

Certificate of Conformity

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Issued in compliance with the Council Directive Regulation (EU) 2017/745 on medical devices concerning medical devices, class I (Non Sterile)

Medical / Surgical Application- Fiber Optic Products

List of the Fiber Optic products covered by the certificate No - ECIC-MDR/22-23/17

- · Optic Fiber Cable variety in- Fiber bundle diameter and length and connectors,
- Optic Fiber Pad / Blanket,
- Multi Branch Optic Fiber Cable,
- · LED Protable Light,
- · Ring Fiber Optic Light,
- · Fiber Mount Assembly,
- Head Light

Manufactured by the company

Applied Optical Technologies Pvt. Ltd.

A - 147, Waghle Industrial Estate, Road Number 24, Thane West, Thane - 400604, Maharashtra, India.

Have been manufactured under consideration of European Medical Device Regulation (EU) 2017/745. The Products are conforming to the essential requirements of the Medical Device Regulation (EU) 2017/745.

EC International Certifications performed an assessment of the technical file of the medical devices in terms of intended use under the relevant sections of the above mentioned Directive and the relevant harmonized European standards: EN ISO 7153-1:2016 and EN ISO 14971:2019.

Any change of the Medical Device shall be immediately reported to EC INTERNATIONAL CERTIFICATIONS in order to examine validity of this certificate.

Certificate No: ECIC-MDR/22-23/17
Certificate Issue Date: 18.05.2022
Certificate Re-Issue Date: 08.08.2023
Certificate Expiry Date: 17.05.2025

Authorized Signatory

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