



**MICRO
LYN**

Installation Certificate

Customer Details

Laboratory Name: **M/s TATA 1mg Technologies**
Contact Person: **Ms. Nicky Anand**
Address 1: **Tata Steel Bsl Ltd**
Address 2: **Meramandali Township, Dhenkanal,**
City: **Odisha - 759121**
Post Code: **759121**
Country: **India**

Tel:
Fax:
Email:

Installation Date: **13 / 02 / 2024**
Installation Engineer: **A. Rajesh Kannan**

Customer Info (Optional)

Approx Lab Throughput: 200.
No. of staff: 5
Total instruments in Lab: 10

Analyser Details

Instrument Model: Dirui CS480
Serial Number: 2300480CS0054K

Accessories

ISE (Y/N): YES
PC: YES S/No:
Monitor: YES S/No:
Printer: NO S/No:

Environmental Requirements

Water System: Yes
Air Conditioning (Y/N): Yes Ambient temp if known: 25°C
UPS (Y/N): Yes
LIS (Y/N) Name: Yes

Warranty Details

No. of Years: 1

Declaration

The analyser has been correctly installed, adequate operator training given and performance meets requirements.

Nicky Anand
Customer Signature

A. Rajesh Kannan
Installer Signature

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331
info@microlynhealthcare.com
www.microlynhealthcare.com



**MICRO
LYN**

INSTALLATION QUALIFICATION

Instrument Name : **DIRUI CS-480 AUTO CHEMISTRY
ANALYZER**

Laboratory/Hospital : **Tata 1MG Technologies Pvt Ltd
Meramandali Township, Dhenkanal,
Odisha.**

Supported By : **Microlyn Healthcare Pvt Ltd
Chennai**



**MICRO
LYN**

INSTALLATION QUALIFICATION PROTOCOL

This Installation Qualification Protocol Is Performed On the Installation Located At

**Tata 1MG Technologies Pvt Ltd
Meramandali Township, Dhenkanal,
Odisha**

The purpose of this installation qualification protocol is to define the qualifications and the acceptance standard in order to verify that instrument installation, normal operation and function of the Dirui CS-480 Auto chemistry analyzer in the laboratory. The satisfactory outcome of this procedure assures that the system functions according to the parameters.

- ❖ **Microlyn Healthcare Pvt. Ltd.** is responsible for installation of **Dirui CS-480** Auto chemistry analyzer at **TATA 1MG TECHNOLOGIES** Biochemistry department per the attached protocol.
- ❖ An authorized Microlyn Healthcare Pvt. Ltd. representative will physically check the system and proceed for the installation.
- ❖ This installation protocol will be followed as specified by the manufacturer. Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- ❖ On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- ❖ Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.
- ❖ Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.
- ❖ The results of these installation activities are the base for the subsequent Operational & Performance Qualification Protocol.

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331
info@microlynhealthcare.com
www.microlynhealthcare.com



**MICRO
LYN**

REPORT SIGN OFF:

Protocol Prepared By

Designated Company Person Name: Rajesh Kannan A

Designation: Manager Service and Technical Support

Date: 19/2/2024

Protocol Prepared For

Customer / Contact Person Name: Ms. Nicky Anand

Hospital / Institution: Tata 1MG Technologies Pvt Ltd

Address: Meramandali Township, Dhenkanal, Odisha

Equipment Information:-

Equipment Name: Dirui CS-480 Auto Chemistry Analyzer

Model/Type: CS480

Serial No: 2300480CS0054K

Equipment Installed Location: Clinical Laboratory

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331

info@microlynhealthcare.com

www.microlynhealthcare.com



INSTRUMENT INSTALLATION QUALIFICATION PROTOCOL

Dirui CS-480 Auto-Chemistry Analyzer found to be the satisfactory installation condition at biochemistry department with comply the installation requirement based on the below described items.

