

Certificate of Compliance



We hereby declare that the technical files of all the items in each product group of complied with the requirements of the Medical Device Regulation - (Council Regulation 2017/745).

Certificate No.: CE-5240

Manufacturer

Name PIONEER HEALTHCARE TECHNOLOGIES

**Address SECOND FLOOR, S 297, RAWAT COMPLEX, SHIVALIK NAGAR,
OPPOSITE PNB BANK, HARIDWAR - 249403, UTTARAKHAND**

Product : AS PER APPENDIX-I

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Medical Device Regulation -(Council Regulation 2017/745).

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	10th January 2024
1st Surveillance Audit Due	09th January 2025
2nd Surveillance Audit Due	09th January 2026
Certificate Expiry (subject to the company maintaining its system to the required standard)	09th January 2027



Authorised Signatory

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Appendix-I

Appendix to Certificate no.:- CE-5240

Manufacturer :- PIONEER HEALTHCARE TECHNOLOGIES

Address :- SECOND FLOOR, S 297, RAWAT COMPLEX, SHIVALIK NAGAR, OPPOSITE PNB BANK, HARIDWAR, UTTARAKHAND



This certificate referred to above covers the following products like:

Products:-

1. ENDOSCOPY CAMERA WITH INBUILT LED LIGHT SOURCE
2. ENDOSCOPY UNIT
3. MINI LED SOURCE
4. LED LIGHT SOURCE
5. HEAD BAND
6. FIBER OPTIC HEAD BAND
7. FIBER OPTIC CABLE
8. VIDEO OTOSCOPE
9. ENT OPERATING MICROSCOPE
10. NEURO/PLASTIC SURGICAL MICROSCOPE
11. EYE/DENTAL SURGICAL MICROSCOPE
12. ENT EXAMINATION /OPD TREATMENT UNIT WITH PATIENT CHAIR AND SURGEON STOOL
13. ENT SURGICAL HAND INSTRUMENTS
14. CO2 INSUFFLATORS
15. TURP SET INCLUDING OF WORKING ELEMNET & OTHER INNER RESECTOSCOPY SHEATH
16. PLASMA SYSTEM
17. ENT MICRODEBRIDER
18. CYSTOSCOPY SET
19. HYSTEROSCOPY SET
20. LAPROSCOPY SET
21. SPINE INSTRUMENTS SET
22. ORTHOSCOPY SET
23. CAUTERY MACHINE

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Authorised Signatory



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