Health Services Central Drugs Standard Control Organisation (HQ) (Blood Centre Division)

Food & Drugs Administration Bhawan, Kotla Road, New Delhi -110002 Dated:

To

8 DEC 2023

The Drugs Controller & Licensing Authority, Public Health Laboratory Campus, Red Cross Road, Thiruvananthapuram, Kerala-695037.

Subject: Renewal of Blood Centre license no. 133/28C/KER/DC-CLAA/2002 granted on 22.07.2002 for the period of 21.07.2022 to 20.07.2027 for processing of Whole Human Blood I.P & its components including apheresis issued in favor of M/s. Dr. Somervell Memorial CSI Medical College and Hospital situated at Karakonam P.O. Thiruvananthapuram, Dist. Kerala State-695504 -reg.

Ref. No. - 1. Your office letter no. DC/989/2023-ML2 dated 23.07.2023.

Sir.

With reference to the letter cited above on the subject matter, CLAA hereby approves the renewal of Blood Centre license no. 133/28C/KER/DC-CLAA/2002 granted on 22.07.2002 for the period of 21.07.2022 to 20.07.2027 for processing of Whole Human Blood I.P & its components including apheresis issued in favor of M/s. Dr. Somervell Memorial CSI Medical College and Hospital situated at Karakonam P.O. Thiruvananthapuram, Dist. Kerala State-695504.

Two copies of the renewal certificate in Form 26-G duly approved by the CLAA are enclosed herewith for further necessary action by your Administration.

- The Blood Bank may be re-inspected periodically at least once in a year from the date of licensing by a team comprising of Drugs Inspectors of CDSCO and State Licensing Authority and if required with an expert. The report may be forwarded to this Directorate for information.
- The Blood Bank should comply with all the provisions prescribed under schedule F Part XII-B of the Drugs Rules.

Encl: - Certificates as stated above in duplicate

Yours faithfully,

(Dr. RAJEÉV SINGH RÁGHUÝANSHI) CENTRAL LICENCE APPROVING AUTHORITY

Copy forwarded for information:

- The Deputy Drugs Controller (I), CDSCO Bhawan, No 31(14), Jothi Venkatachalam
 Salai, Atkinson Road, Periamet, Chennai, Tamil Nadu-600003.
- M/s. Dr. Somervell Memorial CSI Medical College and Hospital situated at Karakonam P.O. Thiruvananthapuram, Dist. Kerala State-695504...



FORM 26 G (see rule 122-F)

CERTIFICATE OF RENEWAL OF LICENCE TO OPERATE A BLOOD CENTRE FOR PROCESSING OF WHOLE HUMAN BLOOD AND /OR FOR PREPARATION OR SALE OR DISTRIBUTION OF ITS COMPONENTS

- No. 133/28C/KER/DC-CLAA/2002 granted on 22.07.2002. The Director, Certified that the Licence 1. Medical College and Hospital Karakonam P.O, Dr.Somervell Memorial CSI M/s. Thiruvananthapuram Dist., Kerala State, Pin - 695 504, for the operation of a Blood Centre for processing of the preparation of its components at the premises Blood and/ or for College and Hospital Karakonam Medical CSI Memorial Somervell M/s. Thiruvananthapuram Dist., Kerala State, Pin - 695 504 is here by renewed to with effect from 21.07.2022 to 20.07.2027.
- Name(s) of the Items 2.
 - Whole Human Blood IP 1.
 - Concentrated Human Red Blood Corpuscles IP 2.
 - Platelet Concentrate IP 3.
 - Fresh Frozen Plasma BP 4.
 - Cryoprecipitate AHF IP 5.
 - Single Donor Plasma peloto of 6.
- Name(s) of Competent Technical Staffs 3.

1. Medical Officer :- Dr. Apuca Susan Mathew MD ((Pathology)
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MD (Pathology) Dr. Anu J MD (Pathology) Dr. Reeba Mary Rajan MD (Pathology) Dr.Prabha Raj R.L MD (Pathology) Dr. Rini Francis MD (Pathology) Dr. Viji Viyayan

Dr. Rahul Chandran C.H MD (Pathology)

DMLT Smt. Simi U.K. Technical Supervisor:-2.