S. No	Installation Requirement Item	Description	Requirement Qualification	Remark
1.	Power Supply	AC220V, 50Hz Power: 2000VA Circuit Breaker: 250V, 20A	Satisfactory	The department fully equipped with online UPS power supply
2.	Grounding Condition	A good grounding condition	Satisfactory	Nil
3.	Discharge Equipment	5m within mainframe Height: below 100mm, Inner diameter: above 50mm	Satisfactory	Nil
4.	Ground	The ground should be level up	Satisfactory	Nil
5.	Temperature and Humidity	Temperature: 15 - 32°C Humidity: 32 - 85%RH	Satisfactory	Nil
6.	Air condition	Air condition	Satisfactory	Centralized Air condition
7.	Dehumidifier	Dehumidifier	Satisfactory	Nil
8.	Water Supply Equipment	5m within the mainframe Water supply: 40L/hour Conductivity: below 1us/cm	Satisfactory	Nil
9.	Water Supply Mode	RO water plant	Satisfactory	Purified water equipment
10.	Communication Interface	Is there standard PC RS-232	Yes	Nil



**MICRO
LYN**

Verify the Pre-installation Checks:-

If any deficiencies were noted during the pre-installation check, verify they are resolved before installation.

Check the Supplies:-

Make sure an adequate supply of reagents, control and calibrator are available at the site.

Inspect Packing Box:-

Inspect all boxes for damage. Notify shipper of damages if any.

Unpack the Analyzer:-

- ❖ Remove the packing material of the Analyzer.
- ❖ Place the Instrument on the ground.
- ❖ Remove fixing tapes and transportation tapes.
- ❖ Fix sample and reagents probe, reaction cuvette and ISE electrode assemble.
- ❖ Connect water supply and waste water tube.
- ❖ Connect the AC Adaptor to Power Supply Point.
- ❖ Install operation software and communicate operation software with analyzer.

Installation Information:-

Name of the Instrument: Dirui CS480 Auto Chemistry Analyzer

Physical Verification of the instrument before installation: Satisfactory

Description of the equipment along with the components: Computer, Keyboard & accessories.

Date of Installation: 13/2/2024

Name of Engineer (S): Rajesh Kannan

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331
info@microlynhealthcare.com
www.microlynhealthcare.com



**MICRO
LYN**

Installation conclusion:-

Overall instrument installation requirements found to be satisfied, handed over the instrument for operation & performance qualification.

Installation Certificate: Enclosed

Installation Protocol Remarks:

Action to be taken (if any):

Reports Sign Off:-

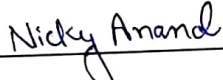
Designated Person Name: Rajesh Kannan A

Laboratory Personal Name: Ms. Nicky Anand

Designation: Service Manager

Designation: Lab Manager

Signature: 

Signature: 

Date: 19/2/2024

Date: 20/02/24

Attachments:

1. Instrument Installation certificate





**MICRO
LYN**

PERFORMANCE QUALIFICATION

Instrument Name : **DIRUI CS-480 AUTO CHEMISTRY
ANALYZER**

Laboratory/Hospital : **Tata 1MG Technologies Pvt Ltd
Meramandali Township, Dhenkanal,
Odisha.**

Supported By : **Microlyn Healthcare Pvt Ltd
Chennai**



**MICRO
LYN**

PERFORMANCE QUALIFICATION PROTOCOL

This Performance Qualification Protocol Is Performed On the Installation Located At

Tata 1MG Technologies Pvt Ltd
Meramandali Township, Dhenkanal,
Odisha

The purpose of this performance qualification protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the Dirui CS-480 Auto chemistry analyzer in the laboratory. The satisfactory outcome of this procedures assures that the system functions according to the parameters.

- ❖ This protocol will define the documentation that will be used to evaluate the instrument and documented in accordance with the user specification requirements. Successful completion of this protocol will verify that the instrument performance consistently meets pre-determined specifications under normal conditions.
- ❖ Performance checks will be carried out by repeatedly running the system on its intended schedule and record the information/data to demonstrate that it consistently meets the required performance, as expected.
- ❖ Department personnel along with the trained personnel from Iris Healthcare will perform qualification studies as mentioned in this protocol.
- ❖ Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.
- ❖ The performance qualification protocol will verify the instrument test results accuracy and precision by reviewing the calibration & controls results within the acceptance limits.



