

SYSMEX XN-350
AUTOMATED HEAMATOLOGY ANALYZER

INSTALLATION
QUALIFICATION

For

“SR Diagnostics Center, Sewa Rural, Jhagadia”

Marketed by:
Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

Table of Contents

Sr. No.	Contents	Page No.
I	Approval of the IQ procedure	3
II	Instructions	4
III	Scope	5
IV	Ancillary Information	6
V	Installation Qualification	8
VI	Installation Procedure	11
VII	Comments	13
VIII	System Certification	14

I. Approval of the IQ procedure:

Both **SR Diagnostics Center, Sewa Rural, Jhagadia and Transasia** are jointly responsible for the installation of the system **SYSMEX – HEMATOLOGY Analyzer, Model: XN-350, Serial No. _12302** in the **SR Diagnostics Center, Sewa Rural, Jhagadia** as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name : Mr. Manthan Vaja
Title : **INSTALLATION QUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.**

Signature: 

Date: 19/07/2018

Validation Team from SR Diagnostics Center, Sewa - Rular:

Name : Dr. Gayatri Desai
Designation : Lab Incharge
Department : Laboratory

Signature: 

Date: 19/07/2018

Customer Authorizations:

Name : Dr. Gayatri Desai
Title : **INSTALLATION QUALIFICATION**
Site : **SR Diagnostics Center, Sewa Rural
Jhagadia**

Signature: 

Date: 19/07/2018

II. Instructions

1. This document is to be completed at the time the system is shifted to its current location (new) and set up for operation.
2. An authorized TRANSASIA representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be noted and dated.
3. Employee of (Customer) **SR Diagnostics Center, Sewa Rural, Jhagadia** will verify each result and sign in the last page. The members of the validation team will carry this out.
4. ALL deviations from normal specification to include any problems with installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.
5. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

III. Scope

This Installation Qualification protocol will be performed on the SYSMEX-Hematology Analyzer, Model **XN-350 Serial No. 12302** located in (add) **SR Diagnostics Center, Sewa Rural, Jhagadia**. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

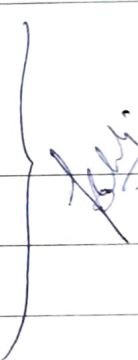
IV. Ancillary Information.

a. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument is purchased under Purchase order No. _____, Dt. _____ sent against Quotation number _____ dt. _____ is in compliance with the specifications of the Purchase order.

Verified By : _____ Date : _____

b. Utilities

Sr.No.	Utility	Yes / No	Verified By	Date
1.	Environmental condition as per requirement: (Ambient range of temperature 15 – 35 °C, air conditioning facility, non exposure to direct sunlight, non-interference from high frequency radio waves)	Yes / No		19/07/18
2.	Adequate space for installation : (Minimum in mm. W 450 X D 660 X H 450)	Yes / No		
3.	Cellpack DCL, SULFOLYSER,,Lysercell WDF, Fluorocell WDF and Cell Clean	Yes / No		
4.	Power Source Requirements*	Yes / No		

* Encircle applicable source

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

c. The instrument has been verified for the following

Sr.No.	Verification	Yes / No	Verified By	Date
1.	Instrument is identified	Yes / No	[Signature]	19/07/18
2.	Manufacturer's specifications are included	Yes / No		
3.	Accessories / Consumables are listed	Yes / No		
4.	Manufacturer's certificate of Compliance attached	Yes / No		

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature *Desai*

Date: 19/07/2018

V. Installation Qualification

A. Equipment Description

This Sysmex XN-350 is a fully automated Hematology analyzer for in vitro diagnostic use in clinical laboratories. The XN - 350 provides accurate and precise test results for () parameters.

Instrument identification		Verified by	Date
Equipment Name	Automated Hematology	}	}
Model	XN -350		
Manufacturer	Sysmex Corporation		
Marketed By	Transasia		
Equipment #	XN - 350		
Serial Number	12302		
Size (in mm)	W 450 X D 660 X H 450		
Power	AC 220 V		
Frequency	50 - 60 Hz		
Power Consumption	Less Than 250 VA		

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

Consumables:

Consumables such as Cellpack DCL, SULFOLYSER, Lysercell WDF, Fluorocell WDF, and Cell Clean were supplied along with instrument.

Currently a sufficient stock of the same is being maintained

Yes No

C. List of Manuals, Certificates and Drawings

Transasia provides the following with the instrument.

