



Certificate of Analysis for i2000SR  
Template

Flextronics Manufacturing (Singapore) Pte. Ltd.  
1 Kallang Place  
Singapore 339211  
Main: +65 6507 6507  
www.flextronics.com

ARCHITECT i2000SR  
Certificate of Analysis

Serial No: ISR64824

Product Name: Architect i2000SR  
Test Procedure: TP 94000 Rev: AW  
Tested Date: 30 Aug 2021

Item	Criteria	Result	Judge
Calibration of Pipettes	1) 1111 Sample Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
	2) 1112 R1 Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
	3) 1113 R2 Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
	4) 1117 STAT Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
System Start-up	1) 2130 Flush Fluids Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
Temperature Status Check	<b>3520 Temperature Status</b>		
	A) P Path Zone 1	36.4 – 37.6 °C	A) <u>37.0</u> °C
	B) P Path Zone 2	36.4 – 37.6 °C	B) <u>37.0</u> °C
	C) P Path Zone 3	36.4 – 37.6 °C	C) <u>37.0</u> °C
	D) P Path Zone 4	36.4 – 37.6 °C	D) <u>37.0</u> °C
	E) P Path Zone 5	36.4 – 37.6 °C	E) <u>37.0</u> °C
	F) P Path Zone 6	36.4 – 37.6 °C	F) <u>37.0</u> °C
	G) Pre-trigger	32.0 – 37.6 °C	G) <u>35.8</u> °C
	H) Trigger	32.0 – 37.6 °C	H) <u>35.8</u> °C
	I) Wash Zone 1	34.0 – 36.5 °C	I) <u>35.5</u> °C
	J) Wash Zone 2	34.0 – 36.5 °C	J) <u>35.5</u> °C
	K) Reagent Cooler	2.0 – 12.0 °C	K) <u>5.4</u> °C
			<div>Pass</div> <div>Fail</div>

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### ARCHITECT i2000SR Certificate of Analysis

Serial No: ISR64824

Item	Criteria	Result	Judge
Optics Tests	<b>1020 Optics Background Test</b>		
	A) No RV, open position 3 - 500	66	(Pass)
	B) Empty RV 3 - 500	44	
	C) RV with Fluid 3 - 500	50	
	<b>1045 Optics Verification Test</b>		
	A) Mean 1 : Target Value (RLU) ±18% LSL Target Value USL 26403 ~ 32199 ~ 37995	31601 RLU	(Pass)
	B) Mean 2 : Target Value (RLU) ±18% LSL Target Value USL 110251 ~ 134452 ~ 158653	131777 RLU	
	C) Mean 3 : Target Value (RLU) ±18% LSL Target Value USL 2130328 ~ 2597961 ~ 3065594	2555758 RLU	
	D) %CV 1 0.00 5.00	0.85 %	
	E) %CV 2 0.00 5.00	0.64 %	
	F) %CV 3 0.00 5.00	0.79 %	
	G) Range Deviation (%) 0.00 21.50	0.36 %	
Electrical Safety Tests	1) Ground Continuity Test Test passes all the test point without errors	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	(Pass) Fail
	2) Hypot Test Test passes without error	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	(Pass) Fail

The above product has been manufactured in accordance with Abbott operating procedures and conforms in all respects with the specific final product specifications as tested and inspected by Product Test.

Final Disposition	(PASS)	FAIL
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Data Verification By	Thong Choi Choi	<i>Thong</i>	22 Mar 2022
	Printed Name	Signature	Date
QA Approval By	Duraisamy Dayalan	<i>Duraisamy</i>	22 MAR 2022
	Printed Name	Signature	Date

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### ARCHITECT i2000SR Certificate of Analysis

Serial No: ISR64825

Product Name: Architect i2000SR  
Test Procedure: TP94000 Rev: AW  
Tested Date: 30 Aug 2021

