

Done

NEUATION

DRY BATH

I Therm D150-2

IQ -OQ -PQ DOCUMENT

QUALIFICATION OF DRY BATH - I THERM D150-2

MAKE : Neuation, India
MODEL NO : Dry Bath - iTherm D150-2
SERIAL NO : 67049734
INSTALLATION NO : 03
PURCHASE ORDER NO : MPUH/10/2021/PUR/29

DESCRIPTION OF SYSTEM / EQUIPMENTS:

DRY BATH- i therm D150-2 is the equipment which is used for specific applications such as Enzymatic reactions/kinetics, quantification assays, lysis reactions etc. For further detail refer User manual.

SAFETY REQUIREMENT:

- ✓ Ensure that only trained staff work with the appliance.
- ✓ Socket must be earthed (protective ground contact).
- ✓ Set up the appliance in a spacious area on an even, stable, clean, non-slip, dry and fireproof surface.

QUALIFICATION OF DRY BATH - I THERM D150-2

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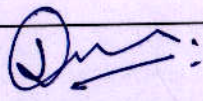
QUALIFICATION OF DRY BATH - I THERM D150-2


CHECKLIST FOR INSPECTION OF DRY BATH- iTherm D150-2(To be checked on receipt of the equipment)

SL. NO.	ITEM	QTY	ACCEPTANCE CRITERIA	OBSERVATION
1.	DRY BATH- iTherm D150-2	1 No	Available along with Package	OK
2.	Standard Attachment	1 No	Available along with Package	OK
3.	Operating Manual	1 No	Available along with Package	OK
4.	Warranty Registration Card	1 No	Available along with Package	OK

Checking sign off:

QUALIFICATION OF DRY BATH - I THERM D150-2

Name of the Engineer	Signature/Date
Kamlesh Padhyas	 : 28/12/2021

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

INSTALLATION QUALIFICATION

1. Purpose: The purpose of Installation Qualification is to establish that the Dry Bath and its Components are as per the specifications and are installed as per the approved procedure.

QUALIFICATION OF DRY BATH - I THERM D150-2

2. **Scope:** Installation Qualification to be performed at the time of installation.

3. **Responsibility:** R&D, Engineering, Safety and Quality Assurance.

4. **Critical Variables to be met:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
1.0 Location suitability:		
1.1 Size & Location of Dry Bath	The instruments should not be exposed to direct sunlight and placed rigid table	OK
1.2 Weight & Structural suitability	The civil structure should be suitable to accommodate the Dry Bath	OK
1.3 Utilities		
<u>Electrical supply:</u>	Should be 230 VAC, 50-60 Hz.	OK
<u>Safety provisions:</u>	Proper Earthing should be provided.	
<u>Environmental conditions:</u>	Temperature 25 °C	
2.0 Installation as per manufacturers instruction	Engineering/Production/ Quality Assurance To certify.	OK
3.0 Safety		
3.1 Earthing.	Should be provided with Electric supply.	OK
4.0 Documentation		

QUALIFICATION OF DRY BATH - I THERM D150-2

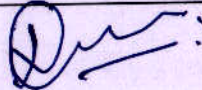
4.1 Manuals	Manufacturer's manual	OK
4.2 Training	No. of personnel to be trained	4

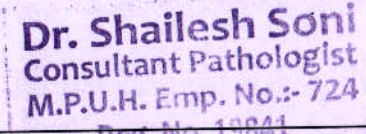

TECHNICAL DETAILS

Product	I therm D150-2
Temperature Range	Ambient +5 to 120°C
Temperature Uniformity	±0.4°C
Temperature Stability	±0.5°C
Set-up Block material	Aluminium
Number of Blocks	2 NOS
Display	Digital
Programmable Mode	Yes
Timer	1 min-99hr 59mins & infinite
Dimension	325×202×115 mm
Input voltage	230V 1.5A
Power consumption	250W

QUALIFICATION OF DRY BATH - I THERM D150-2

Checking sign off:

Name of the Engineer	Signature/Date
Kamlesh Padhiyar	 28/12/2021

Name of the Department Head	Signature/Date
 Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

OPERATIONAL QUALIFICATION

1. **Purpose:** The purpose of Operation Qualification is to establish that the Dry Bath and its Components are as per the specifications and are installed as per the approved procedure.

2. **Scope:** Operation Qualification to be performed at the time of Operation..

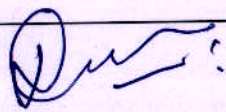
3. **Responsibility:** R&D, Engineering, Safety and Quality Assurance.


