



International Certifications

CERTIFICATE OF COMPLIANCE

Certificate No : ECIC-MDR/124-23

Initial Issued Date : January 04, 2024

Certificate Expiry Date : January 03, 2027

Manufacturer : Remi Elektrotechnik Ltd.

Head Office : 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.

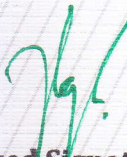
Product : Thawing Bath / Water Bath, Platelet Agitator/Platelet
Incubator, Therapeutic Chair /Blood Donor Chair, Blood
Bank Refrigerator /Blood Storage Cabinet, Blood Collection
Monitor, Blood Bag Tube Sealer, Plasma Freezer, Blood
Bank Centrifuge, Centrifuge Bucket Equalizer, PRP
Centrifuge, Automated Blood Bag Tube Stripper, Plasma
Expressor

Model No : As per attached Annex - I

This is to certify that the technical documentation as required for the devices has been reviewed and found to comply with the requirements and the relevant harmonized European standards: ISO 13485:2016, ISO 14971:2019, BS EN ISO 20417:2021, EN ISO 15223-1:2016, EN 60601-1:2020, BS EN 60601-1-2:2015+A1:2021

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





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Annex 1 to Certificate No. - ECIC-MDR/124-23

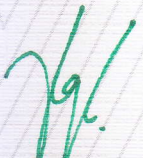
Issued for the company: "Remi Elektrotechnik Ltd."

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

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

Sr. No.	Products	Model
1	Thawing Bath / Water Bath	CB-704, CB-705, RWB 6
2	Platelet Agitator/Platelet Incubator	PI 10, PR 10, PI 10 Ultra, PR 10 Ultra, PI 20 Ultra, PR 20 Ultra, PI 20 Ultra L, PR 20 Ultra L
3	Therapeutic Chair / Blood Donor Chair	Dzire 1X, Dzire 2X, Dzire 3X, Dzire 4X, PDV 1X, Flabo X, Flabo 2X, Flabo XR, RDC 2 X,, RDC 3 X, RDC 3M, RDC 3M, RDC 4M
4	Blood Bank Refrigerator / Blood Storage Cabinet	BR 40 SR, BR 70 SR, BR 120 SR BR 50, BR 50 Ultra, BR 60, BR 60 Ultra, BR 120, BR 120 Ultra, BR 180, BR180Ultra, BR240, BR240Ultra, BR300, BR300Ultra, BR 400, BR 500, BR 400 Ultra, BR 500 Ultra, WBR80, WBR100, BSR 200, BSR 300, BSR 400, BSR 500, BSR 700, BR 135 SR, BR 200SR, BR 280 SR, BR 360 SR, LR 200 SR, LR 300 SR, LR 350 SR, LR 500 SR, Serocool E 200, Serocool E 300, Serocool E 400, Serocool 200 Ultra, Serocool 300 Ultra, Serocool 400 Ultra
5	Blood Collection Monitor	BCM-10 Ultra, BCM-20 Ultra, BCM-30 Ultra, BCM-40 Ultra
6	Blood Bag Tube Sealer	Weldon-B, Weldon-P.




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

Sr. No.	Products	Model
7	Plasma Freezers	RPFV 130, RPF 224, RPF 224 Ultra, RPF 336, RPF 336 Ultra, PDV 90 Ultra, PDV 185 Ultra, PDV 360 Ultra, PDV 390 Ultra, PDV 490 Ultra, PDV 500 Ultra, PDV 650 Ultra, PDV 700 Ultra, RPFV 130, RPF 224, RPF 224 Ultra, RPF 336, RPF 336 Ultra; PSF 200, PSF 300, PSF 400, PSF 500, PSF 600, HEMODESK S, HEMODESK M, HEMODESK L, HCRF 250, HCRF 250D; PDSF 200, PDSF 300, PDSF 400, PDSF 500, PDSF 700, UDFV-90, UDFV-185, PDV 90 D, PDV 185 D, ULT-90, ULT-185, ULT-360, PDV 90 Ultra, PDV 185 Ultra, PDV 360 Ultra, ULT-390, ULT-490, ULT-650
8	Blood Bank Centrifuge	KBM 70, KBM 70 Plus, KBM 80 Plus, KBM 80i Plus, KBM 90 Plus, KBM 90i Plus, KBM 80 Plus LCD, KBM 80 Plus TFT
9	Centrifuge Bucket Equalizer	CBZ 50 Plus
10	PRP Centrifuge	PRP-41 Plus, PRP Ultra, PRP Plus
11	Automated Blood Bag Tube Stripper	RQS A
12	Plasma Expressor	Xpress A, Xpress M
13	Vaccine Freezer	RQF 125, RQF 240



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