1. Operator's Manual

D. Change Control Procedure

The instrument will not be altered, enhanced, modified or substituted for another system until a formal Change Control Authorization is approved from Transasia Bio-Medicals Ltd. and **Dr. Gayatri Desai at SR Diagnostics Center, Sewa Rural Jhagadia.**

E. Maintenance

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the operations manual Chapter 13

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Transasia offers several levels of Maintenance Agreements and Performance Testing services to assist you in maintaining **GLP/GMP** compliance. Contacting your local representative and requesting the additional Service Agreement can supply additional information.

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

C. Equipment Logs

Title	Location	Verified by	Date

Sample page of the logbook is attached to this document

Effective date:

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

VI. Installation Procedure

(These had been performed at the time of original installation at the initial location)

1. **Check Before Installation**

Refer to Chapter 7 of Sysmex XN 350 Service Manual

3. **Grounding**

Refer to Chapter 1 of Sysmex XN 350 Service Manual

4. **Installation Environment & Space**

Refer to Chapter 1 of Sysmex XN 350 Service Manual

5. **Connect Air & Reagent Tubes**

Refer to Chapter 7 of Sysmex XN 350 Service Manual

6. **Connect Connection Cord & Power Cord**

Refer to Chapter 7 of Sysmex XN 350 Service Manual

7. **Turn Power On**

Refer to Chapter 7 of Sysmex XN 350 Service Manual

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

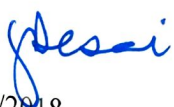
VII. COMMENTS:

- Installation done Successfully

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

VIII. System Certification

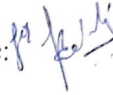
Study data has determined that the system described in this document either meets all criteria outlined in this independently Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By : Transasia Representative

Name : Mr. Manthan Vaja

Title : INSTALLATION QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature: 

Date : 19/07/2018

Customer Authorizations:

Name : Dr. Gayatri Desai

Title : INSTALLATION QUALIFICATION

Site : SR Diagnostics Center, Sewa Rural
Jhagadia

Signature: 

Date: 19/07/2018

SYSMEX XN – 350
AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL
QUALIFICATION

For

“SR Diagnostics Center, Sewa Rural, Jhagadia”

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 13485 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

Table of Contents


Sr. No.	Contents	Page No.
I	Approval of the OQ procedure	3
II	Instructions	4
III	Scope	5
IV	Operational Qualification	6
V	System Certification	13

I. Approval of the OQ procedure:

Both **SR Diagnostics Center, Sewa Rural, Jhagadia** and **Transasia** are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: **XN-350**, serial no. **12302** in the **SR Diagnostics Center, Sewa Rural, Jhagadia** as per protocol attached.


Protocol Performed by: **Transasia Representative**

Name : Mr. Manthan Vaja
Title : OPERATIONAL QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature: 
Date: 19/07/2018


Validation Team from **SR Diagnostics Center, Sewa Rural, Jhagadia**:

Name : Dr. Gayatri Desai
Designation : Lab Incharge
Department : Laboratory

Signature: 
Date: 19/07/2018

Customer Authorization:

Name : Dr. Gayatri Desai
Title : OPERATIONAL QUALIFICATION
Site : SR Diagnostics Center, Sewa Rural
Jhagadia

Signature: 
Date: 19/07/2018

II. Instructions

1. The TRANSASIA representative will check each module and enter the specific data as described in the Operational Qualification. Each result will be noted and dated.
2. Employee of **SR Diagnostics Center, Sewa Rural, Jhagadia** will verify each result and sign in the last page. The member/s of the validation team will be responsible for the same.
3. Any deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section of the OQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION. This will be an additional cost to the purchasing institution (CUSTOMER). However this additional cost will be waived when this test is conducted at time of initial performance check of new instruments.
4. Any test data, which does not meet the specified acceptance criteria, will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
5. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Product Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model **XN-350**, Serial No. **12302** located in **SR Diagnostics Center, Sewa Rural, Jhagadia**, (city/state or prefecture) This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

IV. Operational Qualification

a. Instrument Identification

Verified Date

1. Model Name XN – 350
2. Serial Number 12302 _____

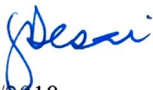
b. Following is a list of tests to be performed and verified:

<u>Test No.</u>	<u>Test Name</u>	<u>Test Purpose</u>	<u>Verified Date</u>
1.	Whole Blood (WB) X- aspiration motor operation	To the WB aspiration motor operation	
2	Sheath Motor Test.	To check Operation of Sheath Motor	19/07/18
3.	Diagnostic Test for Auto Sampler and Bar code reader	To Check operation of Auto sampler and Barcode reader.	

