



Divine Touch Medi - Clinic



(An ISO 9001: 2015 Certified Multispeciality Clinic & Diagnostics Centre)

Date: 12/12/2023

Ref. Lab MELT ID: NABL/NABLCL006736

To,
Chief Executive Officer
National Accreditation Board for Testing and Calibration Laboratories
NABL House
Plot- 45, Sector 44,
Gurgaon - 122002, Haryana
Near HUDA City Centre Metro Station, Behind Fortis Hospital
Tel. no.: 91-124-4679700 (30 lines)
Fax: 91-124-4679799
Website: www.nabl-india.org


Sub: Declaration regarding conversion of Partnership Firm to Limited Liability Partnership (LLP) Firm.

Dear Sir,

We, DIVINE TOUCH MEDI CLINIC, located in Agartala, Tripura bearing user name no **NABLCL006736**, would like to declare we are in the process of initiation of conversion of the **Partnership Firm to Limited Liability Partnership (LLP) Firm** or any other legal entity as per NABL notifications and regarding this we shall require some time . We understand the importance of maintaining compliance with NABL regulations, and we are committed to ensuring a seamless transition that adheres to all applicable standards. As part of this conversion process, we anticipate that certain governmental administrative procedures and documentation requirements will need to be fulfilled which is time consuming. However, considering the size and scale of our laboratory, we anticipate that this conversion may take some time to complete but we assure that we try utmost to complete the process within 31.12.2023.

Thank you for your understanding and cooperation in this matter. We look forward to your positive response and appreciate your continued support.

With regards


Mr. Raib Roy
(Partner /Laboratory Head)
M-8014251101



A Multi-speciality Health Care Destination

Colonel Chowmuhani, Agartala, Tripura (W), Pin-799001, Contact Us : 9089016161, 8575092597, E-mail : divinetouch.mediclinic@gmail.com

53

9857

IV-359

Scanned.



त्रिपुरा TRIPURA



164390

Admissible under rule 21
 duly stamped under the Indian
 Stamp Act, 1899
 Scedule T. No.
 Fees Paid

Samir Ranjan Bhattacharjee

Litan Jato

Subscribed by Charadey

Rajib Roy

723.00
 6.00

 729.00

Dist. Sub-Registrar,
 West Tripura, Agartala

CH. No. *4378/15*
 Bench Clerk
 O/o. the District Sub-Registrar,
 West Tripura, Agartala.

DEED OF PARTNERSHIP

THIS DEED OF PARTNERSHIP is made on this the 30 th day of AUGUST 2015 A.D.

AMONG.

1) SRI SAMIR RANJAN BHATTACHARJEE, Son of Late Sati Ranjan Bhattacharjee Roy, resident of Ramnagar Road No.8, P.S. West Agartala, District, West Tripura, PIN 799002, by faith Hindu by occupation Business, Indian by nationality, Here-in-after Called the **FIRST PARTY.**

Contd...P/2.

Samir Rajin Baral & Co
Litom Saha
Subscribed by Chowdhury
Rajib Roy.

Page No.2

2. **SRI. LITAN SAHA** , Son of Shri Mrityunjoy Saha, resident of Shibnagar, College Road, P.O. Agartala College P.S. East Agartala ,District, West Tripura by faith Hindu by occupation business, Indian by nationality, Here-in-after Called the **SECOND PARTY**.

3. **SRI SUBHADEEP ROY CHOUDHURY** , Son of Shri Sankar Kumar Cohoudhury resident of Shibnagar College Road , P.O. Agartala College , P.S. East Agartala ,District, West Tripura by faith Hindu by occupation business, Indian by nationality, Here-in-after Called the **THIRD PARTY**.

AND

4. **SHRI RAJIB ROY**, Son of Shri Pradip Kumar Roy, resident of Amtali, Uttar Madhya Para P.S. Amtali ,District, West Tripura by faith Hindu by occupation business, Indian by nationality, Here-in-after Called the **FOURTH PARTY**.

WHEREAS the above named persons have decided to form a Partnership firm in the name and style of M/S DIVINE TOUCH MEDI CLINIC or this day the 11th day of May, 2015 with the object run a multi facility Diagnostics and Health Care OPD and related business. This firm may be engaged with any type of legal business and may enter into agreement deals with any individual, firm, Pvt. Ltd. Co Public limited company societies etc. The place of business will be a Colonel Chowmuhani, Agartala , West Tripura ,Tripura State(India) or any other place/places in India with proper licences from the appropriate authority and firm may open chain of business as the case may be.

Contd...P/3.



Samin Ranjan Bealasing
Litem Lha
Subhadra Prasad
Rajib Roy.

Page No.3.

NOW THIS INDENTURE ISL WITNESS AS FOLLOWS:-

- 1) That, the parties referred above shall carry on the business of multi facility diagnostic and health care OPD and related business in the Partnership firm under the name and style of **M/S DIVINE TOUCH MEDI CLINIC** at Colonel Chowmuhani, Agartala , West Tripura , Tripura State, (hereinafter referred to as the Firm) but by their mutual consent may start and carry on any other business or business under any other name or names at any other places of place(s).
- 2) That, the business of the Partnership pursuant to this Deed partnership shall be deemed to have commenced with effect from 11th day of May, 2015.
- 3) That the capital required for the business of partnership shall be contributed time to time by the parties in such manner in all respect as may be agreed to among them and such capital may be paid interest as may be mutually agreed from time to time at the rate of rates not exceeding 12% per annum.
- 4) That, all the parties referred above shall be working partners and shall attend diligently to the business of the partnership and carry on the same for the greatest advantage of the firm.
- 5) That, all the working partners may be paid salary w.e.f. 11th day of May, 2015 for the work of the Firm as may be agreed mutually from time to time among all the parties in accordance with the provision of Income tax laws as well as business necessities and other factors, subject however, that the monthly salary to each such partners shall not exceed as under.

Contd. P/4.

Samir Ranjan Bhattacharjee
Litan Saha
Subha Deep Roy Chowdhury
Rajib Roy.

Page NO.4.

NAME OF WORKING PARTNERS MAXIMUM BASIC SALARY NOT TO EXCEED.

