22 June 2021 21 June 2024

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# Certificate of Approval

This is to certify that the Management System of:

## ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

### The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.



**Paul Graaf** 

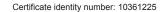
Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited



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## **Certificate Schedule**

Location **Activities** 

#### **ELITechGroup B.V.**

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

### ISO 13485:2016

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

### ELITechGroup B.V.

Kanaaldijk 90, 6956 AX Spankeren, The Netherlands

Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

### ISO 13485:2016

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.



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# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: ELITechGroup Inc.

370 West 1700 South

Logan Utah 84321 USA

Facility ID Number: F000174

Holds Certificate No: MDSAP 689350

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

jany C Stade

Original Registration Date: 2019-03-28 Effective Date: 2022-01-11 Expiry Date: 2025-01-10

Page: 1 of 1

MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit."





# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: ELITechGroup Inc.

370 West 1700 South

Logan Utah 84321 USA

Holds Certificate No: FM 703046

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-05-12 Effective Date: 2022-01-11 Latest Revision Date: 2021-12-23 Expiry Date: 2025-01-10

Page: 1 of 1

...making excellence a habit."







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Chamber of Commerce 09175642

To: Whom it May Concern

### Regulatory status of parts & accessories

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.

Adriaan P. Intveld

Manager Quality Assurance & Regulatory Affairs





Part number	Description	IVD medical device	IVD accessory	general laboratory use	spare part	supporting part
1540-001	Anti-Slip sheet					✓
2206-007	Cooling Liquid (1 L)					✓
3062-021	Sample cup (1000 pcs)		✓			
3062-033	Sample tube 6 ml (500 pcs)					✓
3062-040	Water container 10 L					✓
3062-041	Water container 5 L					✓
3066-155	Syringe 100 μl		✓			
3066-156	Syringe 1 ml		✓			
3069-040	Keyboard Dust cover					✓
3069-047	Keyboard Dust cover					✓
3070-518	Cap holder					✓
3070-538	Cap rotor Left					✓
3070-539	Cap rotor right					✓
3201-002	Dichromate 8 Abs (25ml)		✓			
3365-192	USB Stick					✓
3374-003	Mains cable (USA)					✓
3374-059	Pumpunit cable		✓			
3374-066	Mains cable					✓
3374-097	Serial Null-modem cable					✓
3374-286	USB Extension cable					✓
4804-038	Reagent identification Disc					✓
6001-826	Diluted Waste container		✓			
6001-827	Concentrated Waste container		✓			
6001-860	Water container		✓			
6001-861	Tube assy (analyser)		✓			
6001-872	Tube assy (cooling unit)		✓			
6002-102	Assorter unit				✓	
6002-386	System software on CD		✓			
6002-706	Reaction Rotor set (3 pcs)		✓			
6002-726	System Disc		✓			
6002-817	Bottle 30 ml (20 pcs)		✓			
6002-818	Bottle 15 ml (20 pcs)		✓			
6002-904	Water container 5 L		✓			
6002-910	Assorter unit				✓	
6002-913	External tubing		✓			
6003-074	System software on USB stick		✓			
6003-444	Diluted Waste Container 5 L		✓			
6003-466	Keyboard Support option					✓
6003-797	CW Waste Container 2 L		✓			
6003-808	Assorter unit				✓	



### **ion**torrent

## Ion PGM<sup>™</sup> System

Planned Maintenance Checklist

**Pub. No.** 4473624 **Rev.** C

 $Planned\ Maintenance\ is\ a\ procedure\ designed\ to\ protect\ the\ operational\ performance\ of\ the\ Ion\ PGM^{\tiny{\sc M}}\ System.$ 

Customer information	
Customer Organization Name:	
Customer Contact Name:	
Customer Contact Title:	
Customer Organization Location:	
Date Planned Maintenance Performed:	
Planned Maintenance Performed By:	
Service Order Number:	
System information	115
Ion PGM™ Sequencer Serial Number:	Q1
Ion Torrent™ Server Service Tag Number:	
Ion OneTouch™ 2 Instrument	
<b>Note:</b> The Ion PGM $^{\mathbb{M}}$ System planned maintenance service includes maintenance an add-on service for additional Ion OneTouch $^{\mathbb{M}}$ 2 Instruments, for the add-on service(s). Otherwise, enter "N/A" in the optional fields.	enance for <b>one</b> Ion OneTouch™ 2 Instrument. If the customer has record the instrument serial numbers and the Service Order Number
Ion OneTouch™ 2 Instrument Serial Number:	
(Optional second instrument) Ion OneTouch $^{\!$	
Service Order Number for this add-on service:	
(Optional third instrument) Ion OneTouch $^{\!\scriptscriptstyleM}$ 2 Instrument Serial Number:	
Service Order Number for this add-on service:	
Ion OneTouch™ ES	
<b>Note:</b> The Ion PGM $^{\mathbb{N}}$ System planned maintenance service includes maintenance service for additional Ion OneTouch $^{\mathbb{N}}$ ESs, record the instrument s Otherwise, enter "N/A" in the optional fields.	
Ion OneTouch™ ES Serial Number:	
(Optional second instrument) Ion OneTouch™ ES Serial Number:	
Service Order Number for this add-on service:	

