



Italia

CERTIFICATO

Nr. 50 100 8666 Rev.005

SI ATTESTA CHE / THIS IS TO CERTIFY THAT

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

OPTIKA S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA RIGLA 30
IT - 24010 PONTERANICA (BG)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione, ricerca e sviluppo, fabbricazione, controllo qualità ed assistenza tecnica relativamente a strumentazione scientifica, microscopi ottici ed accessori (IAF 19)

Design, research and development, manufacturing, quality control and technical assistance related to scientific instrumentation, microscopes and accessories (IAF 19)



SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TUV Italia S.r.l.

Validità / Validity

Dal / From: 2024-05-15

Ai / To: 2027-04-24

Data emissione /
Issuing Date

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

2024-05-15

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2009-04-24

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2024-04-24
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2024-04-24

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

CERTIFICATE



This is to Certify that the Management System of

OPTIKA S.R.L.

Via Rigla, 30
24010, Ponteranica (BG), Italy

has been found to conform to the Medical Devices – Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope of operations:

Design, development, manufacture and supply of scientific instrumentation, microscopes and accessories for medical and diagnostic applications

:: Certificate No :: IT54201H

<u>Date of initial registration</u>	<u>Date of this Certificate</u>	<u>Surv. audit on or before / Certificate expiry</u>	<u>Recertification Due</u>
03 November 2021	11 September 2024	02 November 2025	02 November 2027

This Certificate remains valid subject to satisfactory surveillance audits.



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

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(Company Registered in England with Company Number 11488683)

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