- a) Sri Samir Ranjan Bhattacharjee **Rs.12000/- per month**
b) Sri Litan Saha **Rs.12000/- per month.**
c) Sri Subha Deep Roy Chowdhury **Rs.12000/- per month.**
d) Sri Rajib Roy **Rs.12,000/- per month.**

- 6) That, all business expenses shall be borne by the Firm.
- 7) That, the profits/Loss as case may be of the Partnership business shall be divided among the partners as under.

<u>Name of working Partner</u>	<u>Profit</u>	<u>Loss</u>
a) Sri Samir Ranjan Bhattacharjee	35%	35%
b) Sri Litan Saha	25%	25%
c) Sri Subha Deep Roy Chowdhury	25%	25%
d) Sri Rajib Roy	15%	15%

- 8) That, the duration of the partnership shall be at will subject to clause 9.
- 9) That, any partner may retire from partnership firm after giving a notice to the other partners of not less than one month in writing and at the expiry of such notice period he shall be deemed to have retired.
- 10) Upon mutual understanding, each partner or his duly authorized agent shall have free access to the account books of the partnership and shall be entitled to take copies extract from any or all such books and records of the partnership business.

Contd...P/5.

Somir Ranjan Bhattacharya
Litro Inke
Subscribed by Clearly
Rajiv Roy.

Page No.5.

- 11) That, no partner shall have the right to sale, mortgage or transfer his share of interest in the firm to anyone else except to his heir or heirs or any one of the existing partners or to their heir(s). In the event of heir(s) selling his/her share to anyone else, the existing partners shall have a right or permission in respect of such share(s) sold.
- 12) That, the partners shall keep or cause to be kept the books of accounts of the firm at the principal places of its business and make all entries therein, and that all such books of accounts kept shall be closed on 31st March every year.
- 13) That, no partner shall do any act or think whereby the firm or the firm's property may be prejudicially affected.
- 14) That, the terms of the partnership deed may be altered, added to or cancelled by the written consent of the parties to this deed.
- 15) That, for dealing with business bank in the name of the firm can be opened in any bank at any place in India. The bank account will be operated jointly by the first and second party.
- 16) That, the firm can borrow loan from the bank/financial institutions/individual/firms for its business interest but not for the interest of any individual partner(s).
- 17) That, in the case of any dispute arising out of this deed between the parties of this deed, it shall be decided by arbitration as provided for under the Indian Arbitration Act.

Contd...P/6.

Samir Ranjan Bhattacharya
Liton Jha
Subhadat By Chowdhury
Rajib Roy.

IN WITNESS WHEREOF the parties hereto have set and subscribed their respective hands to these presents 30 th day of August, 2015 at Agartala .

- 1) Samir Ranjan Bhattacharya
(First Party)
- 2) Liton Jha
(Second Party)
- 3) Subhadat By Chowdhury
(Third party)
- 4) Rajib Roy.
(Fourth Party)

Witnesses:

1. Subodh Das

2. Samir Debnath

Drafted and identified by : Asim Hasan
Advocate.

Computed printed by : Sudip Kumar Saha
(SUDIP KUMAR SAHA)



17147

Samir Ranjan Bhattacharya



17148

Kirtan Das



17149

Sukhdeep Ghoshal



17150

Rajib Roy

Execution is admitted by
 Sri. Rajib Roy
 S/o. Sri. Rajib Roy
 of Apala P.S. Haldia
 Dist. West Tripura.
 By Case Haldia
 By Profession Business
 Identified by A. R. Ghoshal

Execution is admitted by
 Sri. Rajib Roy
 S/o. Sri. Rajib Roy
 of Apala P.S. Haldia
 Dist. West Tripura.
 By Case Haldia
 By Profession Business
 Identified by A. R. Ghoshal

Dist. Sub-Registrar,
West Tripura, Agartala

5-4-2015
REGISTER

5-4-2015
REGISTER

Registered in Reg IV
 Book No. 6
 Volume No. 35-38
 Page No. 14-359
 Being No. 2015
 For the year 2015

Dist. Sub-Registrar,
West Tripura, Agartala

Executant(s) identified by me
A. R. Ghoshal
 Advocate
 Tripura Bar Association
 Agartala, Tripura (W)





AGARTALA MUNICIPAL CORPORATION
AGARTALA
RENEWED

Municipal Licence No :-1/15/372
New Licence No:-001011500372

holding no : **1760/578**
ward no : **20**

house no : **205478**
touji no : .

Trade Address: **COLONEL CHOWMUHANI PALACE COMPOUND AGT**

The agartala municipal corporation hereby grants this provisional licence to

M/S DIVINE TOUCH MEDI CLINIC

SI No	Licensee Name	Father/Husband Name	Address
2	SRI LITAN SAHA	S/o SRI MRITYUNJOY SAHA	COLONEL CHOWMUHANI PALACE COMPOUND AGT
1	SRI SAMIR RANJAN BHATTACHARJEE	S/o LATE SATI RANJANJAN BHATTACHARJEE	COLONEL CHOWMUHANI PALACE COMPOUND AGT
3	SRI SUBHA DEEP ROY CHWDHURY	S/o SRI SANKAR KUMAR ROY CHWDHURY	COLONEL CHOWMUHANI PALACE COMPOUND AGT
4	SRI RAJIB ROY	S/o SRI PRADIP KUMAR ROY	COLONEL CHOWMUHANI PALACE COMPOUND AGT

Under section 121/201/182 of T.M Act for use of aforesaid premises or a part there of for running gainful activities of (name of business / profession) **MEDICINE SELLER (RETAIL) Big; PATHOLOGICAL DIAGNOSIS CENTRE (Big)** subject to the terms and conditions given below and acknowledge to have received the sum of Rs **3660** only being the lisencc fees for the year **2023 - 2024**



