Erba Lachema s.r.o

DECLARATION OF CONFIRMITY and CALIBRATION

CE

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:H560	K11042109048

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: **Feb-2021**

Manish Airan
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 BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
TRAINING CERTIFICATE				
Instrument Name H-560	AUTOMATED HEAMATOLOGY ANALYZER	Instrument ID	K11042109048	

7th May 2021

TRAINING CERTIFICATE

TO WHOMSOEVER IT MAY CONCERN

This is to Certify that Mr./MS ABHINAV KUMAR THAKUR Technical Staff Team of Sunshine Lab and Diagnostics, Mahaveer Enclave, Delhi, 110045 have successfully completed training on operation and maintenance, under supervision of our Application Specialist Amit Pal. Training held on:- Automated Heamatology Analyzer, Model: H-560

Amit Pal
Sr. Application Specialist

For Transasia Bio-Medicals Ltd.

Erba Lachema s.r.o

DECLARATION OF CONFIRMITY and CALIBRATION

CE

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:H560	K11042109048

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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: Feb-2021

Manish Airan
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

ERBA– H560
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

"Sunshine Lab & Diagnostics"

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

Table of Contents:

I. Approval of the PQ procedure

Both Sunshine Lab & Diagnostics and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer,Model : ERBA – H560, Serial No. in the clinical lab of Sunshine Lab & Diagnostics as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name	:	Amit Pal	Signature:
Title	:	**PERFORMANCE QUALIFICATION**	Date:3-12-21
Company	:	**TRANSASIA BIO-MEDICALS LTD.**	

Validation Team from **TSD** :

Name	:	
Designation	:	
Department	:	

Name	:	
Designation	:	
Department	:	

Customer Authorizations: Sunshine Lab & Diagnostics

Name	:	Dr. P A Kumar	Signature:
Title	:	PERFORMANCE QUALIFICATION	
Site	:		Date:3-12-21

Name	:		Signature:
Title	:	PERFORMANCE QUALIFICATION	
Site	:		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) Anand Diagnostic 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 Sunshine Lab & Diagnostics. 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 Sr. Application Specialist

Signature 

Date 3-12-21

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA -H560, Serial No-K114210 9048 located in Sunshine Lab & Diagnostics. 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 Sr. Application Specialist

Signature 

Date 3-12-21

IV. Performance Qualification

a. Instrument Identification		Verified Date
1. Model Name	ERBA – H560	3-12-21
2. Serial Number	K1104210904	3-12-21

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	3-12-21
03	Further Performance Checks	Regular Maintenance	NA

Validation Team:

Name Amit Pal

Designation Sr. Application Specialist

Signature 

Date 3-12-21

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 Run % times, Data attached

Validation Team:

Name Amit Pal

Designation Sr. Application Specialist

Signature

Date 3-12-21

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:

Name Amit Pal

Designation Sr. Application Specialist

Signature 

Date 3-12-21

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 :3-12-21

Customer Authorizations: Sunshine Lab & Diagnostics

Name : Dr. P A Kumar

Title : PERFORMANCE QUALIFICATION Signature:

Site : Sunshine Lab & Diagnostics Date :3-12-21

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date

OPERATIONAL QUALIFICATION

For

TRANSASIA

ERBA H560 AUTOMATED HEMATOLOGY ANALYZER

Sunshine Lab & Diagnostics

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

MUMBAI – 400 072

Table of Contents

I. Approval of the OQ procedure:

Sunshine Lab & Diagnostics and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: Erba H560, serial no. K1104210948 in the clinical lab of Sunshine Lab & Diagnostics as per protocol attached.

Protocol Performed by: **Transasia Representative**

Name	:	Amit Pal	Signature :
Title	:	OPERATIONAL QUALIFICATION	Date : 3-12-21
Company	:	TRANSASIA BIO-MEDICALS LTD.	

