

Manufacturer	ALCOR Scientific Incorporated 20 Thurber Boulevard Smithfield, RI 02917, USA Telephone 001 401 737 3774
Device Name:	iSED®, Erythrocyte Sedimentation Rate Analyzer
Item (Catalog) Number:	112-00101
Device Class:	General (Other) IVD: Self-Certified
GMDN:	56691 (Automated ESR Analyzer)
Consumables:	IWASH™ (112-12-001) Waste Containers (112-12-002) Seditrol® (DSC01, DSC04, DSC06, 315-00102, 315-00106) Test Cards (112-00250, 112-00500, 112-01000, 112-02000, 112-05000, 112-10000, 112-20000, 112-40000)
Notified Body:	National Standard Authority of Ireland (NSAI) No. 0050 1 Swift Square, Northwood, Santry, Dublin 9, Ireland D09 A0E4 Tel: +353 1 807 3800
EU Authorized Representative:	Emergo Europe Prinsessegracht 20, 2514 AP The Hague, The Netherlands Tel: (31) (0) 70 345-8570, Fax: (31) (0) 70 346-7299
Applicable Standards:	IVD Directive, Annex III Restriction of Hazardous Substances in Electrical & Electronic Eq (RoHS 2) 3 rd Edition, Safety requirements for electrical equipment for measure, control and laboratory use Safety Requirement for electrical Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes Particular requirements for in vitro diagnostic (IVD) medical equipment Electrical equipment for measure, control and laboratory use EMC requirements- Part 1: General Requirements Harmonics Flicker Electrostatic Discharge Radiated Immunity Electrical Fast Transient Burst Surge Immunity Conducted Immunity Immunity to Voltage Dips and Drops

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. All supporting documentation is maintained at ALCOR Scientific Incorporated.

Authorized By: *J.*

Company Representative Name: G. Scott Van Alst
 Title: Management Representative
 Date of Issue: 31 July 2020
 Place of Issue: Smithfield, RI USA