Item	Criteria	Result	Judge
Calibration of Pipettes	1) 1111 Sample Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
	2) 1112 R1 Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
	3) 1113 R2 Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
	4) 1117 STAT Pipettor Calibration Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
System Start-up	1) 2130 Flush Fluids Procedure	<input checked="" type="checkbox"/> Completed <input type="checkbox"/> Not completed	<div>Pass</div> <div>Fail</div>
Temperature Status Check	<b>3520 Temperature Status</b>		
	A) P Path Zone 1	36.4 – 37.6 °C	A) <u>37.0</u> °C
	B) P Path Zone 2	36.4 – 37.6 °C	B) <u>37.0</u> °C
	C) P Path Zone 3	36.4 – 37.6 °C	C) <u>37.0</u> °C
	D) P Path Zone 4	36.4 – 37.6 °C	D) <u>37.0</u> °C
	E) P Path Zone 5	36.4 – 37.6 °C	E) <u>37.0</u> °C
	F) P Path Zone 6	36.4 – 37.6 °C	F) <u>37.0</u> °C
	G) Pre-trigger	32.0 – 37.6 °C	G) <u>35.7</u> °C
	H) Trigger	32.0 – 37.6 °C	H) <u>35.8</u> °C
	I) Wash Zone 1	34.0 – 36.5 °C	I) <u>35.5</u> °C
	J) Wash Zone 2	34.0 – 36.5 °C	J) <u>35.5</u> °C
	K) Reagent Cooler	2.0 – 12.0 °C	K) <u>7.6</u> °C
			<div>Pass</div> <div>Fail</div>

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### ARCHITECT i2000SR Certificate of Analysis

Serial No: ISR64825

Item	Criteria	Result	Judge
Optics Tests	<b>1020 Optics Background Test</b>		
	A) No RV, open position 3 - 500	39	(Pass)
	B) Empty RV 3 - 500	37	
	C) RV with Fluid 3 - 500	31	Fail
	<b>1045 Optics Verification Test</b>		
	A) Mean 1 : Target Value (RLU) $\pm 18\%$ LSL Target Value USL 26403 ~ 32199 ~ 37995	32933 RLU	
	B) Mean 2 : Target Value (RLU) $\pm 18\%$ LSL Target Value USL 110251 ~ 134452 ~ 158653	136260 RLU	(Pass)
	C) Mean 3 : Target Value (RLU) $\pm 18\%$ LSL Target Value USL 2130328 ~ 2597961 ~ 3065594	2607818 RLU	Fail
		LSL USL	
	D) %CV 1	0.00 5.00	0.33 %
	E) %CV 2	0.00 5.00	1.09 %
	F) %CV 3	0.00 5.00	0.61 %
	G) Range Deviation (%)	0.00 21.50	1.89 %
Electrical Safety Tests	1) Ground Continuity Test Test passes all the test point without errors	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	(Pass) Fail
	2) Hypot Test Test passes without error	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	(Pass) Fail

The above product has been manufactured in accordance with Abbott operating procedures and conforms in all respects with the specific final product specifications as tested and inspected by Product Test.

Final Disposition	(PASS)	FAIL
-------------------	--------	------

Data Verification By	Thong Choi Choi	Coching	22 Mar 2022
	Printed Name	Signature	Date
QA Approval By	Duraismy Dayalan	Duraismy	22 MAR 2022
	Printed Name	Signature	Date

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ARCHITECT



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## THE EXTENSIVE MENU FOR CLINICAL CHEMISTRY AND IMMUNOASSAYS ON ARCHITECT SYSTEMS

### CLINICAL CHEMISTRY

#### GENERAL CHEMISTRIES

Acid Phosphatase  
Albumin BCG  
Albumin BCP  
Alkaline Phosphatase  
ALT  
ALT (activated)  
Amylase  
Amylase (pancreatic)  
AST  
AST (activated)  
Bilirubin, Direct  
Bilirubin, Total  
Calcium  
Cholesterol  
CK  
CO<sub>2</sub>  
Creatinine  
Enzymatic Creatinine  
Direct LDL  
GGT  
Glucose  
HDL, Ultra  
ICT Cl<sup>-</sup> (Chloride)  
ICT K<sup>+</sup> (Potassium)  
ICT Na<sup>+</sup> (Sodium)  
Iron  
LDH (Lactate Dehydrogenase)  
Lactic Acid  
Lipase  
Magnesium (Arsenazo)  
Magnesium (Enzymatic)  
Phosphorous  
Total Protein  
Triglyceride  
UIBC  
Urea Nitrogen  
Uric Acid  
Urine/CSF Protein

#### CARDIAC

CK-MB  
Myoglobin

#### SPECIAL CHEMISTRIES

Ammonia  
Bile Acids  
Cholinesterase  
Cholinesterase/Dibucaine  
Copper  
Cystatin C  
D-Dimer  
Fructosamine  
HbA1c  
HBDH

#### SPECIFIC PROTEINS

Alpha-1 Antitrypsin  
Alpha-1 Glycoprotein  
Apolipoprotein A1  
Apolipoprotein B  
ASO  
Beta 2-Microglobulin  
Ceruloplasmin  
Complement C3  
Complement C4  
CRP Vario (High Sensitivity, Standard, Wide Range)  
Ferritin  
Haptoglobin  
IgA  
IgE  
IgG  
IgM  
Lp(a)  
Microalbumin  
Prealbumin  
RF  
Transferrin  
κ Light Chains  
λ Light Chains

#### THERAPEUTIC DRUGS

Amikacin  
Carbamazepine  
Digitoxin  
Digoxin  
Gentamicin  
Lithium  
Phenobarbital  
Phenytoin  
Quinidine  
Theophylline  
Tobramycin  
Valproic Acid  
Vancomycin

#### DRUGS OF ABUSE/ TOXICOLOGY

Acetaminophen  
Amphetamine/  
Methamphetamine  
Barbiturates  
Benzodiazepines  
Benzodiazepines Serum  
Cannabinoids  
Cocaine  
Ecstasy  
Ethanol  
Methadone  
Opiates  
Phencyclidine (PCP)  
Propoxyphene  
Salicylate  
Tricyclic Antidepressants



IMMUNOASSAY

CANCER

AFP  
CA 125 II  
CA 15-3  
CA 19-9 (CA 19-9 XR)  
CEA  
CYFRA 21-1  
HE-4  
Pepsinogen I  
Pepsinogen II  
PIVKA-II  
ProGRP  
PSA, Free  
PSA, Total  
ROMA (HE4/CA125)  
SCC

CARDIAC

BNP  
CK-MB  
Galectin-3  
Homocysteine  
Myoglobin  
NT-proBNP  
Troponin-I (high sensitive)

FERTILITY/PREGNANCY

DHEA-S  
Estradiol  
FSH  
hCG (total beta-hCG)  
LH  
Progesterone  
Prolactin  
SHBG  
Testosterone 2<sup>nd</sup> Generation

INFLAMMATORY DISORDERS

Procalcitonin (BRAHMS)

HEPATITIS

Anti-HAV IgG  
Anti-HAV IgM  
Anti-HBc  
Anti-HBc IgM  
Anti-HBe  
HBeAg Qualitative/Quantitative  
Anti-HBs  
HBsAg Qualitative  
HBsAg Qualitative Confirmatory  
HBsAg Quantitative  
Anti-HCV  
HCVAg

RETROVIRUS

HIV Ag/Ab Combo  
Anti-HTLV I/II

CONGENITALS

CMV IgG  
CMV IgG Avidity  
CMV IgM  
Rubella IgG  
Rubella IgM  
Toxo IgG  
Toxo IgG Avidity  
Toxo IgM

OTHER INFECTIOUS DISEASE

Chagas  
EBV EBNA-1 IgG  
EBV VCA IgG  
EBV VCA IgM  
Syphilis TP

METABOLIC

Active-B12  
Anti-CCP  
B12  
C-Peptide  
Cortisol  
Ferritin  
Folate  
HbA1c  
Insulin  
Intact PTH  
Vitamin D

RENAL

NGAL

THERAPEUTIC DRUG MONITORING

Carbamazepine  
Digoxin  
Gentamicin  
Methotrexate  
Phenobarbital  
Phenytoin  
Theophylline  
Valproic Acid  
Vancomycin

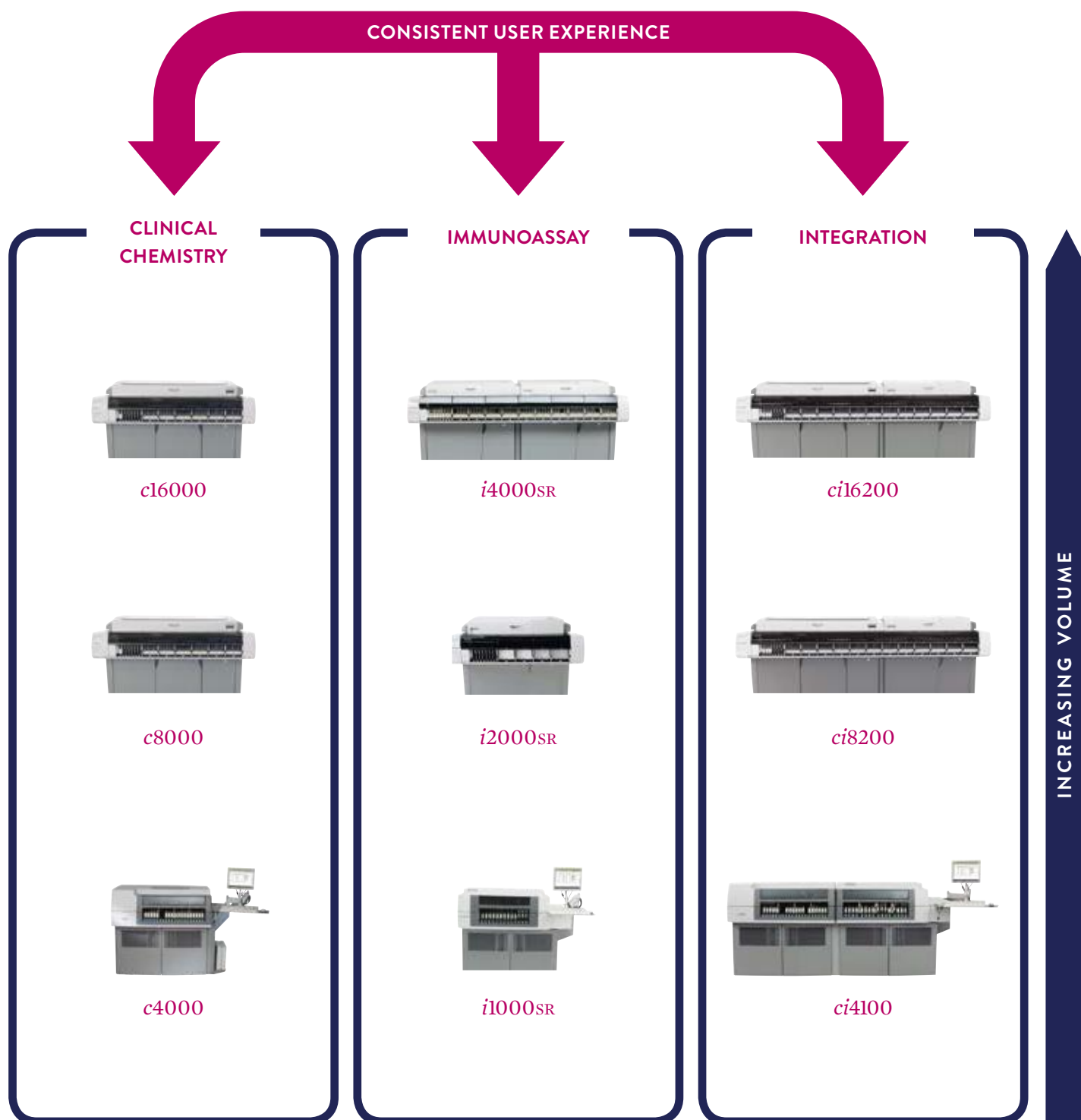
THYROID

Anti-Tg  
Anti-TPO  
Free T3  
Free T4  
Total T3  
Total T4  
TSH  
T-Uptake

TRANSPLANT

Cyclosporine  
Sirolimus  
Tacrolimus

## ARCHITECT SYSTEM FAMILY



[WWW.CORELAB.ABBOTT](http://WWW.CORELAB.ABBOTT)

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All ARCHITECT instruments are Class 1 laser products.





## ARCHITECT i2000SR

### High-speed immunoassay testing with the ARCHITECT solution

#### HIGH PRODUCTIVITY AND SEAMLESS CONSOLIDATION



- **No clinically significant** sample-to-sample carryover (<0.1 ppm tube-to-tube)
- **Robotic Sample Handler (RSH)** eliminates bottlenecks and prioritizes urgent requests
- **Immediate STAT processing** for fast and consistent turnaround time
- **25 refrigerated** reagent positions and flexible kit sizes of 100 or 500 tests provide high reagent test capacity to optimize walkaway time
- **Continuous sample access** allows loading of up to 135 samples via priority (35) and routine (100) positions

#### ENHANCED SYSTEM AND ASSAY DYNAMICS



- **CHEMIFLEX** provides excellent low-end sensitivity and expanded dynamic ranges
- **Maximum throughput** of up to 200 tests per hour
- **Pressure differential technology** enables detection of clots, bubbles and insufficient sample volume to reduce analytical error and improve patient safety
- **Certainty and confidence** in the clinical results

