Certificate of Registration

This is to certify that the
Medical Devices Quality Management System of

M/S SUNRISE INDIA

163 B, Jungle Nakha No 2, Bhagwanpur Khas, Gorakhpur,
Uttar Pradesh - 273007, India

has been accessed and found to be in accordance of

ISO 13485:2016

(Medical Devices Quality Management System)

for the following scope of activities

Manufacturer Of Medical Disposable Products Like Disposable Surgical Gown, Disposable Bed Sheet, Disposable Drapes , Disposable Ot Kits, Disposable Surgical Mask, Disposable Cap, Disposable Apron, Disposable Equipment Covers, Disposable Ppe Kits, Hiv Protection Kit, Disposable Delivery Kit

Certificate Number : 110322069107

Initial Registration Date : 11-Mar-2022
1st Surveillance Date : 11-Feb-2023
2nd Surveillance Date : 11-Feb-2024
Certificate Expiry Date : 10-Mar-2025

To verify certificate, visit at :

www.arscert.com
https://uafaccreditation.org

Accreditation No. : 52201390612

CB-MS-3923

UAF IS A MEMBER OF INTERNATIONAL ACCREDITATION FORUM (IAF).

Issued by ARS Assessment Private Limited

Managing Director

UAF Address : 400, North Center Dr, STE 202, Norfolk, VA 23502, United States of America :

Certification & Inspection

Certificate of Compliance

Certificate Number: UQ-2022042515

This is to certify that

M/S SUNRISE INDIA

at

163 B, Jungle Nakha No 2, Bhagwanpur Khas, Gorakhpur, Uttar Pradesh - 273007, India

Has successfully implemented the Quality management System and been found working satisfactorily as per the norms of "**Good Manufacturing Practice**" as laid down by "**World Health Organisation" which** has been in conformance to the requirements of

WHO-GMP

Scope: Manufacturer Of Medical Disposable Products Like Disposable Surgical Gown, Disposable Bed Sheet, Disposable Drapes, Disposable Ot Kits, Disposable Surgical Mask, Disposable Cap, Disposable Apron, Disposable Equipment Covers, Disposable Ppe Kits, Hiv Protection Kit, Disposable Delivery Kit

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced Models Products.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	25th April 2022
1st Surveillance Audit Due	24th April 2023
2nd Surveillance Audit Due	24th April 2024
Certificate Expiry (subject to the company maintaining its system to the required standard)	24th April 2025

Authorised Signatory

UK Certification & Inspection Ltd.

GOOD MANUFACTURING PRACTICE · WHO - GMP CERTIFIED · QUALITY PRODUCT

71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851

CERTIFICATE

EUROGLOBAL
CERTIFICATIONS (UK) LTD.

Certificate of Compliance

We hereby declare that the technical file of

SUNRISE INDIA

163 B, JUNGLE NAKHA NO 2, BHAGWANPUR KHAS, GORAKHPUR-273003,
UTTAR PRADESH (INDIA)

has been assessed & found to be in conformance with the provisions set forth by the requirement of Directive Medical Devices Directive (MDD) 93/42/EEC.

PRODUCT DESCRIPTION: SURGICAL DISPOSABLE PRODUCTS.

(More Details as per Appendix-I)

The Certification body has performed a sample audit of the above product quality system covering the design, manufacture & final inspection of the certified product(s). The quality system has been assessed, approved and is subject to continuous surveillance according Directive Medical Devices Directive (MDD) 93/42/EEC. No additional test report was carried out from submitted type sample of the product in Compliance with the Specification of the respective standards except those submitted by the Customer.

Certificate No.	**EU6322**		
Date of Initial Registration	25th Feb. 2020	*Issue Date*	25th Feb. 2020
1st Surveillance on or before	25th Feb. 2021	*Expiry Date*	24th Feb. 2023
2nd Surveillance on or before	25th Feb. 2022		

Authorized Signatory

CE

CERTIFIED FOR COMPLIANCE EUROGLOBAL CERTIFICATIONS

ISSUED BY THE Euroglobal CERTIFICATIONS (UK) LTD. CERTIFICATION BOARD

CERTIFICATE

EUROGLOBAL CERTIFICATIONS (UK) LTD.

