



Erba Lachema s.r.o

DECLARATION OF CONFIRMITY and CALIBRATION



The undersigned Erba Diagnostics Ltd., Unit 4, Block K, Vantage Suites, Central Park, Leopardstown, Dublin 18, manufacturer of diagnostic devices, with Company Quality Management System in compliance with standard ISO 13485,

declares, that the device:

Name: H 360

K10012204190

complies with all the essential requirements listed in Annex I of Directive 98/79/EC and obligations specified in Annex III, art. 2 – 5 of Directive 98/79/EC for In vitro Medical-Diagnostic Devices.

Therefore Erba Lachema s.r.o. declares and assures the following:

1. The a.m. device complies with the applicable provisions of Directive 98/79/EC.
2. The a.m. device is not included in the list A and B of the Annex II of Directive 98/79/EC.
3. The manufacturer declares to have established a procedure and to maintain it in order to assure the post-marketing surveillance, according to the Directive of 98/79/EC.
4. All mentioned products are Factory calibrated and Final QC passed at the time of release.

Date of issue:

Aug-2022

Manish Alran
 Representative of Quality Management

Erba Diagnostics Ltd.

Unit 4, Block K, Vantage Suites, Central Park, Leopardstown, Dublin 18
www.erbamannheim.com VAT Reg No : IE3517014VH

This is an electronically generated document requires no signatures.



Certificate of Conformity and Calibration

Transasia Bio-Medicals Ltd., 109-110, 1st Floor, Deep Shikha Building, Rajendra Place, New Delhi - 110 008
Tel.: 011-25732223 Fax: 011-25785451 Email: sz1@transasia.co.in CIN: U39110DL1992PLC000001

TRANSASIA BIOMEDICALS LIMITED

TRANSASIA[®]

TRANSASIA
Bio-Medicals Ltd.



UNMATCHED SERVICE
SINCE 1979...

TRANSASIA
ERBA H360
AUTOMATED HEAMATOLOGY ANALYZER
INSTALLATION
QUALIFICATION
For
"Global Pathology Centre"

Manufactured by ERBA MANNHEIM
&

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

Table of Contents

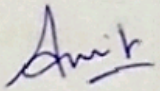
Sr. No.	Contents	Page No.
I	Approval of the IQ procedure	3
II	Instructions	4
III	Scope	5
IV	Ancillary Information	6
V	Installation Qualification	8
VI	Installation Procedure	11
VII	Comments	15
VIII	System Certification	16
IX	Appendices	-
	i	Installation Report Dt.
	ii	ISO 9002 certificate
	iii	Sample Page of the Logbook

I. Approval of the IQ procedure:

Global Pathlogy Centre Laboratory and Transasia are jointly responsible for the installation of the system ERBA HEMATOLOGY Analyzer, Model: H360, Serial No. K10012204190 in the clinical lab of Global Pathlogy Centre as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Amit Pal
Title : INSTALLATIONQUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature: 

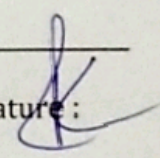
Date: 9-8-2023

Validation Team from :TSD

Name :
Designation :
Department :

Customer Authorizations:

Name : Dr. R S Kushwha
Title : INSTALLATION QUALIFICATION
Site : Global Pathlogy Centre
8-2023

Signature: 

Date : 9-

II. Instructions

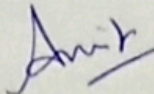
1. This document is to be completed at the time the system is shifted to its current location and set up for operation.
2. An authorized TRANSASIA representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be noted and dated.
3. Employee of Global Pathlogy Centre 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 :

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model H360, Serial No. K10012204190 located in Global Pathology Centre. 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.