AGARTALA MUNICIPAL CORPORATION
AGARTALA
RENEWED

This Licence is valid upto :- 31 Mar 2024

CONDI T I O N S

- 1) That the premises shall not be caused to be used/maintained in a manner likely to cause injury, danger annoyance or offence to the sense of sight, smell or hearing for person residing in the neighborhood and that they shall not cause or maintain in a manner so as to cause any danger to life or injury to the health of persons employed in same business or residing in the neighborhood or injury to any property or in any other way cause or maintain in a manner so as to cause inconvenience to the public.
- 2) That is the Licence is not transferable in respect of place or person.
- 3) That is only relates to the permission as define above and for which it is granted.
- 4) That is only relates to such trade or permission as specified in it.
- 5) That no alternation should be made in the area of the land or in the building to which Licence relates without permission of AMC .
- 6) That is the licence shall be reliable to cancellation for breach of any of the above conditions.
- 7) This licence should be return to this office if the business/ profession is closed/terminated, immediately after closure etc.
- 8) A loudspeaker or public address system shall not be used at night (between 10.00 pm to 6.00am).
- 9) The sound level shall not crossed/exceeds the ambient noise standards as prescribed by the noise pollution (regulation and control)rules, 2000 and state govt. notification.
- 10) This trade licence does not confer any property right over the premises place of trade in favour of the holder of the trade license .
- 11) In case the holder of the trade licence applies for bank loan, the bank /financial institutions are advised to exercise their own due diligence and AMC shall have no liability in this regard.
- 12) The trade licence shall be liable to be cancelled within 7 days notice if the holder of the trade license violates the Govt. of India / Govt. of Tripura Orders/Notifications regarding use of poly bags /plastics.
- 13) RBI to operate as NBFC-MFI without accepting deposits from the public.(It's applicable only for Finance Business)

current rs : **3660** arrear (if any) rs : **0.00** penalty (if any) rs : **0**
total rs : **3660** challan no: **1/MSC/23/2453** dated: **12 Apr 2023**

Asstt Municipal Commissioner
Agartala Municipal Corporation

N.b:- This licence is purely provisional but renewable. this shall not confer any kind of right to the land/ building of the amc/govt.



भारत सरकार
Government of India

MSME
सूक्ष्म, लघु एवं मध्यम उद्यम
MICRO, SMALL & MEDIUM ENTERPRISES

सूक्ष्म, लघु एवं मध्यम उद्यम मंत्रालय
Ministry of Micro, Small and Medium Enterprises

UDYAM REGISTRATION CERTIFICATE

UDYAM REGISTRATION NUMBER

UDYAM-TR-08-0002561

NAME OF ENTERPRISE

M/S DIVINE TOUCH MEDI CLINIC

TYPE OF ENTERPRISE *

S.No.	Classification Year	Enterprise Type	Classification Date
1	2022-23	Micro	26/06/2022
2	2021-22	Micro	31/12/2021

MAJOR ACTIVITY

SERVICES

SOCIAL CATEGORY OF ENTREPRENEUR

GENERAL

NAME OF UNIT(S)

S.No.	Udyog Aadhaar Memorandum	Unit(s) Name
1	TR08E0000421	DIVINE TOUCH MEDI CLINIC

OFFICIAL ADDRESS OF ENTERPRISE

Flat/Door/Block No.	COLONEL CHOWMUHANI	Name of Premises/ Building	COLONEL CHOWMUHANI
Village/Town	AGARTALA	Block	SADAR
Road/Street/Lane	COLONEL MAHIM THAKUR SARANI	City	AGARTALA
State	TRIPURA	District	WEST TRIPURA , Pin 799001
Mobile	9436124765	Email:	divinetouch.medclinic@gmail.com

DATE OF INCORPORATION / REGISTRATION OF ENTERPRISE

11/05/2015

DATE OF COMMENCEMENT OF PRODUCTION/BUSINESS

07/04/2016

NATIONAL INDUSTRY CLASSIFICATION CODE(S)

SNo.	NIC 2 Digit	NIC 4 Digit	NIC 5 Digit	Activity
1	86 - Human health activities	8690 - Other human health activities	86905 - Activities of independent diagnostic/pathological laboratories	Service

DATE OF UDYAM REGISTRATION

28/12/2021

* In case of graduation (upward/reverse) of status of an enterprise, the benefit of the Government Schemes will be availed as per the provisions of Notification No. S.O. 2119(E) dated 26.06.2020 issued by the M/o MSME.

Disclaimer: This is computer generated statement, no signature required. Printed from <https://udyamregistration.gov.in> & Date of printing:- 18/02/2023

For any assistance, you may contact:

1. District Industries Centre: WEST TRIPURA (TRIPURA)
2. MSME-DFO: AGARTALA (TRIPURA)

Visit : www.msme.gov.in ; www.dcmsme.gov.in ; www.champ

Follow us @minmsme & @msmecha



List of
Services

Logged in
as
divineagt1



Dashboard

Dashboard > Organization > Add
Organization

All * marked fields are mandatory

Common
Application
Form

Unique No. : 2021S01815



Enterprise Details



Application
List

Constitution of the Enterprise *

Application
Process

Partnership Firm Regi

Upload
Existing
Licence

Enterprise Name *

DIVINE TOUCH MEDI CLIN

Renewa

ENTERPRISE ADDRESS

Inspecti

Enterprise's Registered
Address

Labour



Divine Touch Medi - Clinic



(An ISO 9001: 2015 Certified Multispeciality Clinic & Diagnostics Centre)

DTMC/CMO/ 758 /23

To

The District Registering Authority,
Chief Medical Officer
West Tripura, Agartala.

Dt.03/10/23



Re:- Provisional Registration under TCE Rules 2021

Ref:- Your letter NO.F.9(306)-CMO(W)-CLE/2015/9812-13 Dt.02/09/2023

Dear Sir,

With reference to above we are submitting herewith following documents :-

1. Copy of Atomic Energy Regulatory Certificate
2. Up to date Tripura State Pollution control Board Certificate
3. Copy of Lease Deed executed by the legal owner of the premises wherein clearly mentioned the permitted activities of our clinic.
4. Copy of Addhar Card of all staff including doctor.
5. Copy of Parcha.
6. Copy of acknowledgement of Fire NOC application

We would like to submit here that Fire department has paid visit at our clinic twice and satisfied with the arrangement of fire protection equipments but NOC is still pending with them. It will not be out of place to mention here that we are running OPD service/Diagnostic and Medicine under single roof. There is no provision of any procedure and patient stay in the clinic.

Our unit was registered under TCE in the year 2015 since then we are running it with all standard protocol and rules and regulation. By these times we have standardised our Laboratory as per NABL protocol and expecting NABL accreditation within near future.

