Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, Netherlands

has been approved by LRQA to the following standards:

ISO 13485:2016

David Derrick - Area Operations Manager UK & Ireland

Issued By: Lloyd's Register Quality Assurance Limited

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.

Current Issue Date: 22 June 2018
Expiry Date: 21 June 2021
Certificate Identity Number: 10093739
Certificate Approval Number: LRQ 00000428

Original Approvals:

ISO 13485 21 November 2016

Product Approval Number: ISO 13485 – 0016037

The scope of this approval is applicable to:

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

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Certificate Identity Number: 10093739

Location	Activities
Van Rensselaerweg 4, 6956 AV Spankeren, Netherlands	ISO 13485:2016 Design, development, manufacture and distribution of clinical chemistry analyzers and erythrocyte sedimentation rate analyzers and tubes for the in vitro diagnostic investigation of samples of human origin.
Kanaaldijk 90, 6956 AX Spankeren, Netherlands	ISO 13485:2016 Warehousing of parts, finished instruments and erythrocyte sedimentation rate tubes.

UKAS MANAGEMENT SYSTEMS
001

ELITechGroup
BIOMEDICAL SYSTEMS
370 West 1700 South
Logan, Utah 84321 USA
435 752 6011
800 453 3725
fax 435 752 4127
web www.elitechgroup.com

EC DECLARATION OF CONFORMITY

Manufacturer's Name: ELITechGroup Inc.

Manufacturer's Address: 370 West 1700 South
Logan, Utah 84321 USA

European Authorized Representative: ELITechGroup B.V.
Van Rensselaerweg 4
Spankeren, Gelderland, 6956 AV
The Netherlands

Declares, under sole responsibility, that the following items,

Devices: Ion Selective Electrodes

Description: Solid state ion selective electrodes

Item Number	Product Name	Description	GMDN Code	EDMA Code
3918-002	Reference Electrode	Reference Ion Selective Electrode	59241	11 04 04 01
3918-003	Carbon Dioxide (CO2) Electrode	Indicator Ion Selective Electrode	60773	11 04 02 01
3918-004	Sodium (Na) Electrode	Indicator Ion Selective Electrode	52896	11 04 01 07
3918-005	Potassium (K) Electrode	Indicator Ion Selective Electrode	52892	11 04 01 06
3918-006	Chloride (Cl) Electrode	Indicator Ion Selective Electrode	52876	11 04 01 03
3918-007	Bypass Electrode	Circuit Bypass Electrode	N/A	N/A

Conform to the applicable sections and the Essential Requirements of the European Union Council Directive concerning InVitro diagnostic medical devices, IVDD 98/79/EC Annex I and Annex III. These products are not in List A, List B nor Self-Testing and as such meet the characteristics in the category of Other/General. In addition, these items conform to the European Union Council Directive concerning RoHS 2, 2011/65/EC.

These items bear the IVD and CE markings. IVD CE

Manufacturer's signature
Bryce McEuen

European Authorized Representative's Signature
Adriaan Intveld

Dawn Perdue
Director of Quality Assurance / Regulatory Affairs

Date: 15 May 2017

Location: Logan, UT U.S.A

Technical Data Sheet
[ULSTAR-1100HG, High Glossy Grade]

Item	Specification		Evaluation Method
Physical Properties	Material	Polypropylene	
	Thickness	87 ± 5 ㎛	TAPPI T-411
	Product Size	Width 110 ± 0.1 mm Length 18 ± 0.1 m	KS B 5203
	Whiteness	88% Min	ASTM E 313
	Maximum Optical Density (Dmax)	1.70 Min	DIN 16536
	Gloss	90% Min	ASTM D 523
	Basis Weight	62 ± 4 g/㎡	TAPPI T-410
Preservation Abilities	Thermal resistance	90% Min	At 50℃, No Color Change during 1 day (Preservability of Max. Optical Density)
	Humidity Resistance	90% Min	At 40℃, 90%RH, 26 hours (Preservability of Max. Optical Density)
	Sunlight Resistance	90% Min	Below sunlight, 28℃, 50%RH, 1day, (Preservability of Max. Optical Density)

1. The data in this sheet represents average and does not constitute a warranty.
2. All the products shall be stored in a dark, cool and dry place below 30℃ / 60% RH.