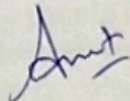
Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team :

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

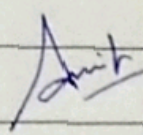
IV. Ancillary Information.

a. Certification of Purchase Order Compliance

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

Verified By : Dr R S KushwhaDate : 9-8-2023

b. Utilities

Sr.No.	Utility	Yes / No	Verified By	Date
1.	Environmental condition as per requirement: (Ambient range of temperature 15 - 30 °C, relative humidity 30% to 85%, air conditioning facility, non exposure to direct sunlight, non-interference from high frequency radio waves)	<input checked="" type="checkbox"/>		
2.	Adequate space for installation : (Minimum in mm. W 360 X D 410 X H 475 for the main unit clearance of around 50 cm from back around 50cm on top and around 50 cm on sides for the main unit)	<input checked="" type="checkbox"/>		
3.	DIL-H360; LYSE1 BOTTLE to be placed within a distance of 2 meters :	<input checked="" type="checkbox"/>		
4.	Power Source Requirements* It should have minimum five 5amps plug. It should have proper grounding. In case of online UPS minimum power handling capacity should be minimum 1KVA Line- Neutral voltage: <u>220</u> Line -Earth voltage: <u>2</u> Neutral-Earth voltage: <u>222</u>	<input checked="" type="checkbox"/>		

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INSTALLATION QUALIFICATION

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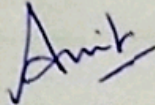
* Encircle applicable source

Validation Team :

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

c. The instrument has been verified for the following

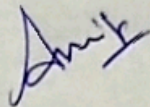
Sr.No.	Verification	Yes / No	Verified By	Date
1.	Instrument is identified	Yes / No		
2.	Manufacturer's specifications are included	Yes / No		
3.	Accessories / Consumables are listed	Yes / No	Amit	9/8/23
4.	Manufacturer's certificate of Compliance attached	Yes / No		

Validation Team :

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

INSTALLATION QUALIFICATION

V. Installation Qualification

A. Equipment Description

This ERBA H360 is a fully automated three part Hematology analyzer for in vitro diagnostic use in clinical laboratories. The instrument provides accurate and precise test results for (22) parameters including three histograms.

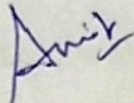
Instrument identification		Verified by	Date
Equipment Name	Automated Hematology	Amit	9/8/23
Model	H360		
Manufacturer	Erba Mannheim		
Marketed By	Transasia		
Equipment #	H360		
Serial Number	K10012204190		
Size (in mm)	W 360 X D 410 X H 475		
Power	AC 220 V		
Frequency	50 - 60 Hz		
Power Consumption	Less Than 250 VA		

Validation Team :

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

Installation Qualification

Consumables such as H-Clean, DIL H360 & LYSE1 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. Instructions For use
2. User's Guide

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 Global Pathology Centre .

E. Maintenance

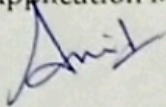
The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the User Manual.

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 :

Name: Amit Pal

Designation: Application Manager

Signature 

Date: 9-8-2023

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INSTALLATION QUALIFICATION	

F. Spare Parts

Transasia strongly recommends the end user maintain a basic of consumable parts onsite to minimize down time due to minor failures. They have provided a list of such consumable parts and the same is also available in the Operator's Manual.

C. Equipment Logs

Title	Location	Verified by	Date
IQ	Global Pathlogy Centre	Dr. R S Kushwha	9-8-2023

Sample page of the logbook is attached to this document

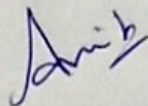
Effective date : 9-8-2023

Validation Team :

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

H. Installation Procedure

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

1. Unpacking Checklist

Refer to Page-16 of ERBA H360 Instruction For Use

2. Check Before Installation

Refer to Page-14 of ERBA H360 Instruction For Use

3. Grounding

Refer to Page-15 of ERBA H360 Instruction For Use

4. Installation Environment & Space

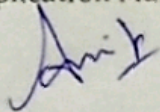
Refer to Page-15 of ERBA H360 Instruction For Use

Validation Team :

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

TRANSASIA BIOMEDICALS LIMITED

INSTALLATION QUALIFICATION

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Bio-Medicals Ltd.

