



REGAL  
REGAL REGISTER (UK) LIMITED

# CERTIFICATE

## Certificate of Compliance

We confirm that the technical documentation for the below mentioned products according conformity to according to the Directive Medical Device Directive (MDD) (93/42/EEC)

### Products:

Blood Bank Refrigerator Centrifuge, Laboratory Refrigerator, Platelet Incubator, Platelet Agitator, Cryoprecipitate Bath, Blood Donor Couch, Blood Collection Monitor, Blood Bag Tube Sealer, Laboratory Oven, Bacteriological Incubator, Laboratory Centrifuge, Laminar Air Flow, Plasma Expresser, Blood Bank Scale, Plasma Thawing Bath, Double Pan Centrifuge Balance, Walk-in Chambers, Stability Chamber, Photo- Stability Chamber, Plant Growth Chamber, Incubators, Water Bath, Ice-lined Refrigerator, Ice-lined Freezers, Circulating Chillers, Re-Circulating Chillers, Shakers, Shaking Incubators, High-Volume Refrigerated Centrifuge and Bio-Safety Cabinet (Class 11A2 and Class 11B2)

Marketed/ Manufactured by:

**Labtop Instruments Private Limited**

**Labtop House, Plot No. 59, Near IPOL, Opposite Amarnon Waliv Phata  
Sativali Road, Vasai (East), District- Palghar, Vasai- 401208, Mumbai,  
Maharashtra, India**

is complying to the applicable essential requirements of according to the Directive Medical Device Directive (MD) (93/42/EEC)

The Regal Register (UK) Ltd. has reviewed manufacturer's technical documentation & Test reports and found it in compliance with above mentioned Directive (s).

This certificate is issued under the following conditions:

1. It applies only to the above referenced set of products. The manufacturer is obligated to assure that all products of the respective model confirm to the type assessed for this certificate.
2. The Certificate remains valid until the manufacturing conditions, the quality systems or relevant legislation are changed subjected to maximum Validity of 3 years.
3. The Certificate validity is conditioned by the positive results of the surveillance audits.
4. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each product of the above referenced models, CE Marking according to the following example.

Certificate No. CE- 2944  
Originally Issue Date : 08<sup>th</sup> January 2019  
Current Issue Date : 18<sup>th</sup> March 2020  
Certificate Expiry Date : 17<sup>th</sup> March 2021  
Recertification Due Date : 07<sup>th</sup> January 2022



Authorized Signatory  
Regal Register (UK) Ltd.

### Statement:

This certificate of conformity based on the evaluation of a sample of the above mentioned products. It does not imply an assessment of the mass-production of the product. The certification body should be informed (revision of technical file) for any modification or alterations made to the aforementioned product type(s). The manufacturer is responsible for the product and ensuring that all manufactured products are in compliance with the specifications declared in the technical construction file.  
Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by contacting the organization. Check [www.regalregistrars.co.uk](http://www.regalregistrars.co.uk) for current status of the certificate. Whilst all due care and skill was exercised in carrying out this assessment, RRUL accepts responsibility only for proven gross negligence. This certificate remains property of RRUL to whom it must be returned upon request.

This Certificate is valid as long as the organization meets RRUL's requirements. The status of the certificate may be checked at [www.regalregistrars.co.uk](http://www.regalregistrars.co.uk)

**REGAL REGISTER (UK) LIMITED**

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