We would humbly request you to kindly renew our registration so that we can serve the people with quality.

Yours faithfully,

Samir Ranjan Bhattacharjee
(S.R.Bhattacharjee)
PARTNER



Encl:- As above

A Multi-speciality Health Care Destination

Colonel Chowmuhani, Agartala, Tripura (W), Pin-799001, Contact Us : 9089016161, 8575092597, E-mail : divinetouch.mediclinic@gmail.com



Divine Touch Medi - Clinic

Your Health Our Mission



(An ISO 9001: 2015 Certified Poly Clinic & Diagnostics Centre)

Ref.DTMC/CMO/ 70/ 123

12/04/2023

To
The Chief Medical Officer,
West Tripura District,
Agartala



Sub: Renewal of Registration under TCE Act.

Ref: Your Show Cause Notice No.F9 (374)-CMO (W)-CLE/2018/
21493-612 Dt.23/03/2023.

Dear Sir,

Kindly refer to above and we would like to inform you that we have received above letter today.

In compliance with your show cause notice we would submit that our clinic was registered in the year, 2015 and every year we used to application for renewal of registration maintaining all norms and protocol of TCE Act. You are also conducted regular inspection of our laboratory every year. As per norms we have submitted prescribed application vide No.DTMC/CMO/597/22 Dt.12/07/2022 along with all relevant documents except "Fire NOC" (the clause newly added in TCE rule, 2021).

However to comply with your requirement we applied for fire NOC by depositing requisite fees.(Copy of acknowledgement is enclosed). They have made inspection and satisfied with the fire fitting equipments installed in your premises. But they have not issued NOC till to date for unknown reason.

In view of above, we would like to inform you that we are running the unit in rented premises since inception and building is well maintained. There is no provision of inpatient stay in the premises. We are rule abiding establishment and follow all protocols of laboratory and clinic. We have given appointment to a good number of unemployed paramedical/qualified boys and girls.

We therefore, request you to kindly relax the clause fire NOC and issue Registration of our unit. We shall deposit the Fire NOC as soon as received by us.

Yours faithfully,

Enclo:- As above

Samir Rn Bhattacharjee
Partner, Divine Touch Medi Clinic

A Multi-speciality Health Care Destination

Colonel Chowmuhani, Agartala, Tripura (W), Pin-799001, Contact Us : 2310117, 9089016161, E-mail : divinetouch.mediclinic@gmail.com



**GOVERNMENT OF TRIPURA
OFFICE OF THE REGISTERING AUTHORITY
WEST TRIPURA:: AGARTALA**

No.F.9(306)-CMO(W)-CLE/2015.

CERTIFICATE OF RENEWAL OF REGISTRATION
(Under Section 6 of the Tripura Clinical Establishment Act, 1976)

This is to certify that the Registration issued vide No.F.9(306)-CMO(W)/CLE/2015
Dated 03-11-2018 under the Tripura Clinical Establishment Act, 1976 in Respect
of "Divine Touch Medi-Clinic" (Path Lab) Situated at
Colonel Chowmuhani, Agartala, Tripura West is hereby
renewed up to 31-03-2021.

District Registering Authority,
The Tripura Clinical Estt. Act & Rules,
O/o the CMO(W) Agartala.
(District Registering Authority)
The Tripura Clinical Establishment Act
Chief Medical Officer (West)
AGARTALA

Supervising Authority
The Tripura Clinical Estt. Act & Rules
O/o the CMO (W), Agartala.
(District Supervising Authority)
The Tripura Clinical Establishment Act
Chief Medical Officer (West)
AGARTALA



AGAPPE

INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CLINIA

AGAPPE DIAGNOSTICS LTD.

ADL/KO/SER/0085/23-24

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CN : 024239MR2998PLC05403

CORPORATE OFFICE / REGIONAL PLANT
Agappe Hills, Pattanamattom IPO, Dpt. Erumantur, Kerala - 683 562, India.
Tel : +91 484 284 7000 | Email: agappe@agappe.in

MUMBAI (REGISTERED OFFICE)
G21 & 402, 4th Floor, Sarvagya Business Centre, 109,
Cable Road, Fortiswada, Andheri (East), Mumbai - 400 099, India.
Tel: +91 22 4300 0000 | Email: mumbai@agappe.in

EQUIPMENT PLANT
X/508-03, Block No. 32, KMFRDA Small Industrial Park,
Nedat, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

DELHI OFFICE
D58/540, 2nd Floor, DLF Tower, Sarvraj Marg,
New Delhi - 110 005, India.
Tel: +91 11 4558 8400 | Email: delhi@agappe.in

KOCHI OFFICE
805, Myra Mall, Plot No.03, Block DN, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 40010451 | Email: kolkata@agappe.in

BANGALORE OFFICE
5-6, 8th Floor, Red Cross Block, He-36 Race Course Road,
Bangalore - 560 001. Tel: +91 80 2228 8388
Email: bangalore@agappe.in

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ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN: L24239MH0998PLC025413

CORPORATE HEAD / REAGENT PLANT
Agappe Hills, Pattimattom (PO), Ottu, Ernakulam, Kerala - 683 562, India.
Tel: +91 484 285 7000 | Email: ap@agappe.in

EQUIPMENT PLANT
K/585 CB, Block No. 32, KEMIRA Small Industrial Park,
Nellikud, Cochin, Kerala, India - 686 721. Tel: +91 464 276 1477.

KOLKATA OFFICE
405, Mittal Mallia, Plot No 80, Block-DK, Sector V,
Salt Lake City, Kolkata - 700 095,
Tel: +91 33 4001 0451 | Email: kolkata@agappe.in

MUMBAI (REGISTERED OFFICE)
405 & 402, 4th Floor, Jeevanji Swasthya Centre, ITX,
Sahar Road, Fortkivoli, Andheri (East), Mumbai - 400 099, India.
Tel: +91 22 4330 8000 | Email: mumbai@agappe.in


DELHI OFFICE
204/5-69, 2nd Floor, DLF Tower, Sakinaka Marg,
New Delhi - 110 015, India.
Tel: +91 11 4358 9436 | Email: delhi@agappe.in

BANGALORE OFFICE
5-4, 2nd Floor, Red Cross Bhawan, No.26 Race Course Road,
Bangalore - 560 001, Tel: +91 80 2226 8088
Email: bangalore@agappe.in

I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE


Both DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA and AGAPPE DIAGNOSTICS LTD. are jointly responsible for the installation of MISPA CLINIA with serial number YM-84001332 as per the attached Installation Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	: Debashis Bhattacharjee	Signature:	
Title	: Manager - Customer Service	Date	: 5/3/21
Company	: AGAPPE DIAGNOSTICS LTD.		