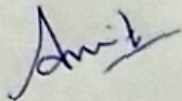
COMMENTS:

Validation Team :

Name: Amit Pal

Designation: Application Manager

Signature



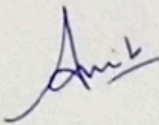
Date: 9-8-2023

VII. 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

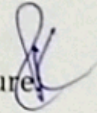
Name : Amit Pal

Title : INSTALLATION QUALIFICATION Signature : 

Company: TRANSASIA BIO-MEDICALS LTD. Date :9-8-2023

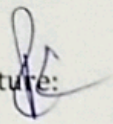
Customer Authorizations:

Name : Dr R S Kushwha

Title : INSTALLATION QUALIFICATION Signature: 

Company : Global Pathlogy Centre Date :9-8-2023

Name : *Dr R.S Kushwaha*

Title : INSTALLATION QUALIFICATION Signature: 

Company: *Global Pathology Centre* Date : *9/8/23*

TRANSASIA BIOMEDICALS LIMITED

TRANSASIA
Bio-Medicals Ltd

INSTALLATION QUALIFICATION

Date:

Reagent Check done

Printer checked

Analyzer switched ON at

SELF CHECK performed

RINSE CYCLE completed

Background limits within acceptable range

Analysis start time

Analysis end time

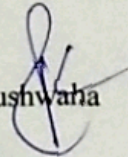
No. of samples analyzed

Shut down procedure done

Analyzer switched OFF at

Recorded by:

Checked by: Dr. R S Kushwaha



Date: 9-8-2023



ERBA-- H360 AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

“Global Pathology Centre”

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

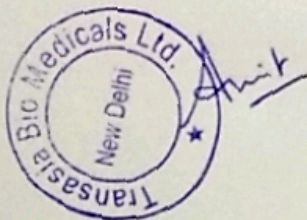


Table of Contents:

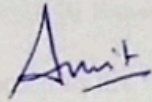
Sr. No.	Contents	Page No.
I	Approval of the PQ procedure	3
II	Instructions	4
III	Scope	5
IV	Performance Qualification	6
V	System Certification	10

I. Approval of the PQ procedure

Both **GLOBAL PATHOLOGY CENTRE Hari Nagar, Delhi 110064** and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer, Model : ERBA – H360, Serial No, K10012204190 in the clinical lab of GLOBAL PATHOLOGY CENTRE as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Amit Pal
Title : PERFORMANCE QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature: 
Date: 9-8-2023

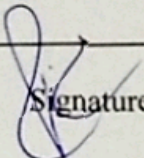
Validation Team from :

Name : Amit Pal
Designation : Application Manager
Department : TSD

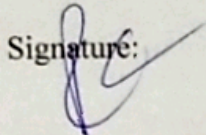
Name :
Designation :
Department :

Customer Authorizations:

Name : Dr. R S Kushwha
Title : PERFORMANCE QUALIFICATION
Site : Global Pathology Centre

Signature: 
Date: 9-8-2023

Name : *Dr. R.S. Kushwha*
Title : PERFORMANCE QUALIFICATION
Site :

Signature: 
Date: 9-8-2023

II. Instructions

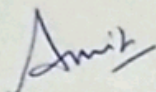
1. An authorized TRANSASIA representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. Performance checks on a regular basis described in the Further Performance Checks (vide-infra) will be responsibility of the customer's personnel.
3. Employee of Global Pathology Centre Laboratory 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. 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:

Name Amit Pal

Designation Application Manager

Signature



Date 9-8-2023

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA -H360, Serial No K10012204190 located in **Global Pathology Centre**. 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.

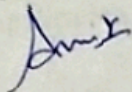
Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team:

Name Amit Pal

Designation Application Manager

Signature



Date 9-8-2023

IV. Performance Qualification

a. Instrument Identification

Verified Date

1. Model Name ERBA - H360 9-8-2023
2. Serial Number K10012204190 9-8-2023

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

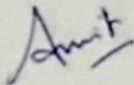
Test No.	Test Name	Test Purpose	Verified Date
02	Sample Processing	Ability to process samples	_____
03	Further Performance Checks	Regular Maintenance	NA

Validation Team:

Name Amit Pal

Designation Application Manager

Signature



Date 9-8-2023

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:

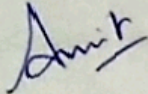
QC Data Attached.

