Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

JS Medicina Electrónica SRL, Bolivia 460, 1603 Buenos Aires, Argentina

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

No.	Cataloque reference number	Commercial name	Generic Device Term	Class**
1	EQ 0720 to EQ 0860	DIESTRO Electrolyte Analyzer	Electrolyte Analyzer	All Others
2	EL 0001D	DIESTRO ISE Reference Digital Electrode	Electrode	All Others
3	EL 0002D	DIESTRO ISE Sodium Digital Electrode	Electrode	All Others
4	EL 0003D	DIESTRO ISE Potassium Digital Electrode	Electrode	All Others
5	EL 0004D	DIESTRO ISE Chloride Digital Electrode	Electrode	All Others
6	EL 0005D	DIESTRO ISE Calcium Digital Electrode	Electrode	All Others
7	EL 0006D	DIESTRO ISE Lithium Digital Electrode	Electrode	All Others
8	EL 0007D	DIESTRO ISE Digital Sample Detector	Sample Detector	All Others
9	EL 0008D	DIESTRO ISE pH DIESTRO Digital Electrode	Electrode	All Others
10	EL 0009D	DIESTRO ISE Bicarbonate Digital Electrode	Electrode	All Others
11	EL 0010D	DIESTRO ISE Magnesium Digital Electrode	Electrode	All Others
12	IN 0050	DIESTRO Fill Port Cleaner	Port Cleaner	All Others

13	SMP	DIESTRO Autosampler	Autosampler	All Others
14	IN 0102 to 0110 IN	DIESTRO ISE Calibrating Pack	Calibrating Pack	All Others
15	IN 0200 to 0205 IN	DIESTRO ISE Calibrating Kit	Calibrating Kit	All Others
16	RE 0319 to 0335 RE	DIESTRO Spare Tubing Kit	Tubing Kit	All Others
17	RE 0305 to 0315 RE	DIESTRO Pack Connection Tubing Kit	Pack Connection Tubing Kit	All Others
18	RE 0350 to 0352 RE	DIESTRO Fill Port	Fill Port	All Others

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

ISO 13485:2003, ISO 9001:2008

Corporate Contact Information

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RESPONSIBLE PERSON'S name: Pharmacist Marcelo Miranda
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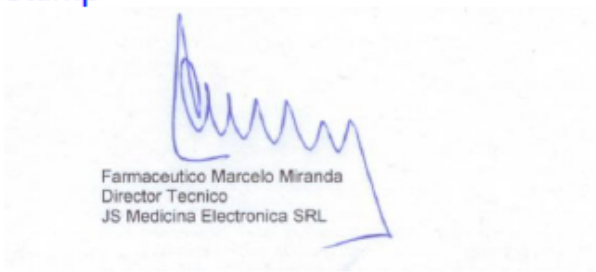
SIGNATURE :
Date: April 5, 2017
Stamp



Signatory established within the EU who has been empowered to enter into commitments on our behalf:

European Authorized Representative (E.A.R.)
Obelis S.A.

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Date : 24/5/2017
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