



Certificate of Registration

Niniejszym potwierdza się, że:

OPTA-TECH Sp. z o. o.

Al. Komisji Edukacji Narodowej 36, lok. U211, 02-797 Warszawa, Polska

Została oceniona przez International Certification Registrar Ltd. w odniesieniu do wymagań systemu zarządzania jakością dla wyrobów medycznych, a wyniki oceny potwierdzają spełnienie wymagań normy:

ISO 13485:2016

Certyfikat pozostaje w mocy pod warunkiem przestrzegania przez Organizację wymagań powyższej normy przez okres ważności certyfikatu w następującym zakresie:

Produkcja, sprzedaż, serwis, dystrybucja nieaktywnych i aktywnych (urządzeń optycznych dla celów medycznych oraz akcesoriów medycznych) wyrobów medycznych.

Data certyfikacji: 4 marca 2025

Data pierwszej certyfikacji: 4 marca 2025

Data wydania certyfikatu: 4 marca 2025

Data wygaśnięcia: 3 marca 2028

Numer certyfikatu: MI000276

- ✱ Technical Area : General non-active, non-implantable medical devices & General active medical devices & Distribution services
- ✱ This certificate is valid by completion of surveillance audit which is conducted within 12 months from the certification date.
- ✱ Refer to appendix for detailed activities and location of each sites.
- ✱ Non-applicable requirements : 7.3, 7.5.2, 7.5.5, 7.5.7, 7.5.9.2

The Seal of ICR Limited was here to affixed
in the presence of :

President



- This certificate is intellectual property of ICR.
- This certificate is only valid by completion of surveillance audit which is conducted at least once a year.
- You can verify the authenticity of this certificate on "Certification Confirm" at www.icrqa.com
- If you can not maintain the certification, this certificate shall be returned to ICR.





Certificate of Registration

This is to certify that :

OPTA-TECH Ltd.

Al. Komisji Edukacji Narodowej 36, lok. U211, 02-797 Warsaw, Poland

Has been assessed by International Certification Registrar Ltd., in respect of their
Medical Device Quality Management Systems and found to comply with

ISO 13485:2016

Approval is hereby granted for registration providing the rules and conditions
relating to certification are observed at all times.

Certification Scope

Production, sales, service, distribution of inactive and active (optical devices for medical purposes and medical accessories) medical devices.

Certification Date: 04th March 2025

Initial Issued Date: 04th March 2025

Certificate Issue Date: 04th March 2025

Expiration Date: 03rd March 2028

Certificate No.: MI000276

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