



Health Technology Certification

EC-CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

SHAH EYE CARE PRIVATE LIMITED

Plot No : 8 & 9, Karur Industrial Area, P. B. Road, Davangere,
Karnataka, India-577006

for design and manufacture of

Ophthalmic Microsurgical Knives

See attachment for Certificate history

Certificate No: 1724C04210402
Issue Date: 24/04/2021
Original Approval: 18/08/2020
Valid until: 26/05/2024
References: W001 1724 02

HTCert is a Notified Body according
to Council Directive 93/42/EEC concerning
medical devices with identification
number 2803

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

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Health Technology Certification

Attachment to Certificate

No: 1724C04210402

Issued: 24/04/2021

Certificate History

Issue date	Certificate Number	Reason for Issuance
18/08/2020	1724C04200801	First issuance
24/04/2021	1724C04210402	Change of company address

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

A blue ink signature of George Pappous, written in a cursive style.

FILIPPOS KOTTIS
Certification Director

A blue ink signature of Filippou Kottis, written in a cursive style.



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CERTIFICATE OF REGISTRATION



*This is to Certify that the
Medical Devices – Quality Management System
of*

SHAH EYE CARE PRIVATE LIMITED

**PLOT 8 TO 9, KARUR INDUSTRIAL AREA, P B ROAD,
DAVANGERE -577006, KARNATAKA, INDIA**

**has been independently assessed and is compliant
with the requirements of**

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

**DESIGN, MANUFACTURE & DISTRIBUTION OF OPHTHALMIC MICRO SURGICAL
KNIVES, TROCAR SETS, OPHTHALMIC INSTRUMENTS, CANNULAS,
CUSTOMS SURGICAL PACK, DRAPES, SURGICAL GOWNS,
TABLE / TROLLEY CLOTH, 3PLY MASK.**

:: Certificate No :: IN53417H

Date of initial registration	30 October 2020
Date of this Certificate	30 October 2020
Surveillance audit on or before	29 October 2021
Recertification Due / Certificate expiry	29 October 2023

This Certificate is remains valid subject to satisfactory surveillance audits.

Emmanuel ADEMOSU
Director



For verification and updated information concerning the present certificate visit to http://staunchlyservices.com/search_certified_client.php
This Certificate is the property of Staunchly Management & System Services Limited and shall be returned immediately when demanded

STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED

Labrynth Business Centre, 43 Middle Hill Gate, Stockport,

Great Manchester, England-SK1 3DG

Web :- www.staunchlyservices.com

E-mail :- info@staunchlyservices.com

Phone :- +44 740 482 3687

Company Registered in England and Wales with Company Number 11488683





Certificate of Registration 2021

This is to certify that the registration of

SHAH EYE CARE PRIVATE LIMITED

PLOT NO: 8 & 9, KARUR INDUSTRIAL AREA, P.B. ROAD, DAVANGERE
KARNATAKA, INDIA - 577006

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd. with the information provided by the above company.

FEI Number : 3013530125
Date of Expiration : December 31, 2021
U.S. Agent : LIBERTY MANAGEMENT GROUP LTD.
Certificate Number : 3012260120

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

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LMG LIBERTY
MANAGEMENT
GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

A handwritten signature in black ink, reading "Manoj Zacharias", is located above the printed name.

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: December 26, 2020