



Government of India / भारत सरकार
 Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय
 Department of Commerce / वाणिज्य विभाग
 Directorate General of Foreign Trade / विदेश व्यापार महानिदेशालय
 Office of the Additional Director General of Foreign Trade Ahmedabad /अपर महानिदेशक विदेश व्यापार का
 कार्यालय अहमदाबाद

3rd Floor HUDCO Bhavan Ishvar Bhuvan Road Navrangpura AHMADABAD GUJARAT 380009 / तीसरी
 मंजिल, हुडको भवन, ईश्वर भवन रोड, नवरंगपुरा, अहमदाबाद, अहमदाबाद, गुजरात, 380009
 Email Office : ahmedabad-dgft@nic.in . Phone Office : 07925506297

FREE SALE AND COMMERCE CERTIFICATE

Certificate No.:FSCC000004AM25

The Medical Devices/Instruments as per Annexure (Total items) manufactured by PLANTECH MEDICAL SYSTEMS PVT LTD & 55 57 58 TIRUPATI INDUSTRIAL ESTATE B/H. AMBAR CINEMA OPP. MUNICIPAL QUARTERS SARASPUR AHMEDABAD are "freely permitted for sale in India as well as freely exportable".

This certificate is valid for a period of two years from the date of issue 05/04/2024 .

S. No.	Name of Product - Technical Specifications	ITC(HS) Code	Manufacturers / Exporters name and address	Is the product licensed under the Drugs and Cosmetics Act for manufacture and sale	Description of the product including use (attach literature if required.)
1	Other- Ophthalmic Equipments And Instrument for Diagnostic Surgical and Sight Saving	94021090	Plantech Medical Systems Pvt Ltd & 55 57 58 Tirupati Industrial Estate Opp. Municipal Quaters B/h. Amber Cinema	No	Ophthalmic Equipments and Instrument for Diagnostic




DIVYA P. JOSHI
 ASST SECRETARY SERVICE CENTER
 GUJARAT CHAMBER OF COMMERCE & INDUSTRY
 AHMEDABAD

Signature Not Verified

Digitally Signed,
 Name: DEEPSHIKHA (Assistant DGFT)
 Date: 01-May-2024 15:37:01
 Reason: deepshikha.its@gov.in
 Location: RA AHMEDABAD

		Saraspur Ahmedabad		Surgical and Sight Saving Purpose
	90185090	Plantech Medical Systems Pvt Ltd & 55 57 58 Tirupati Industrial Estate Opp. Municipal Quaters B/h. Amber Cinema Saraspur Ahmedabad	No	Ophthalmic Equipments and Instrument for Diagnostic Surgical and Sight Saving Purpose


CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia / Country: VIET NAM
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được chứng nhận / hợp pháp hóa lãnh sự / Certified

5. tại / at: New Delhi
6. ngày / the: 20/5/2024

7. cơ quan cấp / by: Đại sứ quán Việt Nam tại Ấn Độ

8. Số / No: 0135.37 / 24-HPH

Ký tên và đóng dấu / Signature and seal/stamp
TL ĐẠI SỨ / FOR THE AMBASSADOR
Bí thư thứ nhất / First Secretary

ation by the above firm that items of export shown in Annexure have Clinics for Medical Surgical Purpose and also that items of export nor prohibited for export. The items appearing in this certificate are es Act, 1940 as per declaration of the aforesaid firm.

4 MAY 2024

036568

सं. / No. दिनांक / Date

वाणिज्य मंडल में सहायक सचिव उप सचिव/सचिव के हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Asstt. Secretary/Dy. Secretary/Secretary of Chamber of Commerce Attested.
विदेश मंत्रालय इन हस्ताक्षरों के किसी भी विषय दस्तु की जिम्मेदारी नहीं लेता।
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AHMEDABAD



(पंकज कुमार)
(Pankaj Kumar)
अनुभाग अधिकारी (सत्यापन / ऑ.आर्.)
Section Officer (Attestation/O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

Signature Not Verified

Digitally Signed
Name: DEEPSHIKHA / Assistant DGFT
Date: 01-May-2024 15:37:01
Reason: deepshikha.its@gov.in
Location: RA AHMEDABAD

TRUE COPY



P. R. Gupta
PRIYESH R. GUPTA
NOTARY
GOVT. OF INDIA

Certificate of Compliance

This is to certify that the technical documentation for the product:

OPHTHALMIC CHAIR	SURGEON'S CHAIR SC -16.
1. PANTECH REFRACTION UNIT CS-04	OPERATION TABLE OTB-160
2. PANTECH REFRACTION UNIT CS-04 M	MOTORIZED INSTRUMENT TABLE-AIT 13
3. PANTECH REFRACTION UNIT CS-15	MOTORIZED INSTRUMENT TABLE - STANDARD
4. PANTECH REFRACTION UNIT CS-15M	MOTORIZED INSTRUMENT TABLE - WHEELCHAIR ACCESSIBLE
5. PANTECH REFRACTION UNIT CS-18	DOCTOR STOOL
6. PANTECH REFRACTION UNIT IS-170	PHACO STAND
7. PANTECH REFRACTION UNIT PO-EU	PHOROPTOR ARM
8. PANTECH PRE OPERATING CHAIR	VISION TESTING DRUM
	VISUAL ACUITY SYSTEMS-- VAS 91
	SLIT LAMP Model SL-100

Manufactured by:

Plantech Medical Systems Pvt. Ltd.

58, Tirupati Industrial Estate, Near Jay Bharat Rangshala Comp., B/h Amber Cinema, Saraspur, Ahmedabad - 380024 (Gujarat), India.

