DECLARATION OF CONFORMITY

Cert. No. 1017-00-002, 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:	miniiSED®, Erythrocyte Sedimentation Rate Analyzer
Device (Model) Name	miniiSED ESR Analyzer
Catalog Number / Basic UDI-DI:	112-01017 / 0896406002miniiSEDSD
Intended Use / Purpose	miniiSED® 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:	IVDR Class A per Rule 5b
EMDN:	W02029001 (Erythrocyte Sedimentation Rate Devices)
GMDN:	56691 (Automated ESR Analyzer)
Accessories:	miniiWASH™ (112-12-003), GMDN = 59058, EMDN = V0799 miniiWASTE™ (112-12-004), 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), GMDN = 62804, EMDN = N/A Test Cards (112-02000, 112-03000, 112-05000), GMDN = 62804, EMDN = N/A Test Cards (112-10000, 112-20000), GMDN = 62804, EMDN = N/A Printer (DS-05240), GMDN = 63034, 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 IEC 61010-1:2010 / AMD1:2016 UL 61010-1:2012 / R:2015-07 / R:2016-04 EN 61010-1:2010 / A1:2019	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
IEC 61010-2-101:2015 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 61326-2-6:2013	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: Director, Quality and Regulatory Affairs
Date of Issue: 28 March 2025 Expiry Date: 28 March 2027
Place of Issue: Smithfield, RI USA

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Approved By:

(CO-3924) IFU and Label changes related to recent Emergo review

Description

IFUs for the consumable items (Wash, Waste, Test Cards) added statement regarding where to call if a serious incident were to occur. Add new IFU for iSED PRO Test Cards, a DofC for SEDiTROL, update EQC IFU.

Justification

Responding to regulatory request from Emergo.

Assigned To:	Initiated By:	Priority:	Impact:
Scott VanAlst	Belinda Fralick	Medium	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Scott VanAlst	May 14, 2025 3:18 PM EDT	CO-3924	5	Published
Scott VanAlst	February 7, 2025 9:12 AM EST	CO-3913	4	Superseded
Scott VanAlst	August 14, 2024 9:16 AM EDT	CO-3762	3	Superseded
Scott VanAlst	July 16, 2024 9:15 AM EDT	CO-3667	2	Superseded
Scott VanAlst	October 26, 2023 11:31 AM EDT	CO-3526	1	Superseded
Scott VanAlst	August 30, 2023 2:34 PM EDT	CO-3474	0	Superseded