HORIBA Explore the future

H22NC2193205

Notification No.	
Work Order No.	



Toll Free No.:1800-103-4470

EPORT	CUSTOME	R COPY			Н	IN-M	02- ²⁷⁵⁶⁷		
R DETAILS	INSTRUMENT DETAILS				SERVICE STATUS				
phad Ke	MODEL: PC 200 EQUIP. SL. No.: 2011 (2.0284-D VERSION:				VISITING PURPOSE: REPAIR DATA ERROR INSTALLATION MAINTENANCE UPGRADE CUSTOMER TRAINING				
nd	CALL DETAILS			TIME		SY VISIT			
	COMPLAINT REC				CUSTOMER STATUS R.R WARRANTY AMC CMC DEMO FREE SERVICE CHARGEABLE OTHERS CALL				
1 ,	START	23.6.2	22	2: wpm					
sau	COMPLETED			4					
300-0353	TRAVEL TIME (Eng.	1)		17					
U J -	TRAVEL TIME (Eng.	2)		HOURS	WORKS CARRIED OUT AT ☑ SITE ☐ SERVICE CENTRE				
hkar.	DAILY WORKLOA	D 40-60	<u></u>						
TED:	Preventi	ue A	La	mten	ance	20	, pc 20		
	1 0.1					0			
Fluid, RP Fluid, SP Fluid, W	PTION (Replaced) PSyringe PSyringe PSyringe PSyringe In line	tip tip tip	QTY	Se Se	OST	TAX	EASE APPROVE TOTAL		
						eplaced for Trouble Shooting ed to be returned after Trouble Shooting.			
E-1: ENGINEE	ER'S NAME-2:	FAULT IS NO WE HEREBY COMMENTS	APPE (IF AN	& INSTRUI MPLETED, ROVE Rs NY)	MENT IS V	VORKING R NEED.	SATISFACTORILY		
	R DETAILS Phadke Add By 58353 N: Lkar. TED: Checked The phane To John Manner Third, RP Fluid, RP Fluid, SP Fluid, WI Fluid, WI DESCRI DESCRI DESCRI Third, WI T	R DETAILS INSTRUM MODEL: EQUIP, SL. No.: VERSION: NOTIFICATION NO. CALL DETAILS COMPLAINT RECT START COMPLETED TRAVEL TIME (Eng. DAILY WORKLOA TED: Proventy Travel Time (Eng. DAILY WORKLOA TED: Checked instrum The property of	R DETAILS Phack Read Model: PC 2 00 EQUIP. SL. No.: 2011 (2) VERSION: NOTIFICATION No. CALL DETAILS DATE COMPLAINT RECD. START COMPLETED TRAVEL TIME (Eng. 1) TRAVEL TIME (Eng. 2) DAILY WORKLOAD 40-600 TED: Proventing The phace of the phac	INSTRUMENT DETAILS MODEL: POR ON: PORTION NO. EQUIP, SL. NO.: 2011 (2.02) VERSION: NOTIFICATION NO. CALL DETAILS DATE COMPLAINT RECD. START COMPLETED TRAVEL TIME (Eng. 1) TRAVEL TIME (Eng. 2) DAILY WORKLOAD DAILY WORKLOAD TED: DESCRIPTION (Replaced) TO SAP Syrings to p TUING, RPP Syrings to p TO DESCRIPTION (Trouble Shooting) ON (Spare need to replaced, if any) DESCRIPTION (Trouble Shooting) TO SPAULT RECTIFIED FAULT RECTIFIED TO SPAULT RECTIFIED FAULT RECTIFIED COMMENTS (IF AN) TO SPAULT RECTIFIED COMMENTS (IF AN) TO SPAULT RECTIFIED COMMENTS (IF AN)	R DETAILS INSTRUMENT DETAILS MODEL:	RDETAILS INSTRUMENT DETAILS PAGE MODEL: PC 200 EQUIP. SL. No.: 2011 (2.028 4-D) REPAR VERSION: NOTIFICATION NO. CALL DETAILS COMPLAINT RECD. START COMPLETED TRAVEL TIME (Eng. 1) TRAVEL TIME (Eng. 1) TRAVEL TIME (Eng. 2) DAILY WORKLOAD DAILY WORKLOAD TRAVEL TIME (Eng. 2) DAILY WORKLOAD TO BE FOLLOWING PARTS NEED TO BE REPLACE DESCRIPTION (Replaced) TO BE FILLED IN BY CU. TO BE FILLED IN BY CU. START COMPLETED TO BE FILLED IN STRUMENT IS WERE TO BE REPLACE TO BE FOLLOWING PARTS NEED TO BE REPLACE TO BE FOLLOWING PARTS NEED TO BE REPLACE TO BE FILLED IN BY CU. TO BE FILL	R DETAILS INSTRUMENT DETAILS PAGE MODEL: PC 200 EQUIP. SL. No.: 2011 (200284) VERSION: NOTIFICATION No. CALL DETAILS DATE TIME OTHERS COMPLAINT RECD. COMPLETED 23.6.22 WARD OEMO CALARGEABLE TRAVEL TIME (Eng. 1) HOURS DAILY WORKLOAD OEMO CALARGEABLE TRAVEL TIME (Eng. 2) HOURS DAILY WORKLOAD OEMO CALARGEABLE TRAVEL TIME (Eng. 2) HOURS TO BE STATE CALARGEABLE CALARGEABLE TRAVEL TIME (Eng. 2) HOURS WORKS CARF SITED: WORKS CARF TRAVEL TIME (Eng. 2) HOURS WORKS CARF TRAVEL TIME (Eng. 2) HOURS WORKS CARF TO BE FILLED IN GRAPH MARCH TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) OTY. TOTAL RS. "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) TO BE FILLED IN BY CUSTOMER "Replaced for Trouble Shooting) WE HEREBY APPROVE RS. "COMMENTS (IF ANY)		



HORIBA ABX SAS

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Montpellier, July 12th 2022

Ref.: 22-118 BD/cf

<u>STATEMENT</u>

To whom it may concern,

We, HORIBA ABX SAS, with Headquarters in Parc Euromédecine, Rue du Caducée, BP 7290, 34184 Montpellier Cedex 4, FRANCE, hereby certify:

All HORIBA ABX SAS products which are distributed and for which a Free-Sales-Certificate was issued, are CE marked. The In vitro Diagnostics Directive of the European Union required for all CE marked products, that the manufacturer assures compliance of the products with the requirements of the In Vitro Diagnostics Directive.

This means that all processes in the development and manufacturing of HORIBA ABX SAS products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO13485: 2016.

The mentioned regulations require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. This status has to be assured by schedules maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in HORIBA ABX SAS systems are fully traceable to certified standards or reference materials.

The performance of all HORIBA ABX SAS systems at the customer site is assured if regular QC measurements, cleaning and maintenance procedures, as described in the instructions for use or service documentation, are performed.

By having controlled internal procedures and by running the tasks required in the respective user documentation, all HORIBA ABX SAS systems will perform as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required of the user in order to assure the specified performance of every HORIBA ABX SAS systems.

Only if a user deviates from these manufacturer's recommendations, does he have to establish site specific calibration and verification procedures as part of his accreditation process.

Yours faithfully,

HORIBA ABX SAS

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Caroline Ferrer

Regulatory Affairs Manager

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