DECLARATION OF CONFORMITY

Cert. No. 120-00-002, Rev. 2

Manufacturer	ALCOR Scientific LLC 20 Thurber Boulevard Smithfield, RI 02917, USA Telephone 001 401 737 3774
SRN	US-MF-000029295
Device Family Name:	iSED PRO Fully Automated Erythrocyte Sedimentation Rate Analyzer
Device Trade Name (Model)	iSED PRO Series S
Catalog Number / Basic UDI-DI:	112-00120-SYS / 0850028040iSEDPROLT
Intended Use:	iSED PRO Fully 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 PRO (112-12-006), GMDN = 59058, EMDN = V0799 iWaste PRO Containers (112-12-009), GMDN = 62172, EMDN = W050301029099 deepCLEAN® PRO (112-12-022), GMDN = 59058, EMDN = WO599 SEDiTROL® (DSC01, DSC06), GMDN = 55972, EMDN = W0103010599 External QC (EQC02), GMDN = 55972, EMDN = W0103010599 iSED® PRO Test Cards (120-04000, 120-07500, 120-12500, 120-25000, 120-50000) GMDN=62804, EMDN N/A Thermal Printer (DS-05240), GMDN = 63034, EMDN = N/A Thermal Printer Paper (DS-05233), GMDN = 65796, EMDN = N/A
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
Regulation (EU) 2017/746
EN ISO 14971:2019
IEC 62366-1:2015 +A1:2020
IEC 62304:2006 + AMD1: 2015
ISTA 3E:2017
2015/863/EU (RoHS 3)
2012/19/EU (WEEE)
Regulation (EU) 1907/2006 (REACH)

IEC 62471:2006
EN 55011:2016
EN 61010-2-101:2017
EN 61326-2-6:2021
IEC 60825-1:2014
IEC 61010-1:2010
EN 61010-1:2020

EN 61000-3-2
EN 61000-3-3
EN 61000-4-2:2009
EN 61000-4-3:2006 /A1/A2
EN 61000-4-4:2012
EN 61000-4-5:2014/ A1:2017
EN 61000-4-6:2014
EN 61000-4-8:2010
EN 61000-4-11:2020

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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