Validation Team:

Name Amit Pal

Designation Application Manager

Signature



Date 9-8-2023

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

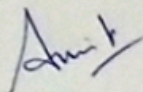
This is to be checked by Levy Jennings plots to be updated once in six months

Validation Team:

Name Amit Pal

Designation Application Manager

Signature



Date 9-8-2023

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.

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

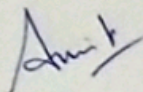
This is to be checked by Levy Jennings plots to be updated once in six months

Validation Team:

Name Amit Pal

Designation Application Manager

Signature



Date 9-8-2023

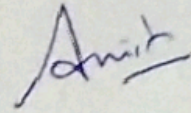
V. System Certification

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 : Amit Pal

Title : PERFORMANCE QUALIFICATION Signature:

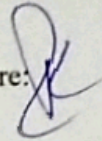


Company: TRANSASIA BIO-MEDICALS LTD. Date : 09-8-2023

Customer Authorizations:

Name : Dr. R S Kushwaha

Title : PERFORMANCE QUALIFICATION Signature:

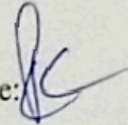


Site : GLOBAL PATHOLOGY CENTRE

Date : 9-8-2023

Name : DR. R-S Kushwaha

Title : PERFORMANCE QUALIFICATION Signature:



Site :

Date : 9/8/2023

File No.	Lot No.	Exp. Date	QC Mode	Level	WBC	RBC	HGB	HCT	PLT
2	E0523N	2023/08/11	Whole Bloc	Normal					
	Date	Time	Operator						
Target					8.01	4.82	13.4	43.3	280
Limits (#)					1	0.24	0.6	3	40
5	2023/08/09	15:37:44	admin		7.77	4.82	12.9	45.6	279
4	2023/08/09	15:36:34	admin		8.03	4.92	13.2	46.6	294
3	2023/08/09	15:35:30	admin		7.92	4.88	13.1	46	281
2	2023/08/09	15:34:06	admin		7.88	4.86	13	46	274
1	2023/08/09	15:26:55	admin		7.69	4.88	13	46.2	276
Mean					7.858	4.872	13.04	46.08	280.8
SD					0.132174	0.036332	0.114018	0.363318	7.854935
CV%					1.682033	0.745727	0.874368	0.788451	2.797341

TRANSASIA BIOMEDICALS LIMITED

TRANSASIA
TRANSASIA
Bio-Medicals Ltd.

Transasia Bio-Medicals Ltd., 109-110, 1st Floor, Deep Shikha Building, Rajendra Place, New Delhi - 110 008
Tel.: 011 - 25732223 Fax: 011-25785451 Email: nz1@transasia.co.in



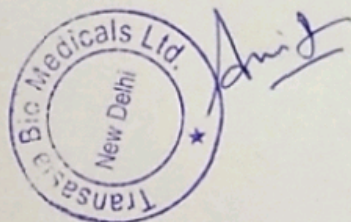
UNMATCHED SERVICE
SINCE 1979...

TRANSASIA
Erba H360
AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL
QUALIFICATION

For
Global Pathology Centre

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



www.transasia.co.in



HO : Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072,

Table of Contents

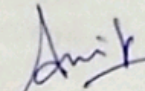
Sr. No.	Contents	Page No.
I	Approval of the OQ procedure	3
II	Instructions	4
III	Scope	5
IV	Operational Qualification	6
V	System Certification	15

I. Approval of the OQ procedure:

Global Pathology Centre and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: Erba H360, serial no. K10012204190 in the clinical lab of Global Pathology Centre as per protocol attached.

