CERTIFICATE

No. 490115

LL-C Certification

This is to certify that the Quality Management System of Medical Devices of

MEDIZINTECHNIK seit 1890 KaWe

KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstr. 56
71679 Asperg
Germany

has been assessed and found to be in compliance with the standard

ISO 13485:2016

applicable to

Development, production and sales of medical devices for general medicine, otolaryngology, ophthalmology, anesthesiology and dermatology.

The certificate has been issued under No. **490115** for the registration period from 16th February 2018 to 15th February 2021.

Approved by

Printed by

S 3137

validity code: **8EEAA4C4-DD7**
Check the validity of this certificate using this code at **www.ll-c.info**

www.ll-c.net

MEDICA

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity CE

Product Name:	Model/Type:
EasyStat and accessories per attachment	pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct
EasyBloodGas and accessories per attachment	pH/pCO2/pO2

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

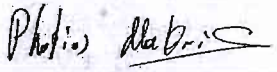
EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:



Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6001	EasyBloodGas Analyzer	21 07 11 01
7001	EasyStat Analyzer	21 07 11 03
7017	EasyStat Analyzer	21 07 11 03
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO2 Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO2 Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 50
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution	11 01 01 27
6402	Red Test Dye Solution	11 30 01 11
6503	EasyBloodGas Capillary Tube Kit	21 07 11 01
6603	EasyBloodGas Demonstration Kit	21 07 11 01
6306	EasyBloodGas Sampler	21 07 11 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 03
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 03
6506	EasyBloodGas Sensor Module	21 07 11 01
6507	EasyBloodGas Valve Module	21 07 11 03
6508	Compression Plate	21 07 11 03
6537	Serial Cable, 9-pin	21 07 11 03
6520	Barcode Reader Kit	21 07 11 03
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyElectrolyte/EasyStat Na Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 07 11 03
7309	Bi-Level Hematocrit Quality Control	11 50 02 90
7603	EasyStat Demonstration Kit	21 07 11 03
7303	EasyBloodGas/EasyStat Capillary Tube Kit	21 07 11 03
7306	EasyStat Sampler	21 07 11 03
7304	EasyStat Pump Tube	21 07 11 03
7506	EasyStat Sensor Module	21 07 11 03
7302	Probe Wipers	21 07 11 03

MEDICA

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity CE

Product Name:	Model/Type:
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH, Na/K/Cl/Ca/Li
EasyElectrolytes and accessories per attachment	EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
~~2113~~	~~EasyLyte Cl- Electrode~~	~~11 04 01 03~~
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
~~2103~~	~~EasyLyte Reference Electrode~~	~~11 04 04 01~~
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenace Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The Design, Development, Manufacture, Service, Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in the diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited CB-MS
OCSM
Accrédité CCN

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sirotenco Sergiu

Of Global Biopharma Group

has completed training for the operation and service of the EasyLyte, EasyBloodGas, and EasyStat analyzers.

November 25 2014

Date

MEDICA

Signed: Randall Rollins
Technical Service Manager

ERMA INC.
Since 1908
2-31-6 Yushima, Bunkyo-ku, Tokyo 113-0034;Japan
Phone:81-3-3818-6281 Fax:81-3-3813-7301
E-mail address:trade@erma.co.jp

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	**Model number**	**Catalog number**
Full Automatic Blood Cell Counter	PCE-210N	01-210-0
Full Automatic Blood Cell Counter	PCE-210	01-210-2
PARTICLE COUNTER	PCE-210N	01-210-3
PARTICLE COUNTER	PCE-210	01-210-4
HEMATOLOGY ANALYZER	PCE-210N	01-210-5
HEMATOLOGY ANALYZER	PCE-210	01-210-6
Fully Automatic Blood Cell Counter	PCE-210	01-210-7

MANUFACTURER		
Name of company	**Address**	**Representative**
ERMA INC.	2-31-6 Yushima, Bunkyo-ku, Tokyo 113-0034, Japan	Yutaka Namiki Technical Manager, International Div.

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone / e-mail**
Emergo Europe	Molenstraat 15 2513 BH, The Hague The Netherlands	+31-70-345-8570 Phone +31-70-346-7229 Fax service@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79 EC Council Directive	Optional

ERMA INC. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices.

COMPANY REPRESENTATIVE: Hiroshi Shimosaka
TITLE: President
DATE: 08/24/2007

SIGNATURE:

ERMA INC. TOKYO JAPAN
Erma
TOKYO
INTERNATIONAL DIV.

EMERGO EUROPE
Quality Assurance & Regulatory Affairs

CE Registration Certificate

This is to certify that, in accordance with the In Vitro Diagnostic Medical Device Directive 98/79/EC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

ERMA Inc.
2-31-6 Yushima, Bunkyo-ku
Tokyo, 113-0034
Japan

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received the In Vitro Diagnostic Medical Device Registrations on the following dates:

21 September 2007
See attached product listing

Emergo Europe Registration Number: NL/CA01/601529

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the In Vitro Diagnostic Medical Devices fulfill the applicable requirements of Directive 98/79/EC.