**MICRO
LYN**

REPORT SIGN OFF:

Protocol Prepared By

Designated Company Person Name: Rajesh Kannan. A

Designation: Manager Service and Technical Support

Date: 19/2/2024

Protocol Prepared For

Customer / Contact Person Name: Ms. Nicky Anand

Hospital / Institution: Tata 1MG Technologies Pvt Ltd

Address: Meramandali Township, Dhenkanal, Odisha

Equipment Information:-

Equipment Name: Dirui CS-480 Auto Chemistry Analyzer

Model/Type: CS480

Serial.No: 2300480CS0054K

Equipment Installed Location: Clinical Laboratory

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331
info@microlynhealthcare.com
www.microlynhealthcare.com



INSTRUMENT PERFORMANCE QUALIFICATION PROTOCOL

1. PERFORMANCE QUALIFICATION PROCEDURES

- Run two controls materials with appropriate normal & abnormal levels at known concentration to check the test items accuracy.
- Perform the reproducibility check by running the Control material for 10 times and verify the CV% is within the limits specified.
- Comparison correlation with appropriate patient test result.

Performance Qualification Conclusion:-

The controls results are obtained as per specifications & tolerance ranges. Verified the calibration & controls results according to the specific limits and considered the satisfactory results herewith certificate that Dirui CS480 Auto Chemistry Analyzer operates correctly according to the instrument specifications.

With the reference to the installation, operation & performance procedures and studies carried out in the laboratory, Dirui CS480 Auto Chemistry Analyzer meets all criteria outlined for respective protocol.

User operation & maintenance hands-on training was to given those respective technical personal in the laboratory according to the protocol.

Performance Protocol Remarks:

Action to be taken (if any):

Attachments:

1. Calibration and controls result raw data
2. Repeatability check data
3. User operation and training certificate



**MICRO
LYN**

Reports Sign Off:

Designated Person Name: Rajesh Kannan A

Laboratory Personal Name: Ms. Nicky Anand

Designation: Service Manager

Designation: Lab Manager

Signature



Signature



Date:

19/2/2024

Date

20/02/2024





**MICRO
LYN**

OPERATIONAL QUALIFICATION

Instrument Name : **DIRUI CS-480 AUTO CHEMISTRY
ANALYZER**

Laboratory/Hospital : **Tata 1MG Technologies Pvt Ltd
Meramandali Township, Dhenkanal,
Odisha.**

Supported By : **Microlyn Healthcare Pvt Ltd
Chennai**

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331

info@microlynhealthcare.com

www.microlynhealthcare.com



**MICRO
LYN**

OPERATION QUALIFICATION PROTOCOL

This Operation Qualification Protocol Is Performed On the Installation Located At

Tata 1MG Technologies Pvt Ltd
Meramandali Township, Dhenkanal,
Odisha

The purpose of this operation qualification protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the Dirui CS-480 Auto chemistry analyzer in the laboratory. The satisfactory outcome of this procedure assures that the system functions according to the parameters.

- ❖ This protocol defines the documentation that will be used to evaluate the instrument and documented in accordance with manufacturer's specifications and intended use.
- ❖ Successful completion of this protocol will verify that the instrumentation identified has been operational in accordance with manufacturer's specifications and intended use.
- ❖ Operational checks will be performed to verify that the instrument operates according to specifications and to record the information/data to demonstrate its functions as expected.
- ❖ Trained knowledgeable personnel from Microlyn Healthcare Pvt. Ltd. along with the department personnel will perform qualification studies as mentioned by the manufacturer.
- ❖ Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.
- ❖ The results of that installation activity are the base for the subsequent of Operational Qualification Protocol.
- ❖ The operational qualification protocol will verify the review of the start-up procedure,
- ❖ Operation processes, instrument routine maintenance, instrument safety handling in the laboratory.