Validation Team from DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA


Name	: Shashita Saha	Signature:	
Designation	: LAB TECH	Date	: 5/3/21
Department	: LAB		

Customer Authorizations:

Name : Shashita Saha

Title : INSTALLATION QUALIFICATION

Signature :



Site : Biochemistry Lab

Date :

5/3/2021

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2006 CERTIFIED COMPANY | CIN : U24239MH1998PLC105413

CORPORATE OFFICE / HEADQUARTERS PLANT
Agappe Hills, Postindustrial Park, Ernakulam, Kerala - 685 502, India.
Tel: +91 484 285 7000 | Email: agappe@agappe.in

EQUIPMENT PLANT
2/585 CB, Block No. 32, SIVITA Small Industrial Park,
Bellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 2477.

KOLKATA OFFICE
406, Meritis Matrix, Plot No-10, Block-09, Sector V,
Salt Lake City, Kolkata - 700 091.
Tel: +91 33 4303 0452 | Email: kolkataoffice@agappe.in

MUMBAI (REGISTERED OFFICE)
401 A 402, 4th Floor, Indragiri Business Centre, 116,
Sukru Road, Pimpri-Chinchwad, (A) Mumbai - 400 095, India.
Tel: +91 22 4200 8000 | Email: mumbaioffice@agappe.in

DELHI OFFICE
DGM 540, 4th Floor, DLF Tower, Shikha Marg,
New Delhi - 110 025, India.
Tel: +91 11 4928 8035 | Email: delhioffice@agappe.in

BANGALORE OFFICE
5-4, 4th Floor, 404 Cross, Shivajinagar, 40/26 Base Course Road,
Bangalore - 560 061. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Installation Qualification. Each result will be noted and dated.
2. The concerned employees of **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** will verify each result and sign in each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the IQ 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**.

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH09987CL15413

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CELEBRATING 25 YEARS
SURGING INNOVATION
DESIGN III: **SCOPE**

AGAPPE

This Installation Qualification protocol will be performed on the **MISPA CLINIA** at **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**. This Installation 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 has been installed 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.

AGAPPE

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | QN: 024200MH2998PLC05413

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IV. INSTALLATION QUALIFICATION

A. Instrument Identification

Verified Date: 05-03-2021

1. Model Name : MISPA CLINIA
2. Serial Number : YM-84001332

B. Following is a list of accessories /consumables verified:

S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit	YES	DB	OK
02	Computer	YES	DB	OK
03	Printer	YES	DB	OK
04	RS232 Connector cable	YES	DB	OK
05	Power cord	YES	DB	OK
06	Waste can	YES	DB	OK
07	Water can	YES	DB	OK
08	Water connector tube	YES	DB	OK
09	Waste connector tube	YES	DB	OK
10	Water pre filter	YES	DB	OK
11	Probe assembly	YES	DB	OK
12	Mixer assembly	YES	DB	OK
13	Reagent tray	YES	DB	OK
14	Cuvette blocks	YES	DB	OK
15	Reagent bottles	YES	DB	OK

ADL/FO/MCD/064/2015/R00

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C. Installation Checks

Purpose: To make sure that the instrument is received with all the major components necessary for operation

S No.	Component	(Yes/No)	Verified By	Comments
1	Major components and accessories are present	YES	RB	OK
2	There is no physical damage to the components	YES	RB	OK
3	Ambient temperature is available	YES	RB	OK
4	Instrument is installed in the floor and leveled properly	YES	RB	OK
5	Power supply is correct	YES	RB	OK
6	Electric connections are tight, weatherproof & earthed	YES	RB	OK
7	Analyzer unit installed as per the manufacturers recommendations	YES	RB	OK
8	Water supply and waste drainage facilities checked	YES	RB	OK
9	Mispa Clinia Detergent Available	YES	RB	OK

Summary:

The information is recorded against each data and the deviations if any is justified / explained properly.

Acceptance criteria:

PARAMETER

PASS

FAIL

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AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2006 CERTIFIED COMPANY | CIN: U24235MH1908PLC115413

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D. Instrument Installation

Date of Installation : 05-03-2021

Installed by : DEBASHIS BHATTA CHARJEE

S No.	Parameter	Done by	Comments
01	Installation of the main unit	<u>DB</u>	OK
02	Installation of the computer system	<u>DB</u>	OK
03	Installation of the printer	<u>DB</u>	OK
04	Connecting the waste tubing	<u>DB</u>	OK
05	Connecting the system water tubing	<u>DB</u>	OK
06	Installing the reagent tray	<u>DB</u>	OK
07	Installation of the probes	<u>DB</u>	OK
08	Installation of the mixers	<u>DB</u>	OK
09	Installing the cuvettes	<u>DB</u>	OK
10	Installation of Wash Station	<u>DB</u>	OK

Acceptance criteria : System should be "Ready" after daily maintenance without any error

PARAMETER ✓ PASS FAIL

Parameter values for verification: System found "Ready" after daily maintenance

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN: U24231MH2009PLC115413

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Purpose: To check the cuvettes run Cuvette Check

Procedure: Manually put more than 40ml Mispac Clinia Detergent in position D of reagent disk and more than 5ml Mispac Clinia Detergent in position D2 of sample disk. Then select **Perform Cuvette Check** and click **Continue** to proceed.

