



Certificate of Compliance

This is to certify that



Confirms that the Class 1 complies according to the directive Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate Number: DRAFT

Manufacturer

Name : DYNA FILTERS PRIVATE LIMITED
Address : DYNA HOUSE, PLOT NO. 14 & 15, RAMTEKDI INDUSTRIAL ESTATE,
PUNE-SOLAPUR ROAD, HADAPSAR, PUNE-411028, MAHARASHTRA, INDIA

Products : BIOLOGICAL SAFETY CABINET

Model Name : Biosure II 2 X 2, Biosure II 3 X 2, Biosure II 4 X 2, Biosure II 5 X 2, Biosure II 6 X 2

Applicable Standards : Low voltage Directive Compliance EN 61010-1:2010, EMC Directive Compliance EN 61326-1:2006 and Design/Performance Criteria Compliance EN 12469:2000 Biotechnology-Performance Criteria for Microbiological Safety Cabinets.

The manufacturer's technical documentation as required for Medical Council according to the directive 93/42/EEC has been reviewed and found to comply with the requirements for Class I Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC. Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity

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.

Date of Certification: 28th April 2025

2nd Surveillance Audit Due: 27th October 2027

1st Surveillance Audit Due: 27th October 2026

Certificate Expiry: 27th October 2028



Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit. (In case if surveillance audit is not allowed to be conducted; this certificate shall be suspended / withdrawn).

The Validity of this certificate can be verified at www.qrocet.com

This certificate of registration remains the property of QRO Certification Limited, and shall be returned immediately upon request.

QRO Certification Limited is accredited by UK Akkreditering Forum Limited, UK (www.ukaf.org.uk)

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