25 September 2007

Rene van de Zande
President & CEO
Emergo Europe

Emergo Europe: Molenstraat 15, 2513 BH, The Hague, The Netherlands
Telephone: +31.70.345.8570 » Fax: +31.70.346.7299 » Online: EmergoEurope.com

EMERGO EUROPE
Quality Assurance & Regulatory Affairs

Annex A to the Emergo Europe CE Registration Certificate

dated 25 September 2007

IVD Medical Device	EDMS Code	Class Per IVDD 97/79/EC	Registration Date
PCE-210	23 01 10 01	Other (Self-Certify)	21 September 2007
PCE-210N	23 01 10 01	Other (Self-Certify)	21 September 2007

Certificate JP06/040143

The management system of

ERMA INC.

Head Office 2-31-6 Yushima, Bunkyo-ku, Tokyo, 113-0034 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 November 2018 until 16 November 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 16 November 2021
Issue 9. Certified since 16 November 2006

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

ERMA INC.

ISO 13485:2016
EN ISO 13485:2016

Issue 9

Detailed scope

1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers
2. Distribution of in-vitro diagnostic products for hemoglobin measurement

Additional facilities

Yoshikawa Branch 3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan

This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/certified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

Hiroshi Shimosaka
President
ERMA, INC.

Declaration of Conformity

We: **ELITechGroup B.V.**
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

Declare under sole responsibility that the product indicated below (including all spares and accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product	**: Clinical chemistry analyzer**
Product No.	**: 6003-400**
Model	**: Selectra ProM**
GMDN code	**: 56678**

Product classification

As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure

In accordance with Annex III of the IVDD

The product (including all spares and accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL)
- All other member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA), including Switzerland

Spankeren, March 2015

A. Altink

Managing Director

Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Certification by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.	DEKRA
	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

Instrument Training

ELITechGroup VITAL SCIENTIFIC

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

Participant: Mr. A. Legun

Company: Global Biomarketing Group-Moldova SRL Moldova

Instrument: Vitalab: XL Series
E Series
Junior Series
Dry ISE
Micro Series
ProXS

Date of training: April 20th – April 23rd, 2010

System Support Manager:

Jan Oostendorp

System Support Engineer:

Frank v.d. Korput

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.

CSQ
www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9190.CRC3**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA
VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2008

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori
Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2008 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2017-10-13	2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 9001:2015 entro il 2018/09/14;
in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 9001:2015 within 2018/09/14;
otherwise the validity of this certificate will expire

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Omago

Data di scadenza del precedente ciclo di certificazione: 2017-10-07
Data di conclusione dell'audit di rinnovo: 2017-10-11
Data della decisione di rinnovo: 2017-10-13

ACCREDIA

IAF: 07, 09, 19, 29

Organismo di Certificazione Federato CISQ
www.imq.it

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.

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

***CISQ/IMQ** as an IQNet Partner hereby states that the organization*

CERACARTA SPA
VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: **2017 – 10 – 13**
First issued on: **2002 – 11 – 26**
for the validity date, please refer to the original certificate issued by IMQ*

Registration Number: IT – 112265

IQNet

Alex Stoichitoiu
President of IQNET

CISQ

Ing. Claudio Provetti
President of CISQ

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Certification *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland*
Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia*
SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* Vinçotte *Belgium* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document
** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

DECLARATION OF CONFORMITY

Forlì, 19th April 2012

The device named " ECG SUPERGEL" (internal code 10158) has been produced by the company Ceracarta Spa on the basis of the essential requirements,see enclosure I of the directive 93/42/CEE,as prescribed in attachment VII of the above directive.
The writing company Ceracarta located in Via secondo Casadei , 14 Forlì, manufacturer of the product named , " ECG SUPERGEL ", declares under its own responsability that such a device satisfies all the requirements of directive 93/42/CEE as amended by 2007/47/EC , about medical devices and in particular that:

- the Dispositive in object satisfies the essential requirements as in enclosure I of Directive 93/42/CEE;
- the Dispositive in object must be considered as belonging to Class I;
- the Dispositive in object must be esclusively used together with electro-medical instruments for recording, diagnosis and therapy, which base their functioning upon the measuring of energy flows of electric, magnetic and ultrasound type;
- The manufacturer has prepared and keeps the technical files updated in accordance with enclosure VII, section 3 of the directive itself.
- Such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.

CERACCARTA spa
IL PRESIDENTE
Marino Bandini

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.

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 Head, Eunpyeong-gu, Eunpyeong-ro, 88, 15F, Surveillance audits shall be conducted at least once a calendar year, except in recertification years. This is to certify that the Management Systems of this company has been found to conform to the above. If the certified client does not allow surveillance or recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

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