

DECLARATION OF CONFORMITY

Manufacturer: ALCOR Scientific Incorporated
20 Thurber Boulevard
Smithfield, RI 02917, USA
Telephone 001 401 737 3774

Device Name: iSED®, Erythrocyte Sedimentation Rate Analyzer

Item Number: 112-00101

Device Class: General IVD: Self-Certified

Consumables: iWASH™, (112-12-001)
Waste Containers, (112-12-002)
Seditrol®, (DSC06)
Test Card, (112-00250, 112-00500, 112-01000, 112-02000,
112-05000, 112-10000, 112-20000, 112-40000)

The undersigned hereby declares, on behalf of the ALCOR Scientific Incorporated, that the above-referenced products are manufactured in accordance with the referenced Directive and complies with the Standards listed:

Directive 98/79/EC Annex III	
IEC 61010-1:2010	Safety requirements for electrical equipment for measure, control and laboratory use
EN 61326-1:2006	Electrical equipment for measure, control and laboratory use
	EMC requirements- Part 1: General Requirements
EN 61000-3-2	Harmonics
EN 61000-3	Flicker
EN 61000-4-2	Electrostatic Discharge
EN 61000-4-3	Radiated Immunity
EN 61000-4-4	Electrical Fast Transient Burst
EN 61000-4-5	Surge Immunity
EN 61000-4-6	Conducted Immunity
EN 61000-4-11	Immunity to Voltage Dips and Drops

All supporting documentation is maintained at:

ALCOR Scientific Incorporated, 20 Thurber Boulevard, Smithfield, RI, 02917, USA

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Date of Issue: 20 September 2014
Place of Issue: Smithfield, RI, USA
Authorized by: *[Signature]*
Name: Ivy E. Pappas
Title: Director of Quality Assurance and Regulatory Affairs



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