EC Declaration of Conformity

Manufacturer: Durico C&T, Inc.
33, Oedap 6-Gil, Sangju-Si
Gyeongsangbuk-Do 37240 Republic of Korea

Phone: +82-2-525-8405
Fax: +82-2-525-7461
E-mail: info@durico.co.kr, http://www.durico.co.kr

European representative: Durico Imaging BVBA
Villastraat 2 C
1830 Machelen, Belgium

Product: Thermal Paper for Video Printer (Super ULSTAR Brand)
Model: ULSTAR-1100HG, ULSTAR-1100HD, ULSTAR-2100HD, ULSTAR-1100HD mibi, ULSTAR-1100HD MATT, ULSTAR-1100S, ULSTAR-1100S mibi, ULSTAR-840HG, ULSTAR-840S

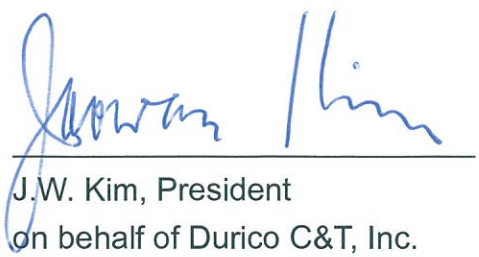
Classification: Class I by the rules of Classification Criteria, Annex IX, MDD 93/42/EEC.

Conformity Assessment Route: Annex VII, MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Place and Date of issue: Korea, May 1, 2019

Signature:



J.W. Kim, President
on behalf of Durico C&T, Inc.

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31701101

Zavet Company Subsidiary

04136, Severo-Syretska St, 3, Kyiv, UKRAINE

ISO 13485:2016

Design, Manufacturing, Sales and Service of Medical Stretchers, Medical Beds, Medical Chairs and Eye Charts

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	11.07.2017
Issue Date	26.12.2019
Expiry Date	25.12.2022
Revision Date/No	26.12.2019 / 5

IAS ACCREDITED Management Systems Certification Body

Deputy General Manager

The certificate inquiry is made by reading QR Code by mobile devices or providing necessary information on http://public.szutest.com.tr.

G-CERTI *Certificate*

hereby certifies that

DURICO C&T INC.

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

has been audited and certified as meeting the requirements & Scope of registration

ISO 9001:2015
Quality Management Systems

Design, Development, Manufacture and Service of Special Paper (Thermal Paper, Ink-jet Paper, Photographic Paper, Mat Sheet)

Certificate No : GK-0233-QC
Valid Period : 22 Jan 2019 ~ 21 Jan 2022
Initial Date : 29 Jan 2010 Issue Date : 17 Jan 2019
Expiry Date : 21 Jan 2022 Code : 07

UIC : MSCB-113-494

Signed for and on behalf of GCERTI
President I.K.Choi

G-CERTI SYSTEM SERVICE
MSCB-113

To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F, Surveillance audits shall be conducted at least once a carlendar year, execpt in recetification years. This is to certify that the Management Systems of this company has been found to confirm to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

IAS ACCREDITED MSCB-113

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

G-CERTI Certificate

G-CERTI hereby certifies that

DURICO C&T INC.

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

Has been audited by G-CERTI and has implemented

Medical Devices-Quality Management Systems

ISO 13485:2016

Scope of Registration

Design, Development, Manufacture and Sevice of Special Paper (Thermal Paper, Ink-Jet Paper, Photographic Paper, Mat Sheet)

Issue Date	**: 30**	**Jun.**	**2017**
Expiry Date	**: 04**	**Jul.**	**2020**
Original Date	**: 05**	**Jul.**	**2014**
Certification No	**: GIS - 0233 - MD**		

Chief Executive

To verify the validity of this certificate please visit : www.gcerti.com
This is to certify that the Management Systems of this company has been found to confirm to the above G-CERTI FI-12-03

ACCREDITED
Management Systems Certification Body
MSCB-113

G-CERTI SYSTEM SERVICE

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0449CM_03_IT

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n.
CERTIFICATE No. **4265/4/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0860CM_02_IT