Complies with the applicable requirements of **Medical Devices Directive 93/42/EEC**

The technical documentation / inspection / test results comply with the requirements of **Medical Devices Directive (MDD)**, hence manufacturer's declaration of conformity according to above directive is accepted. **Plantech Medical Systems Pvt. Ltd.** can place the CE marking as per laid down regulations on the product mentioned as above.

Certificaat Nummer / Certificate No. **CE-BV-2203-4945**



D. Joshi
DIVYA P. JOSHI
ASST. SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

Datum Van Publicatie / Date of Issue : 01/03/2022
Vervaldatum / Date of Expiry : 28/02/2025
Ist Annual surveillance audit due on : 31/01/2023
IInd Annual surveillance audit due on : 31/01/2024

Royal Stancert B.V.

Faithful Beurdelingen - Wereldwijde Beurdelingen

Regd. Office - Joop Geesinkweg 701, 1114 AB Amsterdam, The Netherlands.
(KvK-Nummer 71431802 / RSIN 858713159 - Rechtsvorm - Besloten Vennootschap).

This certificate remains the property of **Royal Stancert B.V.** and must be returned whenever demanded. The validity of this certificate can be verified at <http://www.royalstancert.org>. **Royal Stancert B.V.** is an independent system, product and personal assessment body accredited by Global Euro Accreditation Centre, Georgia. (GCIN - 654). Email: info@royalstancert.org

D. Joshi

Director (Certification)



4945



PAC-GEAC-1506-299



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được chứng nhận / hợp pháp hóa lãnh sự / Certified

5. tại / at: New Delhi
6. ngày / the: 20/5/2024
7. cơ quan cấp / by: Đại sứ quán Việt Nam tại Ấn Độ
8. Số / No: 0135.36.24-HPH

Ký tên và đóng dấu / Signature and seal/stamp

TL ĐẠI SỨ / FOR THE AMBASSADOR
Bí thư thứ nhất / First Secretary



036566

18 4 MAY 2024

सं. / No. दिनांक / Date
वाणिज्य मंडल में सहायक सचिव उप सचिव/सचिव के हस्ताक्षर सत्यापित किए जाते हैं।
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(पंकज कुमार) / (Pankaj Kumar)
अनुमाम अधिकारी (सत्यापन / ओ.आई.) / Section Officer (Attestation/O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली / Ministry of External Affairs, New Delhi





BSCIC



TRUE COPY

P.R. Gupta
PRIYESH R. GUPTA
NOTARY
GOVT. OF INDIA

Certificate

MEDICAL DEVICE -
QUALITY MANAGEMENT SYSTEM

This is to certify that:

PLANTECH MEDICAL SYSTEMS PVT. LTD.

55/57/58, TIRUPATI INDUSTRIAL ESTATE, B/H AMBER CINEMA
OPP. MUNICIPAL QUARTERS, SARASPUR
AHMEDABAD - 380 024, GUJARAT, INDIA

Hereby granted the Certificate Number:

BN22611/21650

Rev. 00

Subsequent to the Assessment of the organization, it has been found to be operating a Medical Device-Quality Management System which complies with the requirements of

ISO 13485:2016

For the following scope:

Design, Manufacture, Installation & Supply of Ophthalmic Equipment & related Instruments such as:
Ophthalmic Refraction Unit, Motorized Instrument Table, Ophthalmic Operation Table, Ophthalmic Laser Table, Pre-Operating Chair, Vision Testing Drum, Visual Acuity Systems, Ophthalmic Chair, ENT Chair, Phoropter Arm, Doctor Operative Stool, Surgeon's Chair, Slit Lamp and Phaco Stand

Technical Area: General Non-Active, Non-Implantable Medical Devices, Non-Active Ophthalmologic Devices, A.1.1.5, General Active Medical Devices, Active Ophthalmologic Devices, A.1.2.5

For
BSCIC CERTIFICATIONS PVT.LTD.

Originally Registered:	31-Jan-2024	1st Surveillance Due on:	30-Jan-2025
Issue Date:	31-Jan-2024	2nd Surveillance Due on:	30-Jan-2026
Expiry Date:	30-Jan-2027		

Sanjey Seth
Sanjey Seth
Managing Director

(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).

Please Re-validate this certificate's status at www.bscic-icc.com at REGISTRATION STATUS
This Certificate of Registration is granted subject to relevant provisions of the BSCIC Certifications PVT. LTD. Contract Terms & Scheme for Registration Form B010 (Latest Version). Please see B010 at our website www.bscic-icc.com
This certificate of Registration remains the property of BSCIC Certifications Pvt. Ltd. and shall be returned immediately upon request.
BSCIC Headquarters: 8work, 1st Floor, 5B/15A, Crown Plaza Mall, Fardabad - 121 007, Haryana, India.

Page 1 of 1

Registered



Divya P. Joshi
DIVYA P. JOSHI
ASST. SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD





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Certified

5. tại / at Núi Đê-lì 6. ngày / the 20/5/2024
7. cơ quan cấp / by Đại sứ quán Việt Nam tại Ấn Độ
8. Số / No 0135.35/24-HPH

Ký tên và đóng dấu
Signature and seal/stamp

TL ĐẠI SỨ / FOR THE AMBASSADOR
Bí thư thứ nhất / First Secretary



036567

10 4 MAY 2024

सं
No.

दिनांक
Date

वर्गिष्ठ मंडल में सहायक सचिव उप सचिव/सचिव के
हस्ताक्षर सत्यापित किए जाते हैं।
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Secretary/Secretary of Chamber of
Commerce Attested.

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(पंकज कुमार)
(Pankaj Kumar)
अनुभाग अधिकारी (सत्यापन / ज.आई.)
Section Officer (Attestation/O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi