BIOMÉRIEUX

43A, Ist Floor, Okhla Industrial Estate, Phase III,
New Delhi-110020
Toll Free No : 1800 118 800 & 1800 102 7791
Email : customercare.india@biomerieux.com

No.: 16616

INSTALLATION REPORT

CUSTOMER DETAILS :

Customer Name : PACE HOSPITALS

Address : Plot No. 23, HUDA Techno Enclave, Patrika Nagar, Madhapur, HYDERABAD. TELANGANA 500081

Contact Person :

Phone : 040-48486868 Mobile : 8885045634 E-mail :

INSTRUMENT & INSTALLATION DETAILS :

Instrument Type : Automated Immunoassay Analyser

Model : MINIVIDAS

Instrument Serial No. : IVD5209998

Version :

Notification No :

Date of Installation: 24/6/2017

Travel Time In Hrs. : 1 HOUR

	Start :	End :
Date :	24/6/17	24/6/17
Time :	12.00 hrs	1 pm

PHYSICAL INSPECTION:

1. Was there any external Damage to the Instrument or Accessories ? Yes / No
2. Were any of the accessories missing ? Yes / No
3. Were any parts loose ? Any unsecured hardware ? Yes / No
4. Checked all connection and Robotic calibration found O.K. Yes / No

If any of the above were answered YES, please elaborate.

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PRE-INSTALLATION CHECKS:

Is Room Air-Conditioned ? Yes / No

Vibration Free Platform ? Yes / No

Source of Supply : Online U.P.S : Yes / No

Specified Capacity & Make : SCHNEIDER 120KV

Output Voltage : Line & Neutral 231 vAC Neutral & Earth 0 vAC Line & Earth 231 vAC

TO BE COMPLETED BY THE CUSTOMER:

The above mentioned instrument has been satisfactorily installed by the Engineer / Application Specialist of bioMerieux India Pvt. Ltd.. Received all standard accessories in good condition.

Customer's Remarks .....

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Signature of Customer : ..... Name & Signature of Engineer : Sunil Kumar

PACE HOSPITALS LIMITED

BIOMÉRIEUX

PRODUCT CERTIFICATE / *CERTIFICAT PRODUIT*

Manufacturer / *Fabricant:*	**BioMérieux SA** **69280 Marcy l'Etoile - France**
Product name / *Nom du produit:*	**miniVIDAS**
Reference / *Référence:*	**410416**
Numéro de série / *Serial number*:	**IVD52**09998

This product has been developed and is manufactured in accordance with the provisions of ISO 9001 and ISO 13485 certified Quality System and with Quality System Regulation requirements (21 CFR 820 – US FDA).
This product is CE marked according to Directive 98/79/EC on in vitro diagnostic medical devices and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
This product has been tested by an independent testing agency with regards to safety and electromagnetic compatibility requirements and shows compliance with the standards mentioned below :
Ce produit a été développé et est fabriqué conformément à notre Système Qualité certifié ISO 9001 et ISO 13485, et conformément aux exigences du Quality System Regulation (21 CFR 820 – US FDA).
Ce produit est marqué CE selon la directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro et directive 2011/65/EU relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques.
Ce produit a été contrôlé aux exigences de sécurité et de compatibilité électromagnétique par un organisme de test indépendant, et est conforme aux normes mentionnées ci-après:

RoHS/Safety/EMC European Standards *Normes européennes de Sécurité,CEM, RoHS*	Testing Agency *Organisme de test*
EN 50581:2012	N/A
EN 61010-1:2001; EN 61010-2-081:2002; EN 61010-2-101:2002; EN60825-1:1994+A1:1997+A2:2001, EN 60825-1:2007 EN 61326-1: 2006; EN 61326-2-6: 2006 (including / *comprenant:* EN 55011:1998+A1:1999+A2:2002 Class/Classe A; EN 61000-4-2:1995+A1:1998+A2:2001; EN 61000-4-3: 2002; EN 61000-4-4: 2004; EN 61000-4-5:1995+A1:2001; EN 61000-4-6:1996+A1:2001; EN 61000-4-8: 1993+A1: 2001; EN 61000-4-11: 2004; EN 61000-3-2:2006; EN 61000-3-3:1995+A1:2001)	IMQ - ITALY
Other International Standards *Autres normes internationales*	**Testing Agency** *Organisme de test*
IEC 61010-1:2001; IEC 61010-2-081:2001; IEC 61010-2-101:2002; IEC60825-1:1993+A1:1997+A2:2001; IEC 60825-1:2007 UL 61010-1 (2nd Edition); CSA C22.2 No 61010-1 (2nd Edition); CSA C22.2 No 61010-2-081:2004; CSA C22.2 No 61010-2-101:2004 CFR 47 part 15 :2008 subpart B; IEC 61326-1: 2005; IEC 61326-2-6: 2005	IMQ - ITALY

This product bears the mark / *Ce produit porte la marque :* C SP® US

	Site	Date
QA/RA Departement/Aff. Réglement. & *Ass. Qualité:*	Florence-Italy	2016-04-07
Name/*Nom*: **Massimo Baroncelli** Signature:		

After the final stage of production, this product was controlled using the protocols mentioned below and meets bioMérieux specifications.
En fin de production, ce produit a été contrôlé selon les protocoles mentionnés ci-après et satisfait aux spécifications de bioMérieux.

Protocol reference *Référence du protocole*
VD0301
VD0302
VD0303