

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



001

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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	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.



001

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

Original Registration Date: 2019-03-28

Effective Date: 2022-01-11

Expiry Date: 2025-01-10



BSI Group America Inc. is an MDSAP authorized auditing organization

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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

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

Latest Revision Date: 2021-12-23

Effective Date: 2022-01-11

Expiry Date: 2025-01-10

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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 assay (analyser)		✓			
6001-872	Tube assay (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 PGM™ System

Planned Maintenance Checklist

Pub. No. 4473624 Rev. C

Planned Maintenance is a procedure designed to protect the operational performance of the Ion PGM™ 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

Ion PGM™ Sequencer Serial Number:

Ion Torrent™ Server Service Tag Number:

Ion OneTouch™ 2 Instrument

Note: The Ion PGM™ System planned maintenance service includes maintenance for **one** Ion OneTouch™ 2 Instrument. If the customer has purchased an add-on service for additional Ion OneTouch™ 2 Instruments, record the instrument serial numbers and the Service Order Number for the add-on service(s). Otherwise, enter "N/A" in the optional fields.

Ion OneTouch™ 2 Instrument Serial Number:

(Optional second instrument) Ion OneTouch™ 2 Instrument Serial Number:

Service Order Number for this add-on service:

(Optional third instrument) Ion OneTouch™ 2 Instrument Serial Number:

Service Order Number for this add-on service:

Ion OneTouch™ ES

Note: The Ion PGM™ System planned maintenance service includes maintenance for **one** Ion OneTouch™ ES. If the customer has purchased an add-on service for additional Ion OneTouch™ ESs, record the instrument serial numbers and the Service Order Number for the add-on service(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™ 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™ 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	O-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

✓	Task
<input type="checkbox"/>	<p>Check the serial number of the Ion PGM™ System, and ensure the system is under contract.</p> <p>The system is on a Service Contract:</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p>If there is no Service Contract, a purchase order must be issued for this visit.</p> <p>This service is covered by a purchase order:</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p>If applicable, enter the Purchase Order #: <input type="text"/></p>

Pre-planned maintenance

✓	Task
<input type="checkbox"/>	Verify that the customer has properly SHUTDOWN the instrument, no reagents remain on the instrument, and all lines are clean and dry.
<input type="checkbox"/>	Review with customer if they have any system concerns. List their concerns in the Comments section below. Note that resolving some customers' concerns may require a separate billable service call.
<input type="checkbox"/>	<p>Verify all required ECOs/updates have been performed. List all ECOs/updates present:</p> <div style="border: 1px solid black; height: 60px; margin-bottom: 10px;"></div> <p>Perform all missing required ECOs/updates. List all ECOs/updates performed:</p> <div style="border: 1px solid black; height: 60px;"></div>

Ion Torrent™ Server maintenance tasks

✓	Task
<input type="checkbox"/>	<p>Check the software versions of the Ion PGM™ Sequencer and the Ion Torrent™ Server. If newer versions are available, discuss the new versions with the customer and update as required.</p> <p>Note: Due to system validation issues, some customers may not want the latest upgrades installed.</p>
<input type="checkbox"/>	<p>Confirm that the customer has changed the following passwords on the server:</p> <ul style="list-style-type: none"> • Default system ionadmin password • Tomcat password
<input type="checkbox"/>	<p>Verify the warranty information for the Ion Torrent™ Server.</p> <ol style="list-style-type: none"> 1. Open this URL: http://www.dell.com/support/home/us/en/19?c=&l=&s 2. Enter the Ion Torrent™ ServerService Tag, then click Submit. <div style="border: 1px solid #ccc; padding: 10px; margin: 10px 0;"> <p>Enter a Service Tag or Express Service Code.</p> <div style="display: flex; align-items: center;"> <input style="border: 1px solid #add8e6; padding: 5px 20px;" type="text" value="ABCD123 or 1234567890"/> <input style="background-color: #4682b4; color: white; padding: 5px 10px; margin-left: 10px;" type="button" value="Submit"/> </div> <div style="display: flex; align-items: center; margin-top: 10px;"> <div> <p>Both product IDs are located on the back or bottom of your device. See details</p> </div> </div> </div> <ol style="list-style-type: none"> 3. Click Warranty, then follow the instructions to obtain the warranty information. <div style="border: 1px solid #ccc; padding: 10px; margin: 10px 0;"> <p>Service Tag: 743HSY1 Express Service Code: 15485210569</p> <p>Add to My Products List</p> <p>View a different product</p> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="border: 2px solid red; padding: 2px;"> Warranty </div> <div> System configuration </div> </div> </div> <ol style="list-style-type: none"> 4. Complete the Dell Server Information Update form found on the PID, then send the completed form to your local service contract sales representative and cc: the Service Development Manager.