(Optional third instrument) Ion OneTouch™ ES Serial Number:	
Service Order Number for this add-on service:	

### Planned maintenance responsibilities

Customer responsibilities: Customers should ensure that all necessary operating supplies and consumables are available. The Ion PGM $^{\text{\tiny{M}}}$  System should be available for the planned maintenance activities. Prior to a Field Service Engineer (FSE) arriving on site for the Planned Maintenance, the Ion PGM $^{\text{\tiny{M}}}$  Sequencer needs to be properly shutdown.

Engineer Responsibilities: The FSE should obtain all necessary PM tools and parts. Wear appropriate personal protective equipment.

### Recommended parts and tools

**Note:** Part numbers are subject to change, please refer to the Ion PGM™ System service spare part list.

Part no.	Description	Quantity
4479642	Squid Port Seals	2
A24792	0-RING, 3/32 ID X 9/32 OD	2 per Ion OneTouch™ 2 Instrument
A24797	O-RING, 4MM ID X 7MM OD	3 per Ion OneTouch™ 2 Instrument
4482701	BOTL,LQD COOLANT OT	1
4462932	Pariposer	1

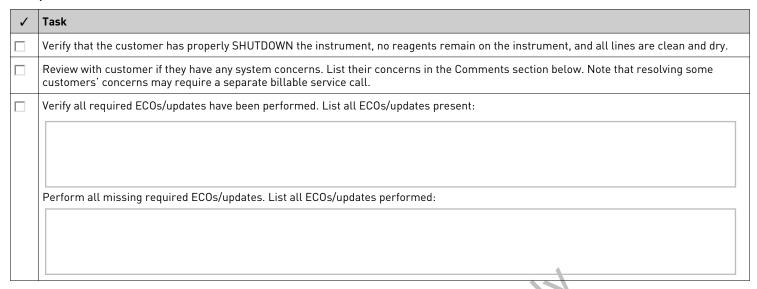
### Planned maintenance introduction

Any deviations from this procedure, plus any parts used in addition to the parts listed above, must be noted on an accompanying service report. Any parts replaced that are not included above are considered billable via a Customer Purchase Order, unless the equipment is covered under a Thermo Fisher Scientific Service Contract or warranty.

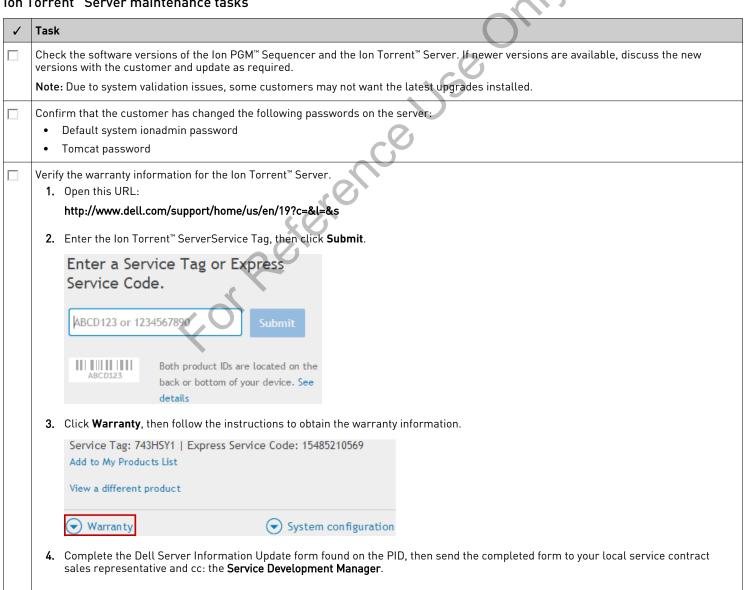
### Service contract verification

1	Task		
	Check the serial number of the Ion PGM™ System, and ensure the system is under contract.		
	The system is on a Service Contract:		
	O Yes O No		
	If there is no Service Contract, a purchase order must be issued for this visit.		
	This service is covered by a purchase order:		
	O Yes O No		
	If applicable, enter the Purchase Order #:		

