

**Registered Office:**  
**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



## *BA200 – Fully Auto Biochemistry Analyser*


### *Installation Qualification Certificate*

*For*

*Omsai Pathology Laboratory ,Latur*

*BioSystems Diagnostics Pvt. Ltd*

**Corporate Office:**  
**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>



ISO 13485

The ISO 13485 certification logo is located in the bottom right corner. It consists of a stylized, overlapping circular graphic in shades of purple and grey, with the text "ISO 13485" printed in a black, sans-serif font within the graphic.

**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



**CERTIFICATE OF INSTALLATION**

Instrument Name : BA200 Fully Auto Biochemistry Analyzer

Serial Number : 832000211

Customer : Omsai Pathology Laboratory ,Latur,  
Central Bus Stand Gate no. 1 Latur -413512

The undersigned performer certifies that the installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

Signature :

Name :

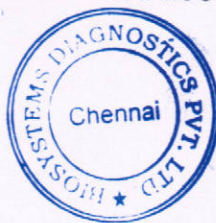
Mr.Nitin Phadatare

Designation :

Service Engineer

Company :

BioSystems Diagnostics Pvt. Ltd.,



Customer

Signature :

Name :

Dr. Kapil Dhumure

Designation :

Lab Incharge

Company :

Omsai Pathology Laboratory ,Latur,

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>

ISO 13485

**Registered Office:**  
**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 /13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492




## INSTALLATION REPORT

Customer Name : Omsai Pathology Laboratory ,Latur,  
Department : Bio-chemistry  
Contact Person : Dr. Kapil Dhumure  
Instrument Model : BA200  
Serial Number : 832000211  
Date of Installation : 01/12/2018

The System was installed along with the necessary accessories. All basic requirements and adjustments were checked and are found to be satisfactory. Preliminary customer training was provided and standardization of all parameters was done. The Instrument is found to be working satisfactorily.

**Corporate Office:**  
**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>



ISO 13485

**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



**INSTRUMENT SETUP :**

- Instrument and computer installed
- Printer Installed
- User software 5.1.3.0 installed
- All necessary cable connections given

**OPERATION INSPECTION :**

- No air bubbles found in the Tubing
- Temperature of the Needles/Reaction & Rotor Chamber are within range
- No unusual noises produced in the system
- Warm up procedure within time limit
- Internal Dosing of all Needle's were fine
- External Dosing of all Wash Station is perfect
- Conditioning of Machine with Air/Wash solution/Distilled water done

For Biosystems Diagnostics Pvt. Ltd

Mr. Nitin Phadatore  
Service Engineer



**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>



**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 /13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492




## INSTALLATION QUALIFICATION

Customer Name : Omsai Pathology Laboratory ,Latur,  
Address : Omsai Pathology Laboratory ,Latur,  
Central Bus Stand Gate no. 1 Latur -413512  
Instrument Model : BA200  
Serial No. : 832000211

### *Operational requirement for the Instrument:*

Requirement	Acceptable Range	Observed Range
Input Voltage	220 $\pm$ 10 V	228 V
Line Frequency	50 or 60 Hz	50 Hz
Ambient Temperature	18 – 30 deg. C	25 deg. C
Distill Water	Type II NCCLS	Available

For Biosystems Diagnostics Pvt. Ltd

  
Mr. Nitin Phadatare  
Service Engineer



**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>

ISO 13485

**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



## ***BA200 - Fully Auto Biochemistry Analyzer***

***Operational Qualification***


***For***

***Omsai Pathology Laboratory ,Latur***

***BioSystems Diagnostics Pvt. Ltd***

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>

A circular logo for ISO 13485 certification is located in the bottom right corner. It consists of a large, light-colored circle with a smaller, white circle inside it, and a white line forming a partial circle around the inner circle. The text "ISO 13485" is printed in a small, black, sans-serif font within the white circle.