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

c. Operational Testing

Test 1


Test Name : Whole Blood Aspiration Motor Test
Purpose : To test the Aspiration Motor movement
Method : Please follow the steps described in chapter 2, page 2.9.1 of Sysmex XN – 350 manual

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Whold Blood Aspiration Motor Test	✓	

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

Test 2

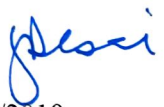
Test Name : **Sheath Motor Test**
Purpose : **To test the Sheath Motor Operation Test.**
Method : **Please follow the steps described in chapter 2, page 2.9.1 of Sysmex XN – 350's manual No.**

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Sheath Motor Motor Test	✓	

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

Test 3

Test Name : **Diagnostics Test for Auto Sampler & Barcode Operation**
Purpose : **To test the Operation of Auto Sampler & Barcode.**
Method : **Please follow the steps described in chapter 2, page 2.9.1&4 of Sysmex XN -350 manual No.**

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Sampler & Barcode Test	✓	

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

d. Operational Procedure

a. Certificate of Training

1. Technician Training

This certifies that the technicians listed below have received basic user training in the following categories for the system described in this Installation Qualification.

Mr. Siddharth Pancholi who is certified by Transasia Bio-Medicals Ltd has conducted the training.

Sr.No.	Training Program	Initials	Date
1.	Instrument Setup	O.K	
2.	System Operation	O.K	
3.	Basic Troubleshooting & Maintenance	O.K	

2. Operator Training

The users responsible for the operation of this instrument will be trained in the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filed as indicated below:

Sr.No.	Operators	Location	Initials	Date
1	Mr. Rajendra	SR Diag. Center	Training	19/07/18
2				
3				
4				
5				

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature

Date: 19/07/2018

b. Customer SOP

Title	Number	Revision #	Effective Date	Location	Verified By	Date
Operating Procedure		NA				

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

COMMENTS:

- NA -

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 19/07/2018

V. System Certification


Study data has determined that the system described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: Transasia Representative

Name : Mr. Manthan Vaja

Title : OPERATIONAL QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature: 

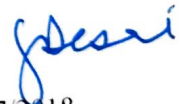
Date : 19/07/2018

Customer Authorizations:

Name : Dr. Gayatri Desai

Title : OPERATIONAL QUALIFICATION

Site : SR Diagnostics Center, Sewa Rural
Jhagadia

Signature: 

Date: 19/07/2018

SYSMEX XN – 350
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE
QUALIFICATION

For

“SR Diagnostics Center, Sewa Rural, Jhagadia”

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 9002 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

Table of Contents:


Sr. No.	Contents	Page No.
I	Approval of the PQ procedure	3
II	Instructions	4
III	Scope	6
IV	Performance Qualification	10
V	System Certification	

I. Approval of the PQ procedure

Both **SR Diagnostics Center, Sewa Rural, Jhagadia** and **Transasia** are jointly responsible for conducting the Performance Check of the Hematology Analyzer. **SYSMEX Model : XN – 350, Serial No. 12302** in the **SR Diagnostics Center, Sewa Rural, Jhagadia** as per the attached protocol.


Protocol Performed By: Transasia Representative

Name : Mr. Siddharth Pancholi
Title : PERFORMANCE QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature: 
Date: 29/03/22


Validation Team from SR Diagnostics Center, Sewa Rural:

Name : Dr. Gayatri Desai
Designation : Lab Incharge
Department : Laboratory

Signature: 
Date:

Customer Authorizations:

Name : Dr. Gayatri Desai
Title : PERFORMANCE QUALIFICATION
Site : SR Diagnostics Center, Sewa Rural
Jhagadia

Signature: 
Date:

II. Instructions

1. An authorized TRANSASIA representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. Performance checks on a regular basis described in the Further Performance Checks (vide-infra) will be responsibility of the customer's personnel.
3. Employee of (Customer) **SR Diagnostics Center, Sewa Rural, Jhagadia** will verify each result and sign in the last page. The members of the validation team will carry this out.
4. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of each PQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION. These will be an additional cost to the purchasing institution (CUSTOMER). However this additional cost will be waived when this test is conducted at time of initial performance check of new instruments.
5. Any test data that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
6. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Production Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 29/03/22

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model **XN-350**, **Serial No 12302** located in **SR Diagnostics Center, Sewa Rural, Jhagadia** (city/state or prefecture). This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 29/03/22

IV. Performance Qualification

a. Instrument Identification

1. Model Name	SYSMEX XN – 350	Verified Date	_____
2. Serial Number	12302		_____


b. Following is a list of tests to be performed and verified:

<u>Test No.</u>	<u>Test Name</u>	<u>Test Purpose</u>	<u>Verified Date</u>
02	Sample Processing	Ability to process samples	–
03	Further Performance Checks	Regular Maintenance	NA

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature 

Date: 29/03/22

c. Performance Testing

Test 1

Test Name:

Sample Processing

Purpose:

Ability to Process Samples

Method:

1. Run the control samples five times consecutively

Acceptance Criteria: Each of the results obtained above should be within the range as specified in the control chart.