DMLT Blood Centre Technician: Smt. Aswathy A.O 3.

DMLT Smt. Manuja V

Smt. Aishwarya O.M DMLT,

GNM Smt. Gilda R.S. Registered Nurse 4.

GNM Smt. Jiji M

MSW Mr. Anil Somakumar S Blood Centre Counsellor:-5.

Date: - 23.07.2023

Dr. K SUJTTH KUMAR

Drugs Controller & Licensing Aut

Kerala State

Drugs Controller General (India) New Delhi

Druga Contro Central Drugs Standard Control Octable Directorate General of Ministry of Haulth & F ovarioment of DA Shavian, Krilla ets New Dahn (16.003)

FORM 28-C (See Rule 122-G)

LICENCE TO OPERATE A BLOOD BANK FOR COLLECTION, STORAGE AND PROCESSING OF WHOLE HUMAN BLOOD AND/ OR ITS COMPONENTS OF SALE OR DISTRIBUTION

Licence 0133/28C/KER/DC-CLAA/2002 Date of issue Number of 22/07/2002 at the premises situated at M/s. Dr.Somervel Memorial * - C.S.I.Mission Hospital, Karakonam.P.O., Thiruvananthapuram - 695 504 is hereby licensed to operate a blood bank to process whole Human Blood at the premises situated at M/s..... * See name change of his poted at - the bottom of this page.

2. M/s. Dr. Somervel Memorial C.S.I.Mission Hospital, Karakonam.P.O., Thiruvananthapuram - 695 504 is hereby licensed to collect store, process and distribute whole blood and/or its components.

3. Name (s) of the item (s)

Name (s) of the item (s)

1. WHOLE HUMAN BLOOD I.P.

2. I will be a second of a single of the

dollater It

4. Name (s) of approved competent Technical Staff:

1. Dr.S.Mohideen Abdul Kadar, MBBS 2. Smt.Mercy Remani Bai, No.4464

3. (i) Smt.B.Lini, B.Sc., MLT Deleted
(ii) Smt.R.L.Rajitha, DMLT Deleted

Medical Officer - Relieved

Registered Nurse

Blood Bank Technician

- 5. The licence authorizes the distribution and the sale and storage of Whole Human Blood I.P, subject to the conditions applicable/to this licence.
- The licence shall be in force from 22/07/2002 to 21/07/2007

* ML2. 9392/2017/DC, dated 10/07/2019.

The name of the hospital has been changed to Dr. Somervey Memorial C.S. I Medical College & Hospital" w.e.f. 13/11/2002.

DRUGS CONTROLLER KERALA STATE

< See Staff Endorsements Overleafy

ML2-15582/12/De (Duplicate He File) Change of tech. Staff - M22-13621/04/De dtd 02 11 2009 1 Smt. Lini B, BSLMLT -DBBT - Left Service well 30/09/04 (3) Sri Benny Joseph, BSI MLT - PBBT Joined wird - Relieved 10 20/19/04 3 Dr. P. Lekshmi Devi, MD (Path) - Addl. BBMO Johned wal 15/11/200 charge of Tech. Stable DRUGS CONTRO', LER. KERALA STATE. MLZ - 799 06/pc old 23/04/07. O Si. Stephan, E, MBBS - M.O wie, L 10/01/06 @ Smt. Bilda R.S. Rigol, No. 16710, Regd. Nuise w.e. & 10/01/06 3 Smt. Florasheya. F. Regd. No. 1058 - Regd. Nume - Redesignated as Tech. Supervisor D 28/02/07. 28/02/07. (5) Sort. Bini P.S. DMLT, B.B. Tubnidan well 28/02/07- Delet THE DRUGE CONTA DRUGS CONTROLLER. KERALA STATE.

STON POLLS

 The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the Rules made under the Drugs and Cosmetics Act 1940

Date: 22/07/2002

Signature:

Sd/-

(S.S. Venkatakrishnan) Drugs Controller

Name and Designation Licensing Authority.