Certificate of Compliance Appendix-I to Certificate No.: EU6322

This Appendix shall be an integral part of the Certificate. All expressionsand terms defined or used in the Certificate shallhave the same meaning in this Addendum, unless the context clearly requires otherwise.

MANUFACTURER : SUNRISE INDIA
PRODUCT GROUP : SURGICAL DISPOSABLE PRODUCTS
BRAND NAME : SUNRISE INDIA

This certificate referred to above covers the following products:

- DISPOSABLE FACIAL PROTECTION
- DISPOSABLE HEADWEAR
- DISPOSABLE HAND PROTECTION
- DISPOSABLE FOOT WEAR
- DISPOSABLE APRONS
- DISPOSABLE SURGICAL GOWNS
- DISPOSABLE TOWEL & ACCESSORIES
- DISPOSABLE SURGICAL DRAPES
- DISPOSABLE EQUIPMENT COVERS
- DISPOSABLE SURGICAL KIT
- HOSPITAL LINEN CLOTH

The CE mark as shown can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of Compliance with al relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product(s). This certificate is issued under the conditions that the quality system maintained in the manufacturing of above referenced Models/Products & remains valid until the manufacturing conditions or the quality systems are changed subject to continuous surveillance according to the EC Guidelines. Further, Certificate is conditioned by positive results of surveillance audits.

Authorized Signatory

CE

CERTIFIED FOR COMPLIANCE EUROGLOBAL CERTIFICATIONS

ISSUED BY THE Euroglobal CERTIFICATIONS (UK) LTD. CERTIFICATION BOARD

Registered Office : 1st Floor, 2 Woodberry Grove, Finchley, London, N12 0DR. UNITED KINGDOM
Website : www.euroglobal.uk.com

The Registration is not a Product Quality Certificate *Subject to successful completion of surveillance audits • Visit for verification on www.euroglobal.uk.com/verify

CERTIFICATE

EUROGLOBAL
CERTIFICATIONS (UK) LTD.

Certificate of Compliance

This is to Certify that the Quality Management System of

SUNRISE INDIA

163 B, JUNGLE NAKHA NO 2, BHAGWANPUR KHAS, GORAKHPUR-273003,
UTTAR PRADESH (INDIA)

has been assessed and registered by Euroglobal and found to be in compliance wit
the requirements applicable as per Quality Management System conforming:

ISO 9001:2015

For the scope of

MANUFACTURING & SUPPLY OF DISPOSABLE SURGICAL PRODUCTS.

Certificate No.	**EU6321**		
Date of Initial Registration	25th Feb. 2020	*Issue Date*	25th Feb. 2020
1st Surveillance on or before	25th Feb. 2021	*Expiry Date*	24th Feb. 2023
2nd Surveillance on or before	25th Feb. 2022		

This Certificate is Valid for 3 years & will remain current subject to the company maintaining its system to the required standard(s). This will be monitored regularly by Euroglobal Certifications (UK) Limited. The certification details & effectiveness are listed at www.euroglobal.uk.com. The registration does not assure the quality of products produced by a quality system. This certificate is granted based on the limited sampling audit as per relevant ISO standard & Euroglobal is not responsible for client's failure to maintain documented quality system.

Authorized Signatory

CERTIFIED ISO 9001

CERTIFI... FOR COMPLIA... EUROGLOBAL CERTIFICATION

■ CERTIFICATE ■ CERTIFICADO ■ CERTIFICATO ■ ZERTIFIKAT ■ شهادة

Certificate of Registration

This is to certify that

ATS SURGICAL

H. No. A82, KH No. 52/28, Nr. Laxmi Dharam Kanta,

Opp. Rohini Jail, Badli Ext, Delhi -110042, India

Has been independently assessed by IMC and is compliant with

the requirement of the standard

ISO 9001:2015

Quality Management System

For the following scope of activities

Mfg. of Medical Disposable Products, Equipment Cover All Kind of Disposable hospital Kit, Surgical Products, Facial Protection, Head Wear, Hand Protection, Foot Wear, Aprons, Surgical Gown, Pad, Towels, Surgical Drapes/Bed Sheets, Surgeon Kit, H.I.V. (AIDS) Kit, Maternity Kit, PPE Kit, Cesarean Kit, Universal Kit, Angiography Kit, T.H.R Kit & TKR Kit

