DECLARATION OF CONFORMITY

Cert. No. 222-00-002, Rev. 5

Manufacturer	ALCOR Scientific LLC 20 Thurber Boulevard Smithfield, RI 02917, USA Telephone 001 401 737 3774
SRN	US-MF-000029295
Device Family Name:	iSED®, Erythrocyte Sedimentation Rate Analyzer
Device Name (Model):	iSED ESR Analyzer
Catalog Number / Basic UDI-DI:	112-00101 (for analyzers > SN 05000) / 0896406002iSED2Elite5D
Intended Use:	iSED®/iSED ELITE Automated Erythrocyte Sedimentation Rate Analyzer is an automated in vitro diagnostic (IVD) device for the determination of an erythrocyte sedimentation rate (ESR) expressed in mm/hr. Testing is performed using EDTA whole blood samples obtained by venipuncture or capillary blood collection. The analyzer is intended to be used in a professional clinical laboratory setting. The analyzer directly measures the aggregation of red blood cells by photometric rheology technology which does not require the use of reagents. Results are reported in units of mm/hr. and correlate with the Westergren method of ESR determination. The quantitative results for sedimentation rate produced by the analyzer are considered non-specific and are used by a clinician to aid in assessing the general health status of a patient. Results from the device are to be used in conjunction with other laboratory results and with the patient condition known by the ordering clinician.
Device Class (Rule):	IVDR Class A per Rule 5b
EMDN:	W02029001 (Erythrocyte Sedimentation Rate Devices)
GMDN:	56691 (Automated ESR Analyzer)
Accessories:	iWASH™ (112-12-001), GMDN = 59058, EMDN = V0799 iWaste Containers (112-12-002, 112-12-005), GMDN = 62172, EMDN = W050301029099 Seditrol® (DSC01, DSC06), GMDN = 55972, EMDN = W0103010599 EQC02 (EQC02), GMDN = 55972, EMDN = W0103010599 Test Cards (112-00250, 112-00500, 112-01000, 112-02000), GMDN = 62804, EMDN =N/A Test Cards (112-03000, 112-05000, 112-10000, 112-20000), GMDN = 62804, EMDN =N/A Thermal Printer Paper (DS-05233), GMDN = 65796, EMDN = N/A deepCLEAN (112-12-020), GMDN = 59058, EMDN = WO599
Notified Body:	Not Applicable
EU Authorized Representative:	Emergo Europe (EUDAMED Actor ID/SRN: NL-AR-000000116) Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands Tel: (31) (0) 70 345-8570
CH Authorized Representative:	MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug, Switzerland Tel: (41) 41 562 01 42

Applicable Standards:

EN ISO 13485: 2016 w/ MDSAP	Quality Management System	EN 61000-3-2	Harmonics
EU 2017/746	*In Vitro* Diagnostics Regulation (IVDR) 2017/746	EN 61000-3-3	Flicker
EN ISO 14971:2019	Application of risk management to medical devices	EN 61000-4-2:2009	Electrostatic Discharge
2011/65/EU	Restriction of Hazardous Substances in Electrical & Electronic Eq (RoHS 2)	EN 61000-4-3:2006 /A1/A2	Radiated Immunity
IEC 62304:2006 + AMD1: 2015	Medical Device Software and Life Cycle Processes	EN 61000-4-4:2012	Electrical Fast Transient Burst
IEC 61010-1:2010 EN 61010-1:2020	Safety requirements for electrical equipment for measure, control and laboratory use - General Requirements	EN 61000-4-5:2014/ A1:2017	Surge immunity
EN 55011:2016	Industrial, Scientific and Medical Equipment – Radio-frequency Disturbance Characteristics (FCC Part 15, CISPR 11, ICES-003)	EN 61000-4-6:2014	Conducted immunity
EN 61010-2-101:2017	Safety Requirement for electrical equipment for measurement, control, and laboratory use for in vitro diagnostic (IVD) medical equipment	EN 61000-4-8:2010	Magnetic field immunity
EN 61326-2-6:2021	Electrical Equipment for Measurement, Control, and Laboratory Use, EMC Requirements: Part 1 & IVD Equipment	EN 61000-4-11:2020	Immunity to Voltage Dips and Drops
ISTA 2A	Partial Simulation Performance Tests – Atmospheric preconditioning, Atmospheric Conditioning, Compression, Random vibration, Drop Shock, Fixed Displacement Vibration		

The undersigned hereby declares, on behalf of ALCOR Scientific, that the above-referenced products are manufactured in accordance with the referenced Directives and comply with the Standards listed. All supporting documentation is maintained at ALCOR Scientific.

Authorized By: G. Scott VanAlst
Title: PRRC, Director of QA and RA
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Place of Issue: Smithfield, RI USA