Protocol Performed by: Transasia Representative

Name : Amit Pal
Title : OPERATIONAL QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

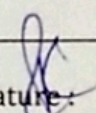
Signature : 
Date :9-8-2023

Validation Team from : TSD

Name :
Designation :
Department :

Customer Authorization:

Name : Dr. R S Kushwha
Title : OPERATIONAL QUALIFICATION
Site : Global Pathology Centre

Signature : 
Date :9-8-2023

II. Instructions

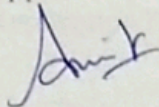
1. The TRANSASIA representative will check each module and enter the specific data as described in the Operational Qualification. Each result will be noted and dated.
2. Employee of Global Pathology Centre will verify each result and sign in the last page. The member/s of the validation team will be 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. 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:

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model H360, Serial No. K10012204190 located in Clinical laboratory of Global Pathology Centre. 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.

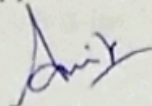
Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

IV. Operational Qualification

a. Instrument Identification

Verified Date

1. Model Name	H360	9-8-2023
2. Serial Number	K10012204190	9-8-2023

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

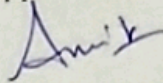
Test No.	Test Name	Test Purpose	Verified Date
1.	Liquid Pump	To verify pressure & vacuum generation	
2.	Syringe Assembly	Capacity of Blood Aspiration Diluent Aspiration & Lyse 1 Aspiration	
3.	Liquid Sensing PCB	To verify Liquid sensing ability Of sensors	

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

c. Operational Testing

Test 1

Test Name : Liquid Pump.

Purpose : To test Liquid Pump

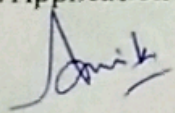
Method : Please follow the steps described in Erba H360 "Service Manual"

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	LIQUID PUMP	✓	

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature 

Date: 9-8-2023

Test 2

Test Name : Syringe Assly

Purpose : To test function

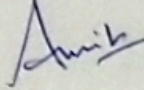
Method : Please follow the steps described in Erba H360 "Service Manual"

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Syringe Assly	✓	

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature 

Date: 9-8-2023

OPERATIONAL QUALIFICATION

Test 3

Test Name : Liquid sensing PCB

Purpose : To test the liquid sensing operation.

Method : Please follow the steps described in Erba H360 "Service Manual"

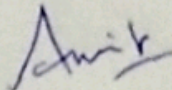
	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Liquid Sensing	✓	

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

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. Amit Pal who is certified by Transasia Bio-Medicals Ltd has conducted the training.

Sr.No.	Training Program	Initials	Date
1.	Instrument Setup	Amit	9/8/23
2.	System Operation		
3.	Basic Troubleshooting & Maintenance		

2. Operator Training

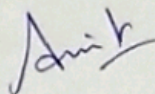
The users responsible for the operation of this instrument will be trained in the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented.

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

b. Customer SOP

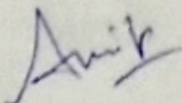
Title	Number	Revision #	Effective Date	Location	Verified By	Date
Operating Procedure		NA				

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature



Date: 9-8-2023

TRANSASIA BIOMEDICALS LIMITED

OPERATIONAL QUALIFICATION

TRANSASIA
Bio-Medicals Ltd.

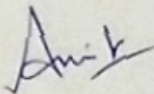
COMMENTS:

Validation Team:

Name: Amit Pal

Designation: Application Manager

Signature



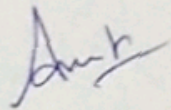
Date: 9-8-2023

VII. 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 : Amit Pal

Title : OPERATIONAL QUALIFICATION Signature : 

Company : TRANSASIA BIO-MEDICALS LTD. Date : 9-8-2023

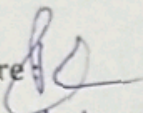
Customer Authorizations:

Name : Dr. R S Kushwha

Title : OPERATIONAL QUALIFICATION Signature :

Company : Global Pathology Centre Date : 9-8-2023

Name : Dr. R.S. Kushwaha

Title : OPERATIONAL QUALIFICATION Signature : 

Company : Global Pathology Centre Date : 9/8/2023