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER	PASS	FAIL
------------------	-------------	-------------

Parameter values for verification: No Error Messages

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2006 CERTIFIED COMPANY | CIN : U24239MH1998PLC15411

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 Fax: +91 80 2228 8288

Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do all checks in Hydro Unit	<i>DB</i>	5/3/21

The screenshot shows a software window titled "Alignment" with a grid of unit buttons: Photometric Unit, Reaction Unit, Sample Carousel, Rgt Carousel, Sample Probe Unit, Reagent Probe Unit, Sample Mixer Unit, Reagent Mixer Unit, Wash Station, Sample Barcode, Rgt Barcode, Hydro Unit, Empty Fluidic Tubes, and Pyrology Unit. Below these is a section for "ISE Unit" and a checklist with 7 numbered items:

- Supply/Drain Conformity Check
- Valve and Floater Test
- Pump Check
- Syringe Check
- Fluidic Prime
- Water Tank Empty Floater Check
- Wash Flow Test

At the bottom right of the window are "Mech Reset" and "Exit" buttons.

Acceptance criteria:

- No error message or air bubbles in the internal tubing's
- All hydraulic units working well without air bubbles / leakage

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2006 CERTIFIED COMPANY | CIN: U24239MH1998PLC05413

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Instrument Installed successfully.

AGAPPE

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. | ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN: U24239MH1998PLC115413

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VI. SYSTEM CERTIFICATION

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

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Debashis Bhattacharjee

Designation : Manager - Customer Service

Signature : *DB*

Company : AGAPPE DIAGNOSTICS LTD.

Date : 5/3/21



Customer Authorizations: **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**

Name : SHASTHITA SANA

Designation : LAB TECH

Signature : *SS*

Title : INSTALLATION QUALIFICATION

Date : 5/3/21

ADL/FO/MCD/064/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN: U24239MH01908PLC115413

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OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CLINIA

AGAPPE DIAGNOSTICS LTD.

ADL/KO/SER/0086/23-24

ADL/FO/MCD/065/2015/R00

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I. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA CLINIA** with serial number **YM-84001332** as per the attached **OPERATIONAL QUALIFICATION** protocol.

Protocol Performed By: Representative of **AGAPPE DIAGNOSTICS LTD.**

Name	: Debashis Bhattacharjee	Signature :	<i>DB</i>
Designation	: Manager - Customer Service	Date	: 5/3/2021
Company	: AGAPPE DIAGNOSTICS LTD.		



Validation Team from DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA

Name	: Shashilita Saha	Signature :	<i>SS</i>
Designation	: LAB TECH	Date	: 5/3/21
Department	: Biochemistry		

Customer Authorizations:

Name : *Shashilita Saha*

Title : OPERATIONAL QUALIFICATION

Site : *Biochemistry department*

Signature :

Date :

ADL/FO/MCD/065/2015/R00

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II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD** representative will check and enter the specific data as outlined in the **OPERATIONAL QUALIFICATION**. Each result will be noted and dated.
2. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end 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**.

ADL/FO/MCD/065/2015/R00

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Email: bangalore@agappe.in



III. SCOPE

This Operational Qualification protocol will be performed on the **MISPA CLINIA** at **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**. This Operational 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 has been installed 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.

ADL/FO/MCD/065/2015/R00

AGAPPE DIAGNOSTICS LTD. | ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CN : U24299WH1998PLC1D4E3

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IV. OPERATIONAL QUALIFICATION

A. Instrument Identification

Verified Date :

1. Model Name : MISPA CLINIA
2. Serial Number : YM-84001332

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

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	DB 5/3/21
02	Daily maintenance	To clean appropriate modules	DB 5/3/21
03	Calibration	To calibrate the system	DB 5/3/21
04	QC check	To confirm that the system is calibrated and working within specifications	DB 5/3/21
05	Reproducibility check	To check the precision [CV %] after calibration	DB 5/3/21
06	Sample programming and Analysis	To run the samples	DB 5/3/21
07	Shut down procedure	To shut down the system	DB 5/3/21

ADI/FO/MCD/065/2015/R00

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Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically. If there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Wait for the instrument to get ready after initialization
- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the MISPA CLINIA by pressing the main switch, then switch on the computer and then the system power
- Double click the analyzer icon to initialize the system software
- Input the password and do as prompted, the system menu pops up if start up is finished
- If not, initialize by again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to display READY status

PARAMETER **PASS** **FAIL**

Parameter values for verification: "READY" on Status Area

ADI/FO/MCD/065/2015/R00

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Test 05: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	DB	5/3/21
02	Running triplicates	DB	5/3/21

Acceptance criteria: Results CV within specified limits

PARAMETER PASS FAIL

Parameter values for verification: CV% within the limits

Test 06: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	DB	5/3/21
02	Programming samples	DB	5/3/21
03	Aspirating the samples	DB	5/3/21
04	Viewing samples in process	DB	5/3/21
05	Review results: Monitoring results	DB	5/3/21

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS FAIL

Parameter values for verification: Sample analysis without any error

ADL/FO/MCD/065/2015/R00

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Test 07: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	RB	5/3/21
02	Following the on screen instructions	RB	5/3/21
03	Switch off the instrument when prompted	RB	5/3/21

Acceptance criteria: Shut down without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: Shut down without any error

V. OPERATIONAL PROCEDURE

Certificate of Training

1. Technician Training

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

S No.	Training program	Initials	Date
1	Instrument Setup	Done	5/3/21
2	System Operation	Done	5/3/21
3	Basic trouble shooting and Maintenance	Done	5/3/21

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VI. COMMENTS

Instrument is ready to use.

AGAPPE

ADL/FO/MCD/065/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24299MH1998PLC115413

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VII. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline 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 Performance Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Debashis Bhattacharjee

Designation : Manager - Customer Service

Signature : *DB*

Company : AGAPPE DIAGNOSTICS LTD.

Date : 5/3/21



Customer Authorizations: **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**

Name : *Shashita Saha*

Designation : *Lab TECH*

Signature : *Saha*

Title : OPERATIONAL QUALIFICATION

Date : 5/3/21

ADL/FO/MCD/065/2015/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC125413

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AGAPPE

PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CLINIA

AGAPPE DIAGNOSTICS LTD.

ADL/KO/SER/0087/23-24

ADL/FO/MCD/066/2015/R00

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN: U24239MH1998PLC115413

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I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** and **AGAPPE DIAGNOSTICS LTD.** are jointly responsible for the installation of **MISPA CLINIA** with serial number **YM-84001332** as per the attached **PERFORMANCE** Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	: Debashis Bhattacharjee	Signature :	<i>[Signature]</i>
Designation	: Manager - Customer Service	Date :	<i>05/03/21</i>
Company	: AGAPPE DIAGNOSTICS LTD.		