#### TRUE FAMILY COMMONALITY



- **Identical technology**, reagents and assay protocols
- **Identical software** that is intuitive to operate
- **Universal ARCHITECT** sample carrier
- **Equivalent results** across all ARCHITECT iSystems

**ARCHITECT i2000<sub>SR</sub> can be integrated with the ARCHITECT c16000 to consolidate clinical chemistry and immunoassay on one platform.**



ARCHITECT i2000<sub>SR</sub>



ARCHITECT c16000

## ARCHITECT Integration Achieves Testing Consolidation

- Excellent STAT turnaround time
- Ease of use
- Improved workflow
- Confidence in results
- Reduced costs



ARCHITECT ci16200

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All ARCHITECT analyzers are Class 1 laser products.

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ARCHITECT *i2000SR*

# High-speed immunoassay testing uniquely designed for you

- STATs prioritized fast
- Advanced CHEMIFLEX technology
- Equivalent results across all ARCHITECT *i*Systems



**CHOOSE TRANSFORMATION**

# Answers when you need them. Advanced systems deliver swift results.

## TRUE FAMILY COMMONALITY

- Identical technology, reagents and assay protocols
- Identical software that is intuitive to operate
- ARCHITECT Universal Sample Carrier

**The benefits:** equivalent patient results across all ARCHITECT *i*Systems



ARCHITECT Universal  
Sample Carrier

## HIGH PRODUCTIVITY AND SEAMLESS CONSOLIDATION OPTIMIZE PERFORMANCE

- No clinically significant sample-to-sample carryover (<0.1 ppm)
- Robotic Sample Handler (RSH) eliminates bottlenecks and prioritizes urgent requests
- Immediate STAT processing for fast and consistent turnaround time
- 25 refrigerated reagent positions
- Continuous sample access, load up to 135 samples via priority (35) and routine (100) areas
- Throughput up to 200 immunoassay tests per hour



Up to 25 color-coded, refrigerated onboard reagent positions and flexible kit sizes of 100 or 500 tests provide high reagent test capacity to optimize walkaway time

**The benefits:** unique approach to consolidation

## ENHANCED SYSTEM AND ASSAY DYNAMICS

- CHEMIFLEX provides excellent low-end sensitivity and expanded dynamic ranges
- Pressure differential technology detects clots, bubbles and insufficient sample volumes to reduce errors

**The benefits:** certainty and confidence in the clinical results



## ARCHITECT *i*2000SR

can be integrated with ARCHITECT c8000 and c16000 to consolidate clinical chemistry and immunoassay on a single platform.

ARCHITECT *i*2000SR



ARCHITECT c16000



ARCHITECT c16200



Refer to the Operations Manual for operational precautions, limitations and hazards. Manuals can be found on [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com).

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See where it will take you at [AbbottDiagnostics.com/Transform](http://AbbottDiagnostics.com/Transform)



## Declaration of Conformity

**Certificate Identification:** 3M74  
**Legal Manufacturer's Name:** Abbott Laboratories  
**Legal Manufacturer's Address:** 1915 Hurd Drive, Irving TX 75038 USA

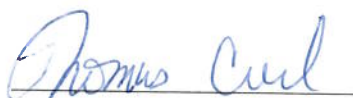
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03M74-02	56701	ARCHITECT i2000 <sub>SR</sub> PROCESSING MODULE	Self-declared

<b>Authorized European Representative (name and address)</b>	Abbott GmbH, Max Planck Ring-2, 65205, Wiesbaden, Germany
<b>Storage site of technical documentation (name and address)</b>	Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, United States
<b>Physical manufacturer (name and address)</b>	Flextronics Manufacturing (SINGAPORE) PTE LTD 1 Kallang Place Singapore, SINGAPORE 339211
<b>Harmonized Standards</b>	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states, and Directive 2011/65/EU, and amending Directive (EU) 2015/863, the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature:



Full Name:

Thomas Creel

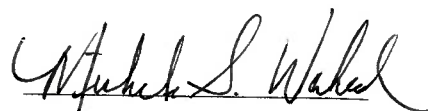
Position:

Director Quality Assurance

Date of Approval:

30-Nov-2021

Signature:



Full Name:

Michele Smith-Waheed

Position:

Associate Director, Regulatory Affairs

Date of Approval:

30-Nov-2021

Date Issued:

30-Nov-2021

Place Issued:

1915 Hurd Dr., Irving, Texas, USA

Supersedes:

31 August 2021

Effective (Date or Lot Number):

30-Nov-2021