Ion PGM™ Sequencer maintenance tasks

✓	Task												
<input type="checkbox"/>	Verify gas tank regulator is set to 30 psi.												
<input type="checkbox"/>	Check all sipper luers and repair as needed.												
<input type="checkbox"/>	Verify that the waste lines extend from the waste block 0.062" to 0.125". Adjust as needed.												
<input type="checkbox"/>	Clean touch screen and verify touch screen calibration using the Screen Cal menu.												
<input type="checkbox"/>	Clean the fan screen on the back of the Ion PGM™ Sequencer.												
<input type="checkbox"/>	Replace the pariposer.												
<input type="checkbox"/>	Replace the squid port seals.												
<input type="checkbox"/>	Perform the Pressure Calibration to verify internal regulator. Confirm the pressure is set to 10.5 ±0.5.												
<input type="checkbox"/>	<p>Verify that you have followed the instructions in Service Bulletin 41.</p> <p>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.</p> <table border="1"> <tr> <td>FSE signature:</td> <td colspan="3"></td> </tr> <tr> <td>Date:</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Notes:</td> <td colspan="3"></td> </tr> </table>	FSE signature:				Date:				Notes:			
FSE signature:													
Date:													
Notes:													
<input type="checkbox"/>	Ion PGM™ Sequencer v1.0 only: Verify that the restrictor lines are zip-tied down in the horizontal position. If they are not, use the information in Service Bulletin 42 to tie down properly.												
<input type="checkbox"/>	<p>Run all Factory tests to verify electronics. Record the values.</p> <table border="1"> <tr> <td>Video:</td> <td></td> </tr> <tr> <td>Touch Screen:</td> <td></td> </tr> <tr> <td>Memory:</td> <td></td> </tr> <tr> <td>Sensors:</td> <td></td> </tr> <tr> <td>Chip Imaging:</td> <td></td> </tr> </table>	Video:		Touch Screen:		Memory:		Sensors:		Chip Imaging:			
Video:													
Touch Screen:													
Memory:													
Sensors:													
Chip Imaging:													
<input type="checkbox"/>	<p>Perform flow rates for R1, R2, R3, R4, W1, and W3 using the Fluid Cal menu. Adjust as needed. Record the values.</p> <table border="1"> <tr> <td>R1:</td> <td></td> </tr> <tr> <td>R2:</td> <td></td> </tr> <tr> <td>R3:</td> <td></td> </tr> <tr> <td>R4:</td> <td></td> </tr> <tr> <td>W1:</td> <td></td> </tr> <tr> <td>W3:</td> <td></td> </tr> </table>	R1:		R2:		R3:		R4:		W1:		W3:	
R1:													
R2:													
R3:													
R4:													
W1:													
W3:													

✓	Task						
<input type="checkbox"/>	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.						
	<table> <tr> <td>HSChip:</td><td><input type="text"/></td></tr> <tr> <td>Main:</td><td><input type="text"/></td></tr> <tr> <td>Chip:</td><td><input type="text"/></td></tr> </table>	HSChip:	<input type="text"/>	Main:	<input type="text"/>	Chip:	<input type="text"/>
HSChip:	<input type="text"/>						
Main:	<input type="text"/>						
Chip:	<input type="text"/>						
<input type="checkbox"/>	Run the Hard Disk test to verify the two hard drives.						

Ion OneTouch™ 2 Instrument maintenance tasks

✓	Task
<input type="checkbox"/>	Replace all the O-rings on the reaction filter manifold.
<input type="checkbox"/>	Check the coolant level in the Liquid Cooling System. Top off to 3/4 full if needed.
<input type="checkbox"/>	Clean the touch screen.
<input type="checkbox"/>	Run the Ion OneTouch™ 2 Instrument factory test. Record the results:
	<input type="text"/>

Ion OneTouch™ 2 Instrument maintenance (optional second instrument)

Note: If this service does not include planned maintenance for a second Ion OneTouch™ 2 Instrument, skip this section.

<input type="checkbox"/>	Replace all the O-rings on the reaction filter manifold.
<input type="checkbox"/>	Check the coolant level in the Liquid Cooling System. Top off to 3/4 full if needed.
<input type="checkbox"/>	Clean the touch screen.
<input type="checkbox"/>	Run the Ion OneTouch™ 2 Instrument factory test. Record the results:
	<input type="text"/>

Ion OneTouch™ 2 Instrument maintenance (optional third instrument)

Note: If this service does not include planned maintenance for a third Ion OneTouch™ 2 Instrument, skip this section.

<input type="checkbox"/>	Replace all the O-rings on the reaction filter manifold.
<input type="checkbox"/>	Check the coolant level in the Liquid Cooling System. Top off to 3/4 full if needed.
<input type="checkbox"/>	Clean the touch screen.
<input type="checkbox"/>	Run the Ion OneTouch™ 2 Instrument factory test. Record the results:
	<input type="text"/>

Ion OneTouch™ ES maintenance tasks

✓	Task
<input type="checkbox"/>	Run the Ion OneTouch™ ES residual volume test. Record the results:
	<input type="text"/>
Ion OneTouch™ ES maintenance (optional second instrument)	
Note: If this service does not include planned maintenance for a second Ion OneTouch™ ES, skip this section.	
<input type="checkbox"/>	Run the Ion OneTouch™ ES residual volume test. Record the results:
	<input type="text"/>

✓	Task
Ion OneTouch™ ES maintenance (optional third instrument)	
Note: If this service does not include planned maintenance for a third Ion OneTouch™ ES, skip this section.	
<input type="checkbox"/>	Run the Ion OneTouch™ ES residual volume test. Record the results: <div style="border: 1px solid black; height: 20px; width: 150px; margin-top: 5px;"></div>

Completion

✓	Task
<input type="checkbox"/>	Update customer contact information.
<input type="checkbox"/>	Review the Planned Maintenance with the customer, and obtain customer signature.

Comments

Approval

FSE Name:

FSE Signature:

Date:

Customer Name:

Customer Signature:

Date:

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

DISCLAIMER

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