

ORIGINAL

Partners:-

Tr. K. Ramachandran
Tr. M. Sivakumar

Form 25
(See Rule 70)

1482

Licence to manufacture for sale drugs other than those specified in the Schedules C and C(1) and X

Number of licence and date of Issue. TN00003912

I. M/S. SUNSHINE SOLUTION

.....is hereby licensed to manufacture the following categories of drugs other than those specified in Schedules C and C (1) and Schedule X to the Drugs and Cosmetics Rules, 1945 on the premises situated at 154/1, AVR Mill compound
Nehruji Road, Theni - 625531

.....under the direction and supervision of the following expert staff :-

(a) Expert staff (Name) :

1. Thiru. K. Vinayagamurthy B.pharm - For Manufacturing
2. Thiru. K. Senthilkumar B.pharm - For Testing

(b) Names of drug (each item to be separated specified).....

Vide list attached

2. The licence authorises the sale by way wholesale dealing and storage for sale by the licensee of the Drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force from 14.09.2015 to 13.09.2020

4. The licence is subject to the conditions stated below and such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date 14.09.2015



Signature: S. Abdul Khader

S.ABDUL KHADER, B.Pharm
Director of Drugs Control I/C.
359, Anna Salai, Chennai-600 006

CONDITIONS OF LICENCE

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and cosmetics Act, 1940.

2. Any change in the expert staff named in the licence shall be forthwith reported to the licensing Authority

3. If the licensee wants to manufacture for sale additional items of drugs not included above he should apply to the licensing Authority for the necessary endorsement as provided in rule 69(5). This licence will be deemed to extend to the categories so endorsed.

3. The licensee shall inform the Licensing 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 a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

GBP. Ms 112-Form 25 - 10 Bks. - 1986.

R.D. NO. 13720/01/2015 dt: 14.09.2015

BY REGD. POST

L. Dis. No. 7132/D1/1/2022

Office of the Director of Drugs Control,
Tamil Nadu, Chennai – 600 006.

Dated: 25.04.2022

Sub: Drugs – Drugs and Cosmetics Act 1940 and Rules made there
under - **M/s. Sun Shine Solution**, 1541/1, AVR Mill Compound,
Nehruji Road, Theni - 625 531. – Validity Certificate - Issued - Reg.

Ref: Application Dated: 19.04.2022 of M/s. Sun Shine Solution, 1541/1, AVR
Mill Compound, Nehruji Road, Theni - 625 531.

The Certificate as requested in the reference cited, is furnished herewith.

✓ To.

M/s. Sun Shine Solution,
1541/1, AVR Mill Compound, Nehruji Road, Theni - 625 531.


DIRECTOR OF DRUGS CONTROL

Vaishu
25.4.22

L. Dis. No. 7132/D1/1/2022

Office of the Director of Drugs Control,
Tamil Nadu, Chennai – 600 006.

Dated: 25.04.2022

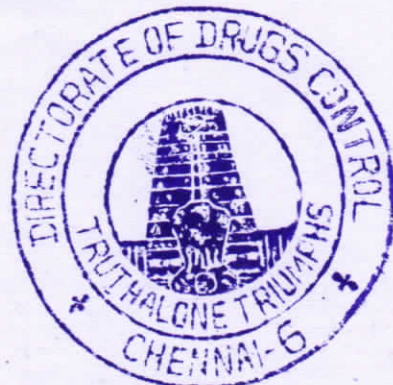
This is to certify that **M/s. Sun Shine Solution**, 1541/1, AVR Mill
Compound, Nehruji Road, Theni - 625 531. is holding licence in **Form 25** Bearing
No. **TN00003912** dated: **14.09.2015** valid upto **13.09.2020**. It is also certified that
they have remitted the licence retention fees for further period from **14.09.2020** to
13.09.2025 as per Drugs Rules 1945 for retaining the License.


DIRECTOR OF DRUGS CONTROL

K. SIVABALAN B.Pharm

Director of Drugs Control
259, Anna Salai, Chennai - 600 006.

NOTE: This Certificate is issued subject to withdrawal at any time under provisions
of Drugs and Cosmetics Act 1940 and Rules 1945.