Sd/-Central Licence Approving Authority

P. HARIPRASAD

Drugs Controller & Licencing

Authority, Kerala State

CONDITIONS OF LICENCE

- The licensee shall neither collect blood from any professional donor or paid donor nor shall be prepare blood components from the blood collected from such a donor.
- The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs & Cosmetics Act, 1940.
- Any change in the technical staff shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.
- 4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.

ML2.7908/2012/DC

Medical officer 1. Dr. Apuca Susan Mathew, MD (Path) W.e.f. 22/04/2008 2. Dr. Abraham John, MD (Path) - Deleted W.e.f. 20/05/2013 3. Dr. Beyaril Chitra. C, MD (Path) - Deleted W.e.f. 17/06/2013 Technical Supervisor _ Smt. Rosemany, BSC MLT, w.e.f. 01/11/2010 - Deluted - Smt. Rini. N.L. Preeja, GNM, w.e.f. 25/08/2010 Registered Nurse Deleted on 06.10.2021 Blood Bank - 1. Smt. Sindhu. P, DMLT, w.e.f. 27/11/2007 Dele Technician 2. Smt. Simi. R, DMLT, w.e.f. 05/01/2009 1 - Deleted DRUGS CONTROLLER KERALA STATE ML2 -7908 2012 DC Endorsement of Technical Staff Blood Bank Technicians :- Mr. Shyja Dar. Y.L., DML 01 03 2014 Deleted 13/04/2021 Ms. Aswathy. A.O, DMLT wich 11/12/201 ML2-15773 2015 DC Technical Supervisor: Ms. Simi, R. DMLT, w.e.f. 01/10/ Deleted 13/04/2021 Blood Bank Technician: - Mr. Sini. U.K., DMLT, w.ef. 22/10/2015

DRUGS CONTROLLER

L See additional staff endovsement in Annexure-I]



GOVERNMENT OF KERALA DRUGS CONTROL DEPARTMENT

ENDORSEMENT OF ADDITIONAL TECHNICAL STAFF

List of additional approved blood bank technical staff of M/s. Dr. Somervell Memorial CSI Medical College and Hospital, Karakonam, Thiruvananthapuram Dist., Kerala State - 695 504, vide Licence No. 133/28C/KER/DC-CLAA/2002 granted on 22/07/2002.

Medical Officer

- 1. Dr. Junu Rajan, MD (Pathology), w.e.f. 01/01/2016. Deleted on 25.01.2019.
- 2. Dr. Lisha S Raj, MD (Pathology), w.e.f. 01/01/2016. Deleted on 22.04.2019.

II. Blood Bank Technician

1. Mr. Akhilesh. B.F, DMLT w.e.f. 03/03/2018. Deleted on . 06.10.2022

Date: 26/04/2019.



RAVI S. MENON Drugs Controller & Licensing Authority, Kerala State

DC 1989 12023 - ML2 Dated 13.06.2023

1. Medical officer

Dr. Ann J, MD (Pathology), wef. 16:01.2020 Dr. Reeba Mary Rajan, M.D (Pathology), wef. 04.10.2020

Dr. Prabha Raj . R. L, MD (Pathology), wef. 17.12.2020.

Dr. Rini Francis, MD (Pathology), Wef. 01.04.2022

Dr. Viji Vijayan, MD (Pathology), wef. 05.05.2022.

Dr. Rahul Chandran C.H, M.D (Pathology), wef. 10.07.2022.

(Original Blood Bank Licence (Form 28C) must be produced along with this list.).

Centre

I. Blood Bank Technician.

Smt. Manuja v , DMLT , wef. 20/07/2018.

Smt Aiswarya O.M, DMLT, wef. 01/06/2022.

III Registered Nurse.

Smt Jiji .M , GNM , wef . 02/10/2021.

IV. Counselor

Mr. Anil Somakumar . 8 (Master of Philosophy in Social work

DRUGS CONTROLLE KERALA STA