



International Certifications

CERTIFICATE OF COMPLIANCE

Certificate No : ECIC-IVDR/122-23

Initial Issued Date : January 04, 2024

Certificate Expiry Date : January 03, 2027

Manufacturer Head Office : Remi Elektrotechnik Ltd.
Remi House, 11, Cama Ind. Estate, Goregaon (East),
Mumbai - 400063, Maharashtra, India.

Manufacturing Unit : 'B' Building, Survey No. 65/1, Valiv, Vasai (East),
Palghar - 401208, Maharashtra, India.

Product : Lab Centrifuges, Cold Cabinet / Lab Refrigerator, Deep Freezer,
Ultra Low Freezers -86 Degrees C & Ice Flakers

Model No : As per attached Annex - I

Issued in Compliance with the applicable Directive No. (IVDR) 2017/746 of the European parliament and of the council on In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746

This is to certify that the technical documentation and test results as required for the device has been reviewed and found to comply with the requirements and the relevant harmonized European standards: EN ISO 14971:2019, ISO 9001:2015, ISO 13485:2016, EN 15223-1:2021, EN ISO 18113-2:2011, EN 61010-2-101:2018, EN 61326-2-2:2021

This certificate is issued under following conditions:

It applies only to the above model of in vitro diagnostics device. The manufacturer must ensure compliance of the specified models of the Bio-chemistry reagents in accordance with this certificate. The certificate remains valid unless changes in technology, Quality system or the regulations invalidated it or at most until March 2027 after meeting the requirements of the relevant EU legislation, the manufacturer must identify every diagnostics medical device in vitro of the above models with the CE mark.

Any change with the product under scope of certificate shall be immediately reported to EC International Certifications in order to examine validity of this certificate.



Authorized Signatory





International Certifications

Annex 1 to Certificate No. - ECIC-IVDR/122-23

Issued for the company: "Remi Elektrotechnik Ltd."

Address: Remi House, 11, Cama Ind. Estate, Goregaon (East), Mumbai - 400063, India.

List of the products covered General IVDR (Others) Classification by the certificate

| Sr. No. | Products | Model |
|---------|---------------------------------|---|
| 1 | Lab Centrifuge | C-852, C-854/4, C-854/6, C-854/8, R-303, R-304, Medico Plus, CM-8 Plus, CM-12 Plus, R-4C, R-8C, RM-12C, R-8CBL, RM-12C BL, R-8M, R12M, R-10M, NEYA-8, NEYA-10, NEYA-16, RM-02Plus, RM-03Plus, Neya-2, Neya-24, Neya-36, Omnicard 12c, Neya-4, Neya-6, Neya-8, Neya-10, Neya-12, Neya-16, NEYA 18, NEYA 18R, NEYA 24, R 12C Plus, R 8C Plus, CPR 24i Plus, Neya 24R, Neya 36R; C 23 Plus, C 24 Plus, C 30 Plus CPR 23 Plus, CPR 24 Plus, CPR 30 Plus, NEYA-10R, NEYA-16R, KPR-70Plus, Neya-12R, R 23, R 24, PR-23, PR-24, HCM 6, HCM 15, HCR 16 Plus, Quikfuge, HCP 7C, HCP 20C, Neya 18R, Neya 24R, Neya 36R; Neya 6 Plus, NEYA 18, Neya-24, Neya-36, HCM 6, HCM 15, HCR 16 Plus, HCP 7, HCP 20 |
| 2 | Cold Cabinet / Lab Refrigerator | CC-6 Plus, CC-10 Plus, CC-12 Plus, CC-16 Plus, CC-19 Plus, CC-28 Plus, CC-35 Plus, Serocool 400, Serocool 300, RLR-200, RLR-300, RLR-400, WCR 50, WCR 80, WCR 100, WCR 120, WCR 150, HCLR 200, HCLR 280, HCLR 370, HCLR 450, HCLR 540, HCLR 800, HCLR 1100, HCLR 200 Ultra, HCDF 100 ULTRA, HCDF 200 ULTRA, HCDF 300 ULTRA, HCDF 400 ULTRA, HCDF 500 ULTRA, HCDF 700 ULTRA; HCLR 280 Ultra, HCLR 370 Ultra, HCLR 450 Ultra, HCLR 540 Ultra, HCLR 800 Ultra, HCLR 1100 Ultra, Serocool E 200, Serocool E 300, Serocool E 400, Serocool 200 Ultra, Serocool 300 Ultra, Serocool 400 Ultra |



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| 3 | Deep Freezer | RQV 200 Plus, RQV 300 Plus, RQV 400 Plus, RQV 500 Plus, RQV 600 Plus, RQVD 200 Plus, RQVD 300 Plus, RQVD 400 Plus, Sero Freeze 245, Sero Freeze 340, RQV 600i Plus, RQFV 170, RQFV 265, RFV-245, RFV-340, RQF 170, RQF 265, RFC-100, RFC-200, RFC-280, RRF 250, RRFD 250, RQF 125, RQF 200, HCRF 250, HCRF 250D; PDSF 200, PDSF 300, PDSF 400, PDSF 500, PDSF 700, HCLF 225, HCLF 325, HCLF 425, HCLF 525, HCLF 625, HCLF 225 Ultra, HCLF 325 Ultra, HCLF 425 Ultra, Sero Freeze 245, Sero Freeze 340, MBT 100; HCLF 525 Ultra, HCLF 625 Ultra, RQF 170, RQF 265, RQFV 170, RQFV 265, RFC-100, RFC-200, RFC-280, RFV-245, RFV-340; RQF 125; RQF 240, Sero Freeze 245, Sero Freeze 340, HCLF 225, HCLF 325, HCLF 425, HCLF 525, HCLF 625, HCLF 225 Ultra, HCLF 325 Ultra, HCLF 425 Ultra, HCLF 525 Ultra, HCLF 625 Ultra, HCRF 250, HCRF 250 D |
| 4 | Ultra Low Freezers -86 Degrees C | UDFV-90, UDFV-185, PDV 90 D, PDV 185 D, ULT-90, ULT-185, ULT-360, ULT-390, ULT-490, ULT-650 |



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