### Pre-planned maintenance



### Ion Torrent™ Server maintenance tasks



### Ion PGM™ Sequencer maintenance tasks

1	Task			
	Verify gas tank regulator is set to 30 psi.			
	Check all sipper luers and repair as needed.			
	Verify that the waste lines extend from the waste block 0.062" to 0.125". Adjust as needed.			
	Clean touch screen and verify touch screen	calibration using the Screen Cal menu.		
	Clean the fan screen on the back of the Ion	PGM™ Sequencer.		
	Replace the pariposer.			
	Replace the squid port seals.			
	Perform the Pressure Calibration to verify in	nternal regulator. Confirm the pressure is set to 10.5 ±0.5.		
	Verify that you have followed the instructions in Service Bulletin 41.  I have verified that there are no exposed wires sitting on the bottom of the instrument chassis; and if there are exposed wires, I have tied them off per the instructions in Service Bulletin 41. I have informed the Customer of the need for the correct Waste Bottle and given them the ordering information, if needed.			
	FSE signature:			
	Date:			
	Notes:	Jse		
	Ion PGM™ Sequencer v1.0 only: Verify that t information in Service Bulletin 42 to tie dow	he restrictor lines are zip-tied down in the horizontal position. If they are not, use the n properly.		
	Run all Factory tests to verify electronics. Record the values.			
	Video:			
	Touch Screen:			
	Memory:			
	Sensors:			
	Chip Imaging:			
	Perform flow rates for R1, R2, R3, R4, W1, a	nd W3 using the Fluid Cal menu. Adjust as needed. Record the values.		
	R1:			
	R2:			
	R3:			
	R4:			
	W1:			
	W3:			

	Task		
	Perform flow rate test for HSChip, Main, and Chip waste lines using the Fluid Cal menu. Adjust and remove clogs as needed. Record the values.		
	HSChip:		
	Main:		
	Chip:		
	Run the Hard Disk test to verify the to	vo hard drives.	
lon (	OneTouch™ 2 Instrument maint	enance tasks	
1	Task		
	Replace all the O-rings on the reaction	on filter manifold.	
	Check the coolant level in the Liquid	Cooling System. Top off to 3/4 full if needed.	
	Clean the touch screen.		
	Run the Ion OneTouch™ 2 Instrument factory test. Record the results:		
Ion C	)neTouch™ 2 Instrument maintenance	(optional second instrument)	
Note	: If this service does not include plann	ed maintenance for a second Ion OneTouch™ 2 Instrument, skip this section.	
	Replace all the O-rings on the reaction	n filter manifold.	
	Check the coolant level in the Liquid	Cooling System. Top off to 3/4 full if needed.	
	Clean the touch screen.		
	Run the Ion OneTouch™ 2 Instrument	factory test. Record the results:	
	OneTouch™ 2 Instrument maintenance :: If this service does not include plann	(optional third instrument) ed maintenance for a third Ion OneTouch™ 2 Instrument, skip this section.	
	Replace all the O-rings on the reaction	on filter manifold.	
	Check the coolant level in the Liquid	Cooling System. Top off to 3/4 full if needed.	
	Clean the touch screen.		
	Run the Ion OneTouch™ 2 Instrument	factory test. Record the results:	
lon (	OneTouch™ ES maintenance tas	iks	
1	Task		
	Run the Ion OneTouch™ ES residual v	olume test. Record the results:	
	OneTouch™ ES maintenance (optional :: If this service does not include plann	second instrument) ed maintenance for a second Ion OneTouch™ ES, skip this section.	
	Run the Ion OneTouch™ ES residual v	olume test. Record the results:	

✓	Task
lon (	OneTouch™ ES maintenance (optional third instrument)
Note	e: If this service does not include planned maintenance for a third Ion OneTouch™ ES, skip this section.
	Run the Ion OneTouch™ ES residual volume test. Record the results:
Com	pletion
✓	Task
	Update customer contact information.
	Review the Planned Maintenance with the customer, and obtain customer signature.
Con	nments
	SOUTH
App	proval
FSE	Name:
FSE	Signature:
Date	
Cust	Signature: :: :omer Name: :omer Signature: ::
Cust	omer Signature:
Date	

The information in this guide is subject to change without notice.

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