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331

info@microlynhealthcare.com

www.microlynhealthcare.com



**MICRO
LYN**

REPORT SIGN OFF:

Protocol Prepared By

Designated Company Person Name: Rajesh Kannan. A

Designation: Manager Service and Technical Support

Date: 19/2/2024

Protocol Prepared For

Customer / Contact Person Name: Ms. Nicky Anand

Hospital / Institution: Tata 1MG Technologies Pvt Ltd

Address: Meramandali Township, Dhenkanal, Odisha

Equipment Information:-

Equipment Name: Dirui CS-480 Auto Chemistry Analyzer

Model/Type: CS480

Serial No: 2300480CS0054K

Equipment Installed Location: Clinical Laboratory

Microlyn Healthcare Private Limited

Plot No : 9&10, Madha Koil 1st Cross Street,
Brindavan Nagar, Neelankarai, Chennai - 600 041.

+91 44 244 91 331
info@microlynhealthcare.com
www.microlynhealthcare.com



INSTRUMENT OPERATIONAL QUALIFICATION PROTOCOL

1. OPERATION QUALIFICATION PROCEDURES

- Instrument Turn On and Turn off Procedures – To check the instrument normal start up processes while login & switch on the instrument. After turning on the analyzer it ensure the instrument startup “Rinsing Incubation Bath” processes & reaction disk temperature optimization.
- Verified system “On-line” and “Off-line” communication link.
- Verified software logon & logoff options between management to operation and vice versa.
- Verified instrument “sleep” mode condition & complete “shutdown” and “startup” processes.
- Placed onboard “Alkaline Detergent” & “Antibacterial Phosphorous Free Detergent”.

1.1 Preliminary Operation

- Carry out the maintenance procedures : yes
- Check the reaction disk temperature : yes
- Check the reagent disk temperature : yes
- Carry out light quantity checkup : yes
- Carry out cell blank test : yes
- If necessary check the probes vertical & horizontal checkup : yes

1.2 Parameter Setup

- Routine parameter setting according to the reagents instruction : yes
- Reagent inventory set up : yes
- Calibration parameter set up : yes
- QC parameter set up : yes



1.3 Reagent Preparation and place reagent disk

- Reagent preparation : Done
- Place the small (S) & large (L) reagents bottle : Use both the bottle
- Check the inner & outer disk reagent positions : yes
- Scan the remaining reagent volume level check : yes

1.4 Calibration & QC Materials Preparation

- Calibration materials preparation according to the instruction : yes
- QC materials preparation according to the instruction : yes

1.5 Calibration & QC Request

- Place the normal saline, calibrator & controls solution with appropriate position :
yes
- Run the calibration test for relevant parameters :
yes
- Run the QC test for relevant the parameters :
yes
- Repeat the calibration & QC if get any alert or alarm message :
yes

1.6 Calibration & QC verification

- Check the calibration & control results : Done



**MICRO
LYN**

Operation Qualification Conclusion:-

With the reference to the instrument operation procedures and studies carried out in the laboratory, the Dirui CS-480 Auto Chemistry Analyzer meets all criteria outlined for respective manufacturer recommended protocols.

Overall instrument installation requirements found to be satisfied, handed over the instrument for performance qualification.

Installation Protocol Remarks:

Action to be taken (if any):

Attachments:

1. Reagents Pack Inserts
2. Calibration and Controls value sheet
3. Light quantity check and cuvette blank test reports

Reports Sign Off:-

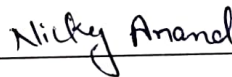
Designated Person Name: Rajesh Kannan A

Laboratory Personal Name: Ms. Nicky Anand

Designation: Service Manager

Designation: Lab Manager

Signature: 

Signature: 

Date: 19/2/2024

Date: 20/02/2024