Validation Team from DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA

Name	: <i>Shashthita Saha.</i>	Signature :	<i>[Signature]</i>
Designation	: <i>Lab Tech.</i>	Date :	<i>05/03/21</i>
Department	: <i>Haematology.</i>		

Customer Authorizations:

Name : *Shashthita Saha.*

Title : PERFORMANCE QUALIFICATION

Site : *Haematology.*

Signature : *[Signature]*

Date : *05/03/21.*

ADL/FO/MCD/066/2015/800

II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. The concerned employees of **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** will verify each result and sign in each page. The member of the validation team will carry this out.
3. All deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the 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**.

ADL/FO/MCD/066/2015/R00

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III. SCOPE

This Performance Qualification protocol will be performed on the **MISPA CLINIA** at **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**. This Performance 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 has been installed 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.

AGAPPE

ADL/FO/MCD/066/2015/R00

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IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date :

1. Model Name : MISPA CLINIA
2. Serial Number : YM-84001332

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

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	<i>[Signature]</i> 05/03/21
02	Daily maintenance	To clean appropriate modules	u
03	Cell blank	To check the cuvettes	v
04	Priming	To check the tubing's, and flow	u
05	Auto gain	To check the cuvette and photometry system	b
06	Calibration	To calibrate the system	b
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	v
08	Reproducibility check	To check the precision [CV %]	o
09	Sample programming and Analysis	To run the samples	v
10	Shut down procedure	To shut down the system	v

ADL/FO/MCD/066/2015/R00

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Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Wait for the instrument to get ready after initialization
- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the MISPA CLINIA by pressing the main switch, then switch on the computer and then the system power
- Double click the analyzer icon to initialize the system software
- Input the password and do as prompted, the system menu pops up if start up is finished
- If not, initialize by again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to display **READY** status

PARAMETER	PASS ✓	FAIL
-----------	--------	------

Parameter values for verification: "READY" on Status Area

ADI/FO/MCD/066/2015/R00

Test 02: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method:

Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Empty waste container	ABD	05/09/21
02	Check Wash solutions	Y	Y
03	Check system water	Y	Y
04	Check Reagents	Y	Y
05	Clean Reagent Block	Y	Y
06	Clean out side area	Y	Y
07	Load supplies and remove outdated and empty reagents	Y	Y
08	Check main menu screen	Y	Y
09	Perform Quality Control	Y	Y

Acceptance criteria : System should be "Ready" after daily maintenance without any error

PARAMETER **PASS** FAIL

Parameter values for verification: System found "Ready" after daily maintenance

ADL/FO/MCD/066/2015/R00

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Test 03: Photometer Check

Purpose: To check the photometer after running some cycles of tests

Photometer Check

1. Execute **Photometer Check**.
2. Make sure that the lamp has been turned on for over 10 minutes. Operate according to screen prompts.
3. If the Status field shows Normal, it indicates that the lamp's light intensity satisfies the requirements of measurement; if it shows "Light intensity is weak" in red, it indicates that the lamp has insufficient light intensity.
4. If an alarm occurs during the check, operate as follows:
 - If an alarm indicates the lamp is off, check if the lamp has been turned on.
 - If the alarm indicates light intensity too strong
 - If the alarm indicates light intensity weak, replace the lamp immediately.

Acceptance criteria:

- No error Messages displayed
- All checks acceptance

PARAMETER	PASS	FAIL
------------------	-------------	-------------

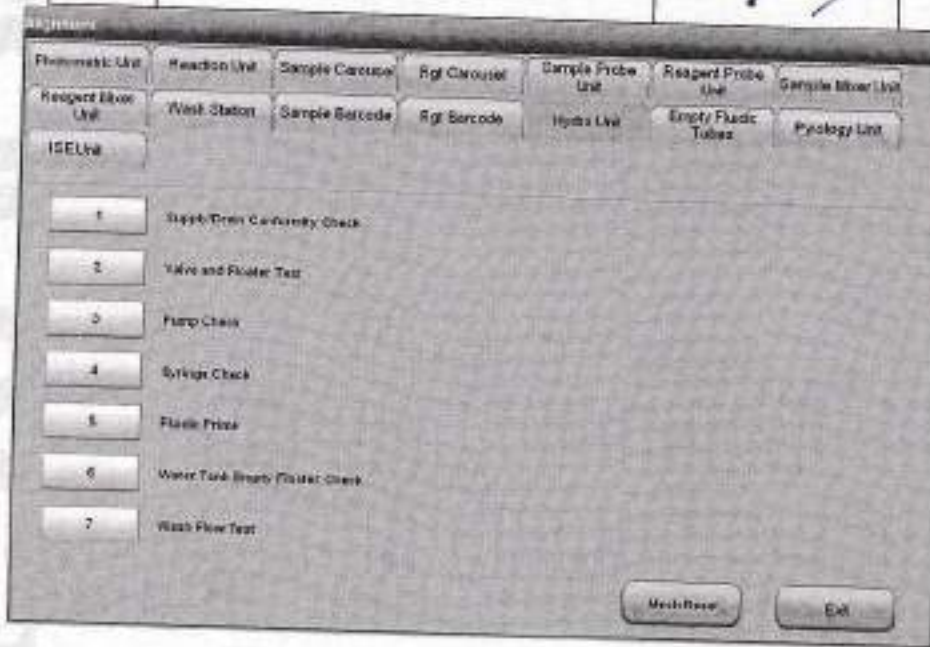
Parameter values for verification: No Error Messages

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Test 04: Priming

Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do all checks in Hydro Unit	<i>AB</i>	05/03/21



Acceptance criteria:

