

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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Authorized by: 
Name: Ivy E. Pappas
Title: Director of Quality Assurance and Regulatory Affairs



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