Validation Team from _____TSD_____

Name	:	
Designation	:	
Department	:	

Customer Authorization: Sunshine Lab & Diagnostics

Name	:	Dr P A Kumar	Signature :
Title	:	OPERATIONAL QUALIFICATION	Date :3-12-21
Site	:	Palam	

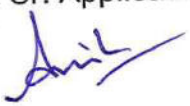
II. Instructions

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 Sunshine Lab & Diagnostics 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 Sunshine Lab & Diagnostics. 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: Sr. Application Specialist

Signature: 

Date:3-12-21

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model H560, Serial No. K11042109048 located in Sunshine Lab & Diagnostics Clinical laboratory of Sunshine Lab & Diagnostics. 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: Sr. Application Specialist

Signature: 

Date:3-12-21

IV. Operational Qualification

a. Instrument Identification **Verified Date**

1. Model Name	H560	3-12-21
2. Serial Number	K11042109048	3-12-21

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& 2 Aspiration	
3.	Liquid Sensing PCB	To verify Liquid sensing ability Of sensors	

Amit

Validation Team:

Name: Amit Pal

Designation: Sr. Application Specialist

Signature:

Date:3-12-21

c. Operational Testing

Test 1

Test Name : **Liquid Pump.**

Purpose : **To test Liquid Pump**

Method :**Please follow the steps described in Erba H560 "Service Manual"**

	PARAMETER	**PASS** / **FAIL**
Parameter values for verification	**LIQUID PUMP**	✓

Validation Team:

Name: Amit Pal

Designation: Sr. Application Specialist

Signature:

Date:3-12-21

Test 2

Test Name : **Syringe Assly**

Purpose : **To test function**

Method : **Please follow the steps described in Erba H560 "Service Manual"**

	PARAMETER	PASS / FAIL
Parameter values for verification	**Syringe Assly**	✓

Validation Team:

Name: Amit Pal

Designation: Sr. Application Specialist

Signature: 

Date:3-12-21

Test 3

Test Name : **Liquid sensing PCB**

Purpose : **To test the liquid sensing operation.**

Method : **Please follow the steps described in Erba H560 "Service Manual"**

	PARAMETER	PASS	FAIL
Parameter values for verification :	**Liquid Sensing**	✓	

Validation Team:

Name: Amit Pal

Designation: Sr. Application Specialist

Signature: Amit

Date:3-12-21

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

Sr.No.	Training Program	Initials	Date
1.	Instrument Setup	Done	3/12/21
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 and the training records will be filed as indicated below :

Sr.No.	Operators	Location	Initials	Date
1	Abhinav	Palam	Given	3-12-21

Validation Team:

Name: Amit Pal

Designation: Sr. Application Specialist

Signature: 

Date:3-12-21

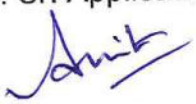
b. Customer SOP

Title	Number	Revision #	Effective Date	Location	Verified By	Date
Operating Procedure		NA	3-12-21	Palam	Amit Pal	3-12-21

Validation Team:

Name: Amit Pal

Designation: Sr. Application Specialist

Signature: 

Date:3-12-21

COMMENTS:

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 :3-12-21

Customer Authorizations: Sunshine Lab & Diagnostics

Name : Dr. P A Kumar

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :3-12-21

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :

INSTALLATION QUALIFICATION

For

TRANSASIA

ERBA H560
AUTOMATED HEAMATOLOGY ANALYZER

Sunshine Lab & Diagnostics

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

Table of Contents

I. Approval of the IQ procedure:

Sunshine Lab & Diagnostics Laboratory and Transasia are jointly responsible for the installation of the system ERBA HEMATOLOGY Analyzer, Model: H560, Serial No. K11042109048 in the clinical lab of Sunshine Lab & Diagnostics as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name : Amit Pal Signature:
Title : INSTALLATIONQUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD. Date: 3-12-21

Validation Team from _____TSD_____:

Name :
Designation :
Department :

Customer Authorizations: Sunshine Lab & Diagnostics

Name : Dr P A Kumar Signature :
Title : INSTALLATION QUALIFICATION
Site : Date :3-12-21

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 Sunshine Lab & Diagnostics 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 Sr. Application Specialist

Signature 

Date 3-12-21

III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model H560, Serial No. K11042109048 located Sunshine Lab & Diagnostics in 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 Sr. Application Specialist

Signature 

Date 3-12-21

IV. Ancillary Information.

a. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument is purchased under Purchase order sent against Quotation is in compliance with the specifications of the Purchase order.