4. **Critical Variables to be met:**

QUALIFICATION OF DRY BATH - I THERM D150-2

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
Operate the instrument as per manufacturer's manual	Should function as desired	OK
Press the ON/OFF key to switch on the Instrument.	Display Indication will be on	OK
To set the timing in mins(i.e.5,10,15), Press Time button then Press +/- button as explained in manual.	Display Indication led will Show Set Timer Value	OK
To set the Temperature, Press TEMP button then Press +/- buttons as explained in manual.	Display Indication will show Set Temperature value	OK
Maintenance and cleaning.	As per given in the manual.	OK
Training.	No. of personnel to be trained _____	4

Checking sign off:

Name of the Engineer	Signature/Date
Kamlesh Padriyas	 28/12/2021

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.- 724 Reg. No. 19841	 28/12/2021

PERFORMANCE QUALIFICATION

1. Purpose: The purpose of Performance Qualification is to establish that the Dry Bath and its Components are as per the specifications and are installed as per the approved procedure.

QUALIFICATION OF DRY BATH - I THERM D150-2

2. **Scope:** Performance Qualification to be performed at the time of Operation.


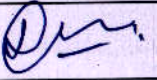
3. **Responsibility:** R&D, Engineering, Safety and Quality Assurance.

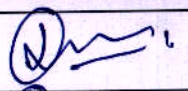

4. **Verification:**

(i) Measure with Calibrated Tachometer.

(ii) The set RPM showed match with the measured RPM.

FOLLOWING PARAMETERS ARE CHECKED FOR ITS PERFORMANCE:

Set in Time	Observed in Time	Acceptable in Time	Deviation in Time	APPROVED BY
00:01:00	00:01:00	± 2%	00:00:00	
00:05:00	00:05:00	± 2%	00:00:00	

Set in Temp	Observed in Temp	Acceptable in Temp	Deviation in Temp	APPROVED BY
37°C	36.8°C	± 0.5	-0.2	
60°C	60.3°C	± 0.5	+0.3	

Checking sign off:

Name of the Engineer	Signature/Date
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QUALIFICATION OF DRY BATH - I THERM D150-2

Kamlesh Paelliyar

Devi

28/12/2021

Name of the Department Head

Signature/Date

Dr. Shailesh Soni
Consultant Pathologist
M.P.U.H. Emp. No.:- 724
Reg. No. 19841

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28/12/2021

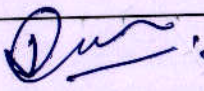
TRAINING CERTIFICATE


This is to certify that the following personal of *Neemika Patel*
are trained how to use the Stirrer as per manual.

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Kamlesh Padhiyar	 28/12/2021

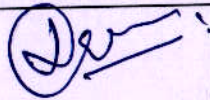
Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

EQUIPMENT HANDOVER CERTIFICATE


This is to certify that the Dry Bath Make Neuation Technologies India has been qualified and is here with approved for regular R & D experiments.

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Checking sign off:

Name of the Engineer	Signature/Date
Kamlesh Pachiyas	 28/12/2021

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Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

INSTALLATION QUALIFICATION REPORT

This is to certify that the DRY BATH- ITherm D150-2 Make Neuation, India has been installed successfully as per user requirement.

MAKE : Neuation, India

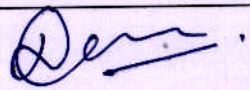
MODEL NO : DRY BATH- ITherm D150-2


0/550 SERIAL NO : QJ0 49734

INSTRUMENT ID : MPUH/LAB/CLIA/EQUIP/10

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Kamlesh Padhiyar	 28/12/2021

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

OPERATION QUALIFICATION REPORT

QUALIFICATION OF DRY BATH - I THERM D150-2

This is to certify that the DRY BATH - I therm D150-2 Make Neuation, India has been installed and is operating as per user manual.

MAKE : Neuation, India

MODEL NO : DRY BATH - I therm D150-2

SERIAL NO : QJ049734

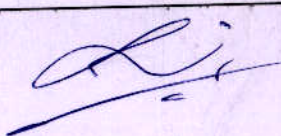
INSTRUMENT ID : MPUH/LAB/CLIA/EQUIP/10

Checking sign off:

Name of the Engineer	Signature/Date
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Kamlesh Padhiyas	Dev:	28/12/2021
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Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

PERFORMANCE QUALIFICATION REPORT

This is to certify that the DRY BATH - I therm D150-2 Make Neuation, India has been installed and is performing as per specifications.

MAKE : Neuation, India

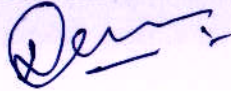
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