Parameters Values for Verification:

RBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	4.55 - 5.03	4.89	Pass	
2.	4.55 - 5.03	4.84	Pass	
3.	4.55 - 5.03	4.83	Pass	
4.	4.55 - 5.03	4.83	Pass	
5.	4.55 - 5.03	4.88	Pass	

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature



Date: 29/03/22

WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	5.6 - 9.6	7.99	Pass	
2.	5.6 - 9.6	8.18	Pass	
3.	5.6 - 9.6	8.03	Pass	
4.	5.6 - 9.6	8.00	Pass	
5.	5.6 - 9.6	7.90	Pass	

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	12.9 - 14.1	13.5	Pass	
2.	12.9 - 14.1	13.5	Pass	
3.	12.9 - 14.1	13.5	Pass	
4.	12.9 - 14.1	13.5	Pass	
5.	12.9 - 14.1	13.6	Pass	

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	160 - 230	212	Pass	
2.	160 - 230	213	Pass	
3.	160 - 230	209	Pass	
4.	160 - 230	215	Pass	
5.	160 - 230	208	Pass	

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature



Date: 29/05/22

Test 2

Test Name:

1. Tests for checking the performance of the instruments during analysis
2. Tests for checking long term performance of the instrument

Purpose:

The purpose of the above checks is to ensure the reliability of the results being obtained.

Method:

1. During Sample analysis:

To run control samples each time the instrument is used for sample analysis and verification of the results of the controls to be within the reference range to be established by performance of the precision experiments.

2. Long term Performance

This is to be checked by Levy Jennings plots to be updated once in six months

Validation Team: SR Diagnostics Center, Sewa Rural, Jhagadia

Name : Dr. Gayatri Desai

Designation: Lab Incharge

Signature

Date: 29/03/22

V. System Certification


Study data has determined that the system described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: Transasia Representative

Name : Mr. Siddharth Pancholi

Title : PERFORMANCE QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature: 


Date: 29/03/22

Customer Authorizations:

Name : Dr. Gayatri Desai

Title : PERFORMANCE QUALIFICATION

Site : SR Diagnostics Center, Sewa Rural
Jhagadia

Signature: 

Date: 29/03/22

CALIBRATION CERTIFICATE

Details of Device Under Calibration :

Date:05-03-2022

Customer Name & Address: SR DIAGNOSTIC CENTRE,SEWA RURAL JHAGADIA	Certificate ID : AZ/21-22/ 1206
Name of Equipment: TRAUNASIA	Calibration Date : 22-02-2022
Manufacturer :SYMEX	Calibration Due Date : 21-02-2023
Model :XS-350	Location of equipment : LAB
Serial No :12302	Ambient Temperature : 27 °C

Test Equipment Used:

sr no	Test equipment	Company	Model	Sr no.	Cali. date	Cali. due date
1	Electrical safety Analyzer	Fluke Biomedical	ESA 620	1685037	01-03-2021	01-03-2022

Electrical Safety Test:

(A) Visual Test:

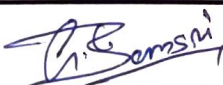

Sr No	Test	Remarks
1	Power Cords , Cable Checking	OK
2	Mains Socket Checking	OK

(B) Safety Analyzer Test

Sr No.	Parameters	Measured Values(Limits)	Remarks
1	Voltage Between live & neutral (Vln)	230.9 (210 -240 V)	Pass
2	Voltage Between live & earth (Vle)	229.9	Pass
3	Voltage Between neutral & earth(Vne)	1.8 (1 - 5 V)	Pass
4	Load current(Ia)	0.18 (0 -0.5 A)	Pass
5	Leakage Current (IL)	149 (0 -500 micro A)	Pass
6	Enclosure Current	3.7 (0 -10 micro A)	Pass
7	Patient Leakage current(PL)	28 (0 -100microA)	Pass

Note:

- (1) Results reported are valid at the time of and under the stated conditions of measurement.
- (2) Calibration has been done as per customer's requirement.
- (3) Measurements are traceable to the National Standard
- (4) NS means Not Specified and DUC means Device Under Calibration
- (5) This document shall not reproduced, except in full, without the written approval of " A to Z Biomedical Services"

Calibrated By:  Gaurang Jansari	Approved By:  Gaurav Desai
---	---

