

DECLARATION OF CONFORMITY

Application of Council Directive(s)

98/79/EC 2003/108/EC 2004/108/EC 2006/95/EC 2011/65/EU

| Essential Safety, Emissions, and Immunity Standard(s) to which Conformity is Declared | Model | Product Description | CE Mark Affixed |
|---|------------------|---------------------|-----------------|
| EN61010-1: 2001 (2nd ed.) EN 61010-2-081: 2001 + A1: 2003 EN61010-2-101: 2002 EN61326-1: 2006 & EN61326-2-6: 2006 EN 55011: 2009 + A1: 2010, Group 1, Class B | A ₂ O | Osmometer | 2012 |

Manufacturer's Name: Advanced Instruments Inc.

Manufacturer's Address: Two Technology Way
Norwood, MA 02062 USA

Type of Device: Laboratory Equipment

Device Classification: General IVD, Self-Certification per 98/79/EC Annex III without Article 6

Model: _____

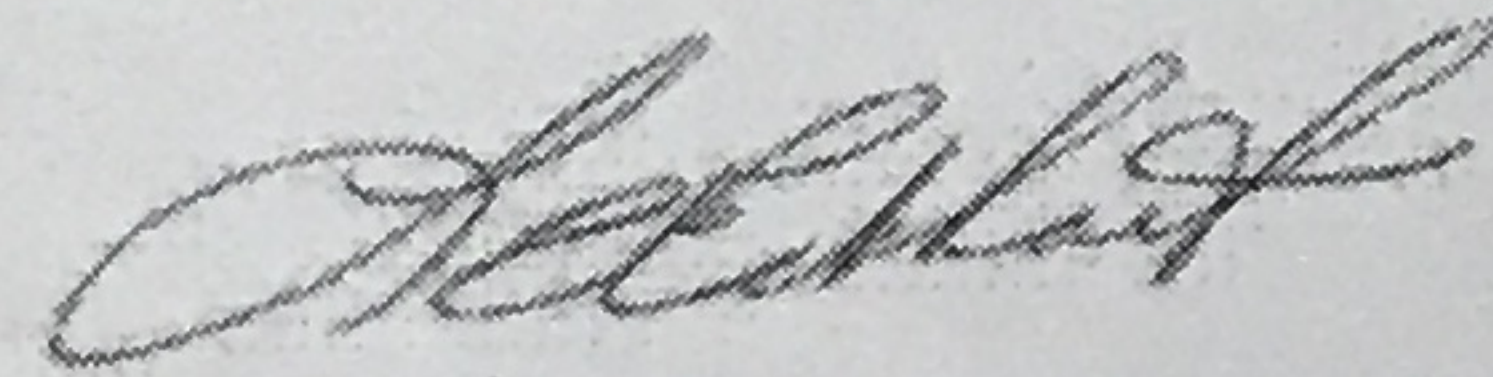
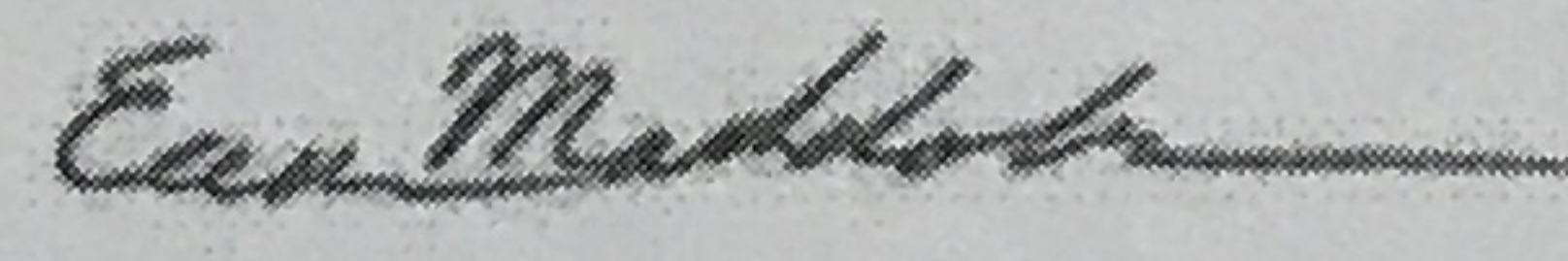
Serial Number: _____

Year of Manufacture: _____

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Manufacturers Representatives

Authorized Representative in the European Union

| | | |
|--|--|---|
|  _____ (Signature) <u>Lee Eckhart, V.P. of Operations</u> (Full Name, Position) <u>Advanced Instruments Inc.</u> (Company) <u>Two Technology Way</u> (Address 1) <u>Norwood MA, 02062 USA</u> (Address 2) <u>+US (781) 320-9000</u> (Telephone) |  _____ (Signature) <u>Evan Maddocks, Quality Manager</u> (Full Name, Position) <u>Advanced Instruments Inc.</u> (Company) <u>Two Technology Way</u> (Address 1) <u>Norwood MA, 02062 USA</u> (Address 2) <u>+US (781) 320-9000</u> (Telephone) | <u>Winckels Medical Devices Expertise</u> (Company) <u>Bergerweg 18</u> (Address 1) <u>6085 AT Horn</u> (Address 2) <u>The Netherlands</u> (Address 3) _____ (Address 4) <u>31-(0)475-58 22 85</u> (Telephone) |
|--|--|---|