License to manufacture for sale or for distribution of drugs other than those specified in Schedules C, C(1) and X

Number of License TN00006384 and Date of Issue 8.9.2021

- 1.
- Thiru K. Ramachandran & Thiru M. Sivakumar
-
- Partners of M/s. SUNSHINE SOLUTION Unit II

is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Schedules C, C(1) and X to the Drugs and Cosmetics Rules, 1945, on the premises situated at

S.No. 1652/3.4 & 1653 D.No.
200/K-1, Madurapuram, periyakulam
Taluk, Theni District - 625 523

under the direction and supervision of the following competent technical staff:

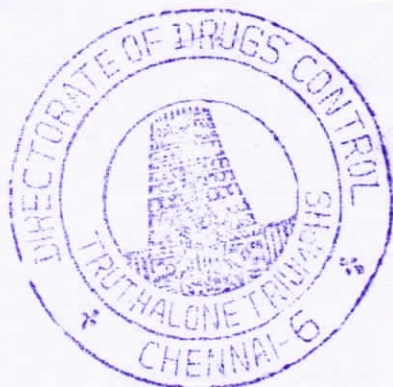
a) Competent technical staff (Names):

- 1.
- Tmt. K. Archanadevi, B.Pharm → Manufacturing
-
- 2.
- Thiru. S. Muthuraman, B.Sc (Micro) - Testing

b) Names of Drugs (each item to be separately specified):

Vide List attached

2. The license authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the license, subject to the conditions applicable to license for sale.
3. The license unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.
4. The license 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 Drugs and Cosmetics Act, 1940.



Signature

K. Sivabalan
8/9/21

Designation

K. SIVABALAN B.Pharm
Director of Drugs Control
359, Anna Salai, Chennai - 600 006.

Licensing Authority

Vaishy
8/9/21A
8/9/2021

Certificate of Registration

This is to Certify that
Medical Device Quality Management System of

SUNSHINE SOLUTION

1541/1, AVR MILL COMPOUND, NEHRUJI ROAD, THENI – 625531,
TAMILNADU, INDIA

has been assessed and found to conform to the requirements of
ISO 13485:2016
for the following scope :

**MANUFACTURER & SUPPLIER OF THE HAEMODIALYSIS FLUIDS,
BICARB PACKETS & CLEANING FLUIDS TO KIDNEY FAILURE PATIENTS.**

Certificate No	: 24EMMS56		
Initial Registration Date	: 28/03/2024	Issuance Date	: 28/03/2024
Date of Expiry	: 27/03/2027		
1st Surv. Due	: 28/02/2025	2nd Surv. Due	: 28/02/2026



Director



(Scan to Verify)

Assurance Quality Certification LLC

Head Office: Sharjah Media City, SHAMS, Sharjah, UAE. e-mail: info@aqcworld.com

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.
Certificate is the property of Assurance Quality Certification LLC and shall be returned immediately when demanded

Certificate of Registration

This is to Certify that
Quality Management System of

SUNSHINE SOLUTION

1541/1, AVR MILL COMPOUND, NEHRUJI ROAD, THENI – 625531,
TAMILNADU, INDIA

has been assessed and found to conform to the requirements of
ISO 9001:2015
for the following scope :

**MANUFACTURER & SUPPLIER OF THE HAEMODIALYSIS FLUIDS,
BICARB PACKETS & CLEANING FLUIDS TO KIDNEY FAILURE PATIENTS.**

IAF CODE : 13

Certificate No	: 24EQMS57		
Initial Registration Date	: 28/03/2024	Issuance Date	: 28/03/2024
Date of Expiry	: 27/03/2027		
1st Surv. Due	: 28/02/2025	2nd Surv. Due	: 28/02/2026



Director



(Scan to Verify)

Assurance Quality Certification LLC

Head Office: Sharjah Media City, SHAMS, Sharjah, UAE. e-mail: info@aqcworld.com,

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.

Certificate is the property of Assurance Quality Certification LLC and shall be returned immediately when demanded

Certificate of Registration

This is to Certify that
Medical Device Quality Management System of
SUNSHINE SOLUTION UNIT II

S.NO.1652/3,4 & 1653, DOOR NO.200/W-1, MADURAPURI,
PERIYAKULAM TALUK, THENI DISTRICT - 625523,
TAMILNADU, INDIA

has been assessed and found to conform to the requirements of
ISO 13485:2016
for the following scope :

**MANUFACTURER & SUPPLIER OF THE HAEMODIALYSIS FLUIDS,
BICARB PACKETS & CLEANING FLUIDS TO
KIDNEY FAILURE PATIENTS.**

Certificate No	: 22IMJA82/R2		
Initial Registration Date	: 18/04/2022	Issuance Date	: 15/11/2023
Date of Expiry	: 17/04/2025		
1st Surv. Due	: 18/03/2023	2nd Surv. Due	: 18/03/2024



Director



(Scan to Verify)

Assurance Quality Certification LLC

Head Office: Sharjah Media City, Sharjah, UAE. e-mail: info@aqcworld.com.

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.

Certificate is the property of Assurance Quality Certification LLC and shall be returned immediately when demanded