

# EAR-CERTIFICATE

(RECITAL 29 OF THE DIRECTIVE 98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES)

**DATE OF ISSUANCE:** 09/09/09

**CERTIFICATE NR:** CO 12416

**MANUFACTURER:** JS Medicina Electrónica SRL  
Bolivia 462 (B1603CFJ) Villa  
Martelli Vicente López  
Buenos Aires, Argentina.

**FACILITIES:** JS Medicina Electrónica SRL  
Bolivia 462 (B1603CFJ) Villa  
Martelli Vicente López  
Buenos Aires, Argentina.

**PRODUCT CATEGORY(IES)** IVD 98/79/EC  
Electrolyte Analyzer Diestro 103 AP & Accessories

**MODEL(S):** See attached annex (1)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with IVD 98/79/EC on 9th September 2009.\*



G. ELKAYAM  
C.E.O.

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Brussels Enterprise  
Commerce & Industry

date & stamp

**SEEN**

by the Brussels Chamber of Commerce

Christine BARTHELEMY

Brussels, the 06 NOV. 2009

\*According to the terms and conditions set out in the agreement signed between Obelis European Authorized Representative Center (O.E.A.R.C) and JS Medicina Electrónica SRL.



Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.) and ISO 9001-2008 certified in accordance to the profession of a European Authorized Representative.



**Annex I: Product List and Part Number**

<b>Instruments and Consumables</b>	
<b>Description</b>	<b>Ref</b>
<b>Diestro Electrolyte Analyzer 103AP V4</b>	<b>EQ 0740 to EQ 0779</b>
<b>ISE Calibrating Kit</b>	<b>IN 0200</b>
<b>ISE Calibrating Pack</b>	<b>IN 0100</b>
<b>Reference Electrode</b>	<b>EL 0001D</b>
<b>Sodium Electrode</b>	<b>EL 0002D</b>
<b>Potassium Electrode</b>	<b>EL 0003D</b>
<b>Chloride Electrode</b>	<b>EL 0004D</b>
<b>Calcium Electrode</b>	<b>EL 0005D</b>
<b>Lithium Electrode</b>	<b>EL 0006D</b>
<b>Sample detector Electrode</b>	<b>EL 0007D</b>
<b>Fill port cleaner</b>	<b>IN 0050</b>
<b>Peristaltic pump tubing</b>	<b>RE 0100</b>
<b>Spare tubing kit</b>	<b>RE 0300</b>
<b>Urine Diluent</b>	<b>IN 0300</b>
<b>Na Conditioner</b>	<b>IN 0600</b>
<b>Diestro Trilevel</b>	<b>IN 0750</b>
<b>Diestro Control</b>	<b>IN 0700</b>

Vertimas tikras  
Martynas Adomaitis  
2018-07-19



**Obelis**

*Europos įgaliotasis atstovavimo centras*

## EAR-SERTIFIKATAS

(Skirtas CE 98/79 direktyvos 29 daliai, In-vitro diagnostikos medicininiam prietaisams)

Išdavimo data: 09/09/09

Sertifikato nr. CO 12416

GAMINTOJAS: JS medicina Electronica SRL, Bolivia 462 (B1603CFJ) Vila Martelli Vicente Lopez, Buenos Aires, Argentina

VEIKLA VYKDOMA: JS medicina Electronica SRL, Bolivia 462 (B1603CFJ) Vila Martelli Vicente Lopez, Buenos Aires, Argentina

PRODUKTO KATEGORIJA (OS): IVD 9/79/EC, Elektrolitų analizatorius Diestro 103AP ir priedai

MODELIAI: Žr. Priedą

Europos įgaliotasis atstovavimo centras Obelis s.a. deklaruoja, kad aukščiau paminėtas gamintojas įvykdė esminius reikavimus keliamus Europos įgaliotojo atstovo, laikantis IVD 98/79/EC, 2009 metų rugsėjo 9d.

*Parašas/atspaudas*

Bruselio įmonių komercija *Atspaudai/parašai*

Pagal sąlygas nurodytas susitarime pasirašytame tarp Europos įgaliotasis atstovavimo centro Obelis ir JS Medicina Electronica SRL

Europos įgaliotasis atstovavimo centras Obelis yra Europos įgaliotųjų atstovų asociacijos narys (E.A.A.R.I ir ISO 9001-2008 sertifikuotas šiam Europos įgaliotojo atstovo darbui)

Korporacijos būstinė Bd. General Wahis 53-1030, Briuselis, registruota būstinė Av. De Tervueren 34 B44 – 1040 Briuselis – Belgija, T: +32 (0) 2 732 5954, F: 32 (0) 2 732 6003, El. paštas: mail@obelis.net

Priedas nr.1.

Prietaisai ir susijusios prekės

Description	Ref
<b>Diestro Electrolyte Analyzer 103AP V4</b>	<b>EQ 0740 to EQ 0779</b>
<b>ISE Calibrating Kit</b>	<b>IN 0200</b>
<b>ISE Calibrating Pack</b>	<b>IN 0100</b>
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<b>Urine Diluent</b>	<b>IN 0300</b>
<b>Na Conditioner</b>	<b>IN 0600</b>
<b>Diestro Trilevel</b>	<b>IN 0750</b>
<b>Diestro Control</b>	<b>IN 0700</b>