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LORI MANNING
Notary Public
 COMMONWEALTH OF MASSACHUSETTS
 My Commission Expires
 November 27, 2020

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DECLARATION OF CONFORMITY

Application of Council Directive(s)

2014/35/EU 2014/30/EU 93/68/EEC 98/79/EC 2012/19/EU 2011/65/EU

| Essential Safety, Emissions, and Immunity Standard(s) to which Conformity is Declared | Models Covered By These Standards | |
|--|---|---------------------|
| | ADVANCED INSTRUMENTS MODELS | PRODUCT DESCRIPTION |
| EN61010-1: 2001, Part 1, 2 nd Edition EN61010-2-101: 2002, Part 2-101 EN61326-1: 2006, Group 1, Class B | 2020, 20G700*, 2020-BIO* 3250, 3320 * = Does Not Include 98/79/EC | Osmometer |
| | FISKE ASSOCIATES MODELS | PRODUCT DESCRIPTION |
| EN61010-1: Part 1, 2 nd Edition EN61010-2-101: 2002, Part 2-101 EN61326-1: 2012, Group 1, Class A | 210 | Osmometer |

Manufacturer's Name Advanced Instruments Inc.

Brand Name (SEE TABLE ABOVE)

Manufacturer's Address Two Technology Way
Norwood, MA 02062 USA

Type of Device Laboratory Equipment

Device Classification General IVD, Self-Certification per 98/79/EC Annex III without Article 6

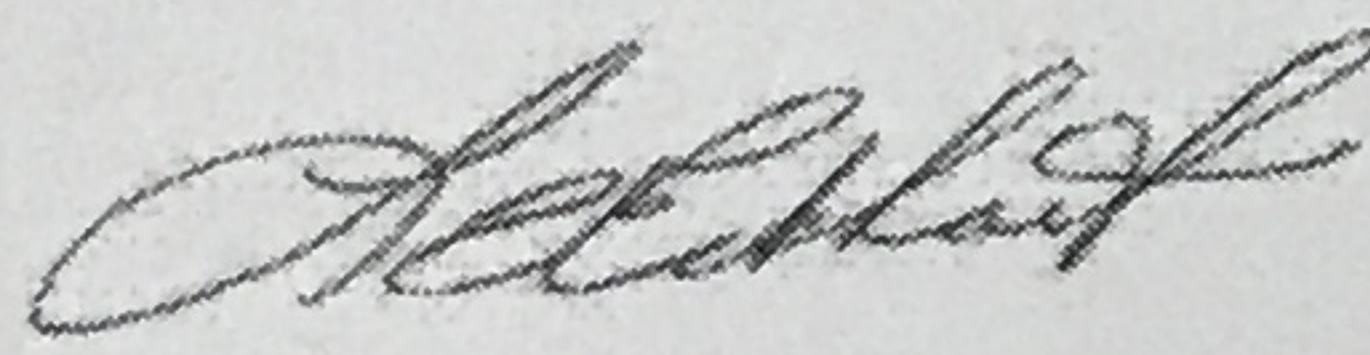
Model _____

Serial Number _____ Year of Manufacture _____

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(Signature)

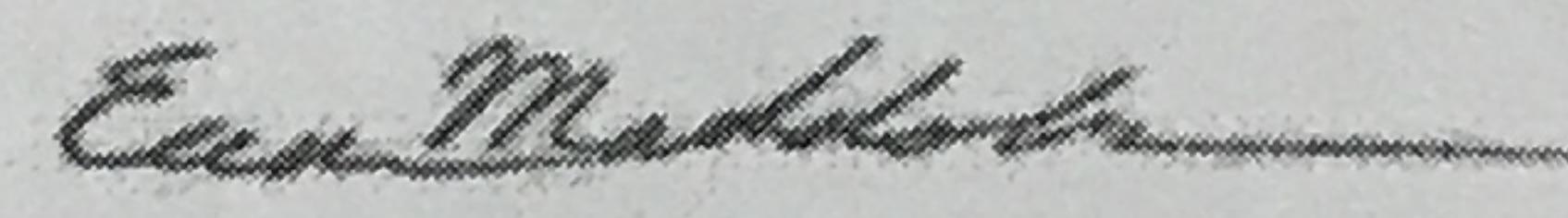
Lee Eckhart, V.P. of Operations
(Full Name, Position)

Advanced Instruments Inc.
(Company)

Two Technology Way
(Address 1)

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+US (781) 320-9000
(Telephone)



(Signature)

Evan Maddocks, Quality Manager
(Full Name, Position)

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