Certificate No. : - IMC-2020-9001-ATSS-2445

To verify this certificate please visit at www.gaafs.us

Date of Certification	24 April 2020
Issuance Date	24 April 2020
1st Surveillance Due	23 April 2021
2ndSurveillanceDue	23 April 2022
Re-Certificate Due	23 April 2023

Authorized Signatory

Validity of this Certificate is subject to annual Surveillance audits done successfully

This certificate remain the property of IMC and must be returned whenever demanded IMC is an independent system product and personal assessment body IMC is accredited by Globle Accreditation Assessment Forum Series (GAAFS)

■ CERTIFICATE ■ CERTIFICADO ■ CERTIFICATO ■ ZERTIFIKAT ■ شهادة

Certificate

This is to certify that

ATS SURGICAL

H. No. A82, KH No. 52/28, Nr. Laxmi Dharam Kanta, Opp.

Rohini Jail, Badli Ext, Delhi -110042, India

Has been assessed and found working satisfactorily as per the norms of
"Good Manufacturing Practice"
as laid down by World Health Organization

Good Manufacturing Practice (GMP) System

For the following scope:

Mfg. of Medical Disposable Products, Equipment Cover All Kind of Disposable hospital Kit, Surgical Products, Facial Protection, Head Wear, Hand Protection, Foot Wear, Aprons, Surgical Gown, Pad, Towels, Surgical Drapes/Bed Sheets, Surgeon Kit, H.I.V. (AIDS) Kit, Maternity Kit, PPE Kit, Cesarean Kit, Universal Kit, Angiography Kit, T.H.R Kit & TkR Kit

Certificate Number: **IMC-2020-GMP-ATSS-2445**

To verify this certificate please visit at www.gaafs.us

Date of Certification	24 April 2020
Issuance Date	24 April 2020
1st Surveillance Due	23 April 2021
2nd Surveillance Due	23 April 2022
Re-Certificate Due	23 April 2023

Authorized Signatory

Validity of this Certificate is subject to annual Surveillance audits done successfully

This certificate remain the property of IMC and must be returned whenever demanded IMC is an independent system product and personal assessment body IMC is accredited by
Globle Accreditation Assessment Forum Series (GAAFS)

Certificate

We hereby declare that the technical file of product complied with the requirement of directives 98/79/EC on Surgical Drapes, Gloves & Mask directive.

Certificate No. – IMC-2020-CE-ATSS-2445

Manufacture

Name : **ATS SURGICAL**

Address : **H. No. A82, KH No. 52/28, Nr. Laxmi Dharam Kanta, Opp. Rohini Jail, Badli Ext, Delhi -110042, India**

Product : **Medical Disposable Products, Equipment Cover All Kind Of Disposable hospital Kit, Surgical Products, Facial Protection, Head Wear, Hand Protection, Foot Wear, Aprons, Surgical Gown, Pad, Towels, Surgical Drapes/Bed Sheets, Surgeon Kit, H.I.V. (AIDS) Kit, Maternity Kit, PPE Kit, Cesarean Kit, Universal Kit, Angiography Kit, T.H.R Kit & TkR Kit**

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives 1907/2006/EC directive.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.gaafs.us

Issuance Date	24 April 2020
1st Surveillance Due	23 April 2021
2nd Surveillance Due	23 April 2022
Re-Certificate Due	23 April 2023

CE

Authorized Signatory

Validity of this Certificate is subject to annual Surveillance audits done successfully

This certificate remain the property of IMC and must be returned whenever demanded IMC is an independent system product and personal assessment body IMC is accredited by Globle Accreditation Assessment Forum Series (GAAFS)

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