

CERTIFICATE

No. 490115



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



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



validity code: **8EEAA4C4-DD7**

Check the validity of this certificate using this code at www.ll-c.info

www.ll-c.net

LL-C (Certification) Czech Republic s.r.o. | Pobřežní 620/3, 186 00 Praha 8



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

Declaration of Conformity

Product Name:

Model/Type:

EasyStat and accessories per attachment

pH/pCO₂/pO₂/Na/K/Cal/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

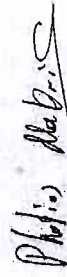
 Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

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 pCO ₂ Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO ₂ 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 01 01 27
2118	Daily Cleaning Solution	11 30 01 11
6402	Red Test Dye Solution	21 07 11 01
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 Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel: 781 275 4892
Fax: 781 275 2731
www.mediacorp.com

Declaration of Conformity

Product Name:

EasyLyte and accessories per attachment

Model/Type:

EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li,
Na/K/Ca/pH, Na/K/Cl/Ca/Li
EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

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

Representative

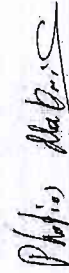
 Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

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
2193	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 Solutions 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 Solutions 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				EasyElectrolytes Accessories	
Catalog No.	Accessory	EDMA Code	Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02	4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02	4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90	4102	Reagent Module, Na/K/Cl	11 04 04 02
2309	EasyLyte Wash Solution (50mL)	11 04 04 90	4103	Reagent Module, Na/K/Li	11 04 04 02
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90	7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90	4203	EasyElectrolyte Cl- Electrode	11 04 01 06
2323	EasyLyte Probe Wipers (6)	21 07 11 02	4204	EasyElectrolyte Li+ Electrode	11 04 01 03
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02	6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 01 04
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02	4207	EasyElectrolyte Spacer Electrode	11 04 04 01
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02	4301	EasyElectrolyte Troubleshooting Kit	11 04 01 90
10745	Anti-Evaporation Caps (500)	21 07 11 02	2118	Daily Cleaning Solution Kit	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02	4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 01 01 27
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02	4403	EasyElectrolyte Urine Diluent	11 30 01 11
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02	2814	Bi-Level Quality Control Kit	11 04 04 90
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11	2815	Tri-Level Quality Control Kit	11 50 02 04
2572	EasyLyte Troubleshooting Kit	21 07 11 02	4405	EasyElectrolyte Na/K/Cl Demonstration Kit	11 50 02 04
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02	4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02	4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
2095	EasyLyte Maintenance Kit	21 07 11 02	4306	EasyElectrolyte Sampler	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02	6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02	6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27	4506	EasyElectrolyte Sensor Module	21 07 11 02
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02	4507	EasyElectrolyte Valve Module	21 07 11 02
2934	EasyLyte Barcode Reader Kit	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

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



A handwritten signature in black ink, appearing to read 'Calin Moldoveanu'.

Calin Moldoveanu

President

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



EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sergiu Jergiu
Of Global Biotechnology Group

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

MEDICA



November 25, 2014

Date

Randall Rollins

Signed: Randall Rollins
Technical Service Manager



**ERMA INC.**

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:





Annex A to the Emergo Europe CE Registration Certificate

dated 25 September 2007

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 Emurgo 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

[illegible]



Certificate JP06/040143

The management system of

ERMA INC.

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



ISO 13485:2016
EN ISO 13485:2016

has been assessed and certified as meeting the requirements of

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.

Authorized by

SGS United Kingdom Ltd
Rosemere Business Park, Epsom, Surrey, Surrey, UK
1-44 (0)151 350-6666 f-44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 N2

Page 1 of 2



0005



Certificate JP06/040143, continued

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



0005



The information issued by the Company subject to the Terms and Conditions of the Certification Scheme accessible at www.sgs.com/terms and www.sgs.com/certification is subject to the limitations of liability, indemnification and jurisdiction set out in the Terms and Conditions of the Certification Scheme. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and constitutes a criminal offence under the laws of the United Kingdom and other countries.

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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

H. Shimosaka

Hiroshi Shimosaka

President

ERMA, INC.



We: **ELTechGroup 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

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	
	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	
EMC	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	DEKRA
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

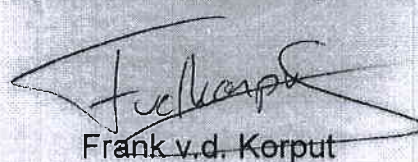
Date of training: April 20th – April 23rd, 2010

System Support Manager:



Jan Oostendorp

System Support Engineer:



Frank v.d. Korput



www.imq.it

CERTIFICATO N. 9190.CRC3 CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY
CERACARTA SPA
VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLÌ (FC)
UNITÀ OPERATIVE / OPERATIVE UNITS

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

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

ISO 9001:2008

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietti 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 elettrodi 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. Production and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electrodiagnostic and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electrodiagnostic devices and for electrodiagnostic equipment. Development and manufacture of electrodes for ECG. Production management and placing on the market of electrodes for ECG. Placing on the market of electrodiagnostic 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 THE 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

[Signature]

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

Data di scadenza del precedente ciclo di certificazione: 2017-10-07
Data della decisione di rinnovo: 2017-10-11



ISO 9001, ISO 9004, ISO 14001, ISO 19011, ISO 26000, ISO 27001, ISO 27002, ISO 27005, ISO 27006, ISO 27007, ISO 27008, ISO 27009, ISO 27010, ISO 27011, ISO 27012, ISO 27013, ISO 27014, ISO 27015, ISO 27016, ISO 27017, ISO 27018, ISO 27019, ISO 27020, ISO 27021, ISO 27022, ISO 27023, ISO 27024, ISO 27025, ISO 27026, ISO 27027, ISO 27028, ISO 27029, ISO 27030, ISO 27031, ISO 27032, ISO 27033, ISO 27034, ISO 27035, ISO 27036, ISO 27037, ISO 27038, ISO 27039, ISO 27040, ISO 27041, ISO 27042, ISO 27043, ISO 27044, ISO 27045, ISO 27046, ISO 27047, ISO 27048, ISO 27049, ISO 27050, ISO 27051, ISO 27052, ISO 27053, ISO 27054, ISO 27055, ISO 27056, ISO 27057, ISO 27058, ISO 27059, ISO 27060, ISO 27061, ISO 27062, ISO 27063, ISO 27064, ISO 27065, ISO 27066, ISO 27067, ISO 27068, ISO 27069, ISO 27070, ISO 27071, ISO 27072, ISO 27073, ISO 27074, ISO 27075, ISO 27076, ISO 27077, ISO 27078, ISO 27079, ISO 27080, ISO 27081, ISO 27082, ISO 27083, ISO 27084, ISO 27085, ISO 27086, ISO 27087, ISO 27088, 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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 responsibility 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 exclusively 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.

CERACARTA 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

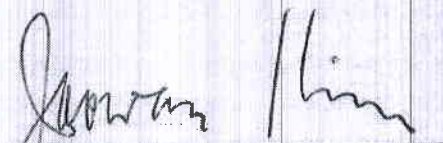
Classification: Class I by the rules of Classification Criteria, Annex IX, MDD 93/42/EEC.

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

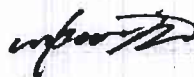
Valid Period : 22 Jan 2019 ~ 21 Jan 2022

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



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 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, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.



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 Service 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 conform to the above G-CERTI FI-12-03