ISO 13485

**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 /13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492




## ***BA200 – Fully Auto Biochemistry Analyzer***

### OPERATIONAL QUALIFICATION

1. System Performance check procedures.
2. System operational certificate.

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>

A circular logo for ISO 13485 certification is located in the bottom right corner. It consists of a large, light purple circle with a white outline. Inside this circle, there is a smaller white circle. The text "ISO 13485" is written in a white, sans-serif font across the bottom of the logo.

ISO 13485

**Registered Office:**

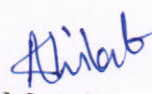
**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



## CERTIFICATE OF OPERATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer  
Serial Number : 832000211  
Customer : Omsai Pathology Laboratory ,Latur,  
Central Bus Stand Gate no. 1 Latur -413512

The undersigned performer certifies that the Operational Qualification Protocol has been successfully completed for the instrument stated above.

Engineer  
Signature :   
Name : Mr. Nitin Phadatar  
Designation : Service Engineer  
Company : BioSystems Diagnostics Pvt. Ltd



Customer  
Signature :  
Name : Dr. Kapil Dhumure  
Designation : Lab Incharge  
Company : Omsai Pathology Laboratory, Latur.

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>





**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 /13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



## SYSTEM PERFORMANCE CHECK PROCEDURE

<b>SYSTEM CHECK</b>	<b>PERFORMANCE</b>
LED Photometric Check	Done
Warm Up	Done
Mechanical Adjustments	Done
Temperature Check	Done
Internal/External Dosing Check	Done

Customer Signature:

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>



**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



## OPERATIONAL QUALIFICATION

### 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.

Protocol Performed By :

BioSystems Diagnostics Pvt Ltd

Name : Mr.Nitin Phadatare

Title : Service Engineer

Company: Biosystems Diagnostics Pvt Ltd

Customer Authorization:

Omsai Pathology Laboratory, Latur.

Name: Dr. Kapil Dhumure

Title: Lab Incharge

ENGINEER SIGNATURE

DATE:



CUSTOMER SIGNATURE

DATE:

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>



**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 /13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



***BA200 - Fully Auto Bio Chemistry Analyzer***

***Performance Qualification***

***For***

***Omsai Pathology Laboratory ,Latur***

***BioSystems Diagnostics Pvt. Ltd***

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>



**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



## **BA200 Fully Auto Biochemistry Analyzer**

### **PERFORMANCE QUALIFICATION:**

The following parameters were checked and found to be within acceptable limits.

<b>Parameter</b>	<b>Check</b>
Vertical Motors – Sample and reagent in Home	Done
Polar Motors – Sample and reagent in Home	Done
Reaction Rotor in home	Done
Sample and Reagent rotor in Home	Done
Ceramic Dispensing pump – Sample and reagent in Home	Done
Optics Initialization: Ok	Done
Peltier cells and drivers test	Done
Rotor Peltier and Sample Reagent Rotor peltier driver test: Ok	Done
Temperature system initialized	Done
LED test: ok	Done
Hardware completely initialized	Done

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>



**Registered Office:**

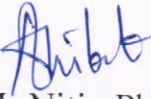
**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492

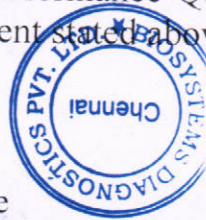


## CERTIFICATE OF PERFORMANCE

Instrument Name : BA200 Fully Auto Biochemistry Analyzer  
Serial Number : 832000211  
Customer : Omsai Pathology Laboratory ,Latur,  
Central Bus Stand Gate no. 1 Latur -413512

The undersigned performer certifies that the Performance Qualification Protocol has been successfully completed for the instrument stated above.

Engineer  
Signature :   
Name : Mr.Nitin Phadatare  
Designation : Service Engineer  
Company : BioSystems Diagnostics Pvt Ltd.,



Customer  
Signature :  
Name : Dr. Kapil Dhumure  
Designation : Lab Incharge  
Company : Omsai Pathology Laboratory ,Latur.

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>