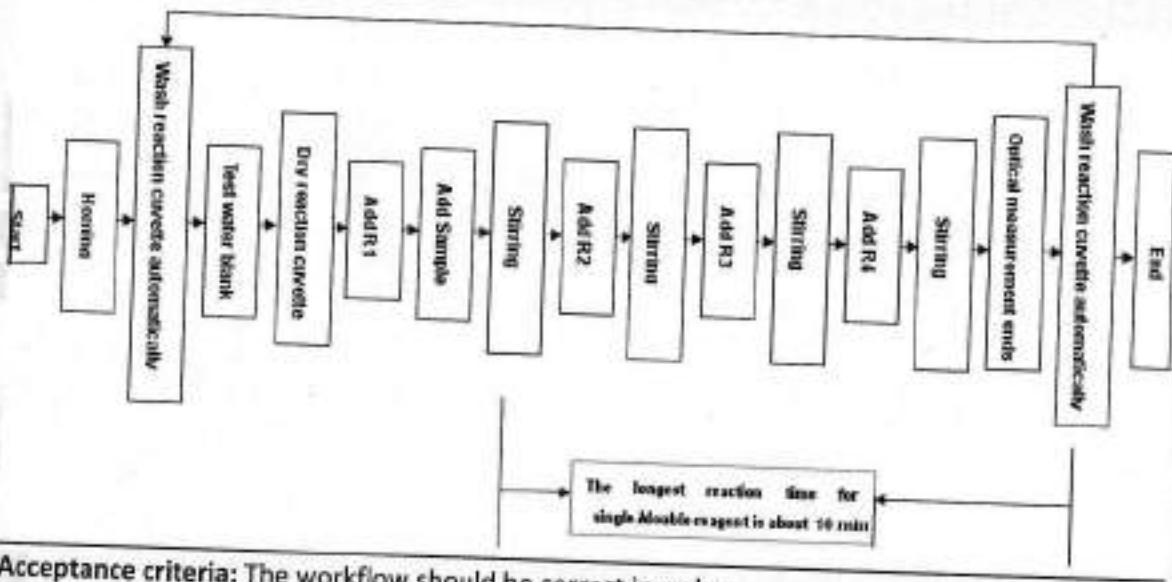
- No error message or air bubbles in the internal tubing's
- All hydraulic units working well without air bubbles / leakage

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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Test 05: Workflow



Acceptance criteria: The workflow should be correct in order

PARAMETER **PASS** FAIL

Parameter values for verification : No unwanted stopping in between

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Test 07: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & within specifications for each assay used.

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	ADG	05/09/21
02	Creating QC file	V	h
03	QC sample programming and analysis	u	m

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER

PASS

FAIL

Parameter values for verification: QC values within $\pm 2SD$

Test 08: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	ADG	05/09/21
02	Running triplicates	V	h

Acceptance criteria: Results CV within specified limits

PARAMETER

PASS

FAIL

Parameter values for verification: CV% within the limits

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Test 09: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	ADG	05/09/21
02	Programming samples	u	u
03	Aspirating the samples	u	u
04	Viewing samples in process	u	u
05	Review results: Monitoring results	u	u

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** FAIL

Parameter values for verification: Sample analysis without any error

Test 10: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	ADG	05/09/21
02	Following the on screen instructions	u	u
03	Switch off the instrument when prompted	u	u

Acceptance criteria: Shut down without any error

PARAMETER **PASS** FAIL

Parameter values for verification: Shut down without any error.

ADL/FO/MCD/066/2015/R00



OPERATIONAL PROCEDURE

Certificate of Training

1. Technician Training

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

S No.	Training program	Initials	Date
1.	Instrument Setup	<i>ASD</i>	05/03/21
2.	System Operation	v	v
3.	Basic trouble shooting and Maintenance	v	v

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1.	Shashita Saha	Lab	<i>SS</i>	5/3/21
2.	Monalisa Debbasana	Pathology		
3.	Resmita Patil	Lab	<i>RP</i>	5/3/21
4.	Rupama Sankar	Lab	<i>RS</i>	5/3/21

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SURGICAL
EQUIPMENT
V COMMENTS

AGAPPE

Instrument is ready to use.

AGAPPE

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VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline 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: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Debashis Bhattacharjee

Designation : Manager - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date :

[Handwritten Signature]
05/03/2021

Customer Authorizations: **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**

Name : *Shashthita Saha.*

Designation : *Lab Tech.*

Title : PERFORMANCE QUALIFICATION

Signature :

Date :

[Handwritten Signature]
05/03/21.

ADL/FO/MCD/066/2015/R00

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**CERTIFICATE OF CALIBRATION**

ADL/KO/SER/0262/23-24

Instrument : **Mispa Clinia Fully Automated Biochemistry Analyser**
 Customer Name : **Divine Touch Medi Clinic, Colonel Chowmuhani, Agartala, Tripura.**
 Date of Installation : **05/03/2021** S/N: **YM-84001332**

Alignment Check

Motion Check	Checked	Remark
Sample Probe	<input checked="" type="checkbox"/>	OK
Reagent Probe	<input checked="" type="checkbox"/>	OK
Mixer Probes	<input checked="" type="checkbox"/>	OK
Reaction Disk	<input checked="" type="checkbox"/>	OK
Reagent Disk	<input checked="" type="checkbox"/>	OK
Sample Disk	<input checked="" type="checkbox"/>	OK
Wash Station	<input checked="" type="checkbox"/>	OK
Lamp	<input checked="" type="checkbox"/>	OK

System	Checked	Remark
Main unit	<input checked="" type="checkbox"/>	OK
Temp. unit	<input checked="" type="checkbox"/>	OK
Mixing unit	<input checked="" type="checkbox"/>	OK
Reaction unit	<input checked="" type="checkbox"/>	OK
Reagent unit	<input checked="" type="checkbox"/>	OK
Sample unit	<input checked="" type="checkbox"/>	OK

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U28230MH0995PLC115413

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**OPTICAL SECTION**

Photometer Unit Alignments	Status	Remarks
Lamp Brightness Adjustment	Done, Reading good	OK.
Signal Collecting Position Adjustment	✓	OK.
Photoelectric Gain Adjustment	✓	OK.

The equipment is calibrated for the different parameters by using Multi Calibrator

Lot.No:_Exp: 33030094 / 28-02-2025.

This is to certify that the above-mentioned product has been calibrated according to the standard operating procedure given by the MINDRAY Medical Systems.

Date of Calibration: **12/SEP/2023**

Next Due : **11/MAR/2024**

For Agappe Diagnostics Ltd.

AB
12/09/23



Authorised signatory

Name: Debashis Bhattacharjee

Designation: Manager - Customer Service

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