Verified By :_Amit Pal Date :_3-12-21

b. Utilities

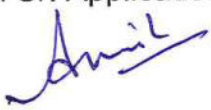
Sr.No.	Utility		Verified By	Date
1.	Environmental condition as per requirement: (Ambient range of temperature 15 – 30 °C, relative humidity 30% to 85%, air conditioning facility, non exposure to direct sunlight, non-interference from high frequency radio waves)	Yes / No	Amit 3/12/21	
2.	Adequate space 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)	Yes / No		
3.	DIL-H560; LYSE1 & LYSE2 BOTTLES to be placed within a distance of 2 meters :	Yes / No		
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:_____ Line –Earth voltage:_____ Neutral-Earth voltage:_____	Yes / No		

* Encircle applicable source

Validation Team :

Name Amit Pal

Designation Sr. Application Specialist

Signature 

Date 3-12-21

c. The instrument has been verified for the following

Sr.No.	Verification		Verified By	Date
1.	Instrument is identified	Yes / No		
2.	Manufacturer's specifications are included	Yes / No		3/12/4
3.	Accessories / Consumables are listed	Yes / No		
4.	Manufacturer's certificate of Compliance attached	Yes / No		

Validation Team :

Name Amit Pal

Designation Sr. Application Specialist

Signature

Date 3-12-21

V. Installation Qualification

A. Equipment Description

This ERBA H560 is a fully automated five part Hematology analyzer for in vitro diagnostic use in clinical laboratories. The instrument provides accurate and precise test results for (29) parameters including three histograms & one scatter-grams.

Instrument identification		Verified by	Date
Equipment Name	**Automated Hematology**		
Model	**H560**		
Manufacturer	**Erba Mannheim**		
Marketed By	**Transasia**		
Equipment #	**H560**		
Serial Number	**K1104042109048**		
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 Sr. Application Specialist

Signature

Date 3-12-21

B. Accessories / Consumables

Validation Team :

Name Amit Pal

Designation Sr. Application Specialist

Signature

Date 3-12-21

Installation Qualification

Consumables such as H-Clean, DIL H560, LYSE1 & LYSE2 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 Sunshine Lab & Diagnostics .

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 Sr. Application Specialist

Signature Amit

Date 3-12-21

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
		Amit Pal	3-12-21

Sample page of the logbook is attached to this document

Effective date: 3-12-21

Validation Team :

Name Amit Pal

Designation Sr. Application Specialist

Signature 

Date 3-12-21

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 H560 Instruction For Use

2. **Check Before Installation**
   Refer to Page-14 of ERBA H560 Instruction For Use

3. **Grounding**
   Refer to Page-14 of ERBA H560 Instruction For Use

4. **Installation Environment & Space**
   Refer to Page-14 of ERBA H560 Instruction For Use

Validation Team :

Name Amit Pal

Designation Sr. Application Specialist

Signature

Date 3-12-21

COMMENTS:

Validation Team :

Name Amit Pal

Designation Sr. Application Specialist

Signature 

Date 3-12-21

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 :3-12-21

Customer Authorizations: Sunshine Lab & Diagnostics

Name : Dr PA Kumar

Title : INSTALLATION QUALIFICATION Signature:

Company : Date :3-12-21

Name :

Title : INSTALLATION QUALIFICATION Signature:

Company: Date :

Date: 3-12-21

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: Amit Pal

Date: 3-12-21