EC DECLARATION OF CONFORMITY

In accordance with the In-vitro Diagnostics Medical Devices Directive 98/79/EC

We: Aurora Photonics Inc.
of: 6019 Fincham Drive
Rockford
Ilinois 61108 USA

Declare under our sole responsibility that the following In Vitro Diagnostics Medical Device:

Product Group	Product Name	Product Code(s)	EDMS Code
ZENIT•AMiDot	PortArray® Fluorometer	50-0100-5030/ 45010	21.02.10.01

and the AMiDot processing software meet the provisions of the Directive 98/79/EC. The device is designed to be run exclusively with the ZENIT•AMiDot Product line (slides and reagents) and AMiDot processing software, which, in turn, are designed for exclusive use with the devices, thus forming a closed system.

Classification: Device not included in Annex II
Conformity assessment route: Annex III applied

Standards applied:
BS EN ISO 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
BS EN ISO 13485:2003 Medical devices. Quality management systems. Requirements for regulatory purposes.
BS EN ISO 18113-2:2009 In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use.
IEC EN6101 0-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements.
IEC EN61010-2-010:2005 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.
IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility.

Testing bodies:

QPS Evaluation Services
81 Kelfield St., Unit 7/8/9
Toronto, Ontario, M9W 5A3
Canada

H.B.Compliance Solutions, LLC
5005 S.Ash Avenue, Suite # A-10
Tempe, AZ-85282

The technical documentation file is maintained by: Aurora Photonics Inc.
Name and address of Authorised Representative for the EU:
Cambridge Life Sciences Ltd.
14 St. Thomas' Place
Cambridgeshire Business Park
Ely
Cambridgeshire CB7 4EX, UK

Signed on behalf of the Manufacturer:

Dennis Dougherty (Vice President)

May 14 2013 USA
Date, place

May 14, 2013 (B)

Aurora Photonics Inc.
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