

# COTEX LAXMI HEALTHCARE PVT. LTD.

Sawangi Meghe, Wardha-442001

## CALIBRATION CERTIFICATE

### 1. Customer

Name and Address of Customer:  
**SHALINITAI MEGHE HOSPITAL AND RESEARCH  
CENTER, WANADONGARI  
HINGNA, NAGPUR, 441110**

Ambient Temp.: (25±2)°C  
RH: 45 %RH to 75 %RH

Procedure No. CLH/CAL/20/TI/SOP/12  
Date of Calibration: 21-04-2022  
Due Date of Calibration: 20-04-2023  
Location of Calibration: ON SITE  
Equipment Status: OK

### 2. Description of item

Name: CENTRIFUGE  
Make: REMI  
Model: R-8C  
Sr.no. NA  
Type: DIGITAL

Department: BIOCHEMISTRY LAB  
Location: BIOCHEMISTRY LAB  
Asset No.: 3126  
Range: 5250RPM  
Calibration Certificate no.: CLH/CAL/SMHRC/CCL/PATH/CENT/01

### 3. Equipment used for Calibration (Master)

Name: Electrical Safety Analyzer  
Make/ Model: Fluke Biomedical/ESA612  
Sr.No. 5188505  
Certificate no. M-220224-2-1  
Validity 26-02-2023

Name: Digital thermohygrometer  
Make/ Model: LUTRON/TM-902C  
Sr.No. NA  
Certificate no. ACS/126/CM/106/2100004  
Validity 02-05-2023

The Masters are traceable to National/International Standards.

### 4. ELECTRICAL SAFETY

#### 4.1) Visual Test Inspection

SR.NO.	TEST	REMARK
1	Device clean and Decontaminated	
2	Physical Damage	OK
3	Power Cord, Cable checking	OK
4	Mains Socket Checking	OK
5	Alarm function	OK
6	Equipment type(B, BF, CF)	OK
7	Equipment class(I, II, III)	B I

B-Body Type, BF-Body Float Type, CF-Cardiac Float Type.

I-Properly Earthed, II-Double Insulated, III-With Extra Safety Low Voltage.

#### 4.2) Electrical Safety Test

SR.NO.	PARAMETERS	DESIRED VALUE	MEASURED VALUE	REMARK
1	Voltage between live to neutral (V <sub>ln</sub> )	220-240 V	229.8 V	OK
2	Voltage between live to earth (V <sub>le</sub> )	220-240 V	228.9 V	OK
3	Voltage between neutral to earth (V <sub>ln</sub> )	0-5 V	0.3 V	OK
4	Load Current (I <sub>a</sub> )	0-10 A	1.2A	OK
5	Earth Leakage Current (IL)	0-500 μA	90.5 μA	OK
6	Enclosure Current	0-10 μA	0.5 μA	OK
7	Patient Leakage Current (PL)	BF 0-100 μA, CF 0-10 μA	0.3 μA	OK
8	Ground Wire Resistance	0Ω -3Ω	1 Ω	OK

5. Performance Test				
SR.NO.	CALIBRATION POINT °c	STANDERED READING °c	UUC READINGS °c	ERROR IN °c
1	1000	999	1000	1
2	2000	1999	2000	1
3	4000	3997	4000	3
4	5000	4999	5000	1
5	5250	5250	5250	0

Remark: 1.The equipment is functioning with in the normal limits.

Note:

- 1) Prior to the calibration of this electrical safety parameters such as ground wire resistance, chassis Leakage, Patient Leakage Current, Patient Lead Leakage Current Isolation Test(mains on applied part), Insulation(optional) 500 V etc. verified as per IEC-60601/62353 and found within limits.
- 2) The standards used for calibration were calibrated by using reference standard traceable to National/International standard & Calibration Points were selected as per customers Specification.
- 3) The reported uncertainty is expanded uncertainty in measurement obtained by multiplying the courage factor  $k=2$ , which corresponds to courage probability of approximately factor  $k=2$ , which corresponds to courage probability of approximately 95% for normal distribution.
- 4) The certificate refers only to the particular item submitted for calibration. UUC stand for normal distribution.
- 5) The calibration results reported in the certificate are valid at the time for and under the stated condition of measurement.
- 6) Calibration point were selected as per customer specification and calibration report traceble to national or international standard
- 7) This certificate shall not be reproduced, except in full unless written permission for the publication of an approved abstract has been obtained from the Technical manager of COTEX LAXMI HEALTHCARE PVT. LTD. WARDHA.

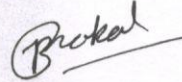
Calibrated By



Calibration Engineer



Approved by



Technical Manager

National Accreditation Board for Testing and Calibration Laboratories

Doc No.:39 Specific Criteria for calibration of Medical Devices

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