Accriva diagnostics

EC DECLARATION OF CONFORMITY

Manufacturer Address:	Accriva Diagnostics, Inc. 6260 Sequence Drive San Diego, CA 92121 USA Tel: (858) 263-2300 Fax: (858) 875-0603
Authorized European Representative:	MDSS GmbH Schiffgraben 41 Hannover, Germany
Notified Body:	BSI Kitemark Court, Davy Ave., Knowhill Milton Keynes MK5 8PP United Kingdom
Notified Body No.:	0086
Product Type:	General Coagulation System - Semi-automated; Activated Clotting Time, Activated Partial Thromboplastin Time, Prothrombin Time
Product Name:	HEMOCHRON® Microcoagulation Test System HEMOCHRON® Signature ELITE Instrument HEMOCHRON® Software HEMOCHRON® Test Cuvettes HEMOCHRON® Controls
EDMA Code:	23 07 10 02 (Coagulation Hardware + accessories + consumables + software) 13 02 01 02 00 (Activated Partial Thromboplastin Time) 13 02 01 01 00 (Prothrombin Time (Quick Test)) 13 02 01 04 00 (Activated Clotting Time) 13 02 50 02 00 (Control Plasmas)
GMDN Code:	55994
Products Description:	See Attachment 1
Applicable Standards:	See Attachment 2

We, Accriva Diagnostics, Inc., hereby declare that the products referenced above meet the provisions of the In Vitro Diagnostics Directive 98/79/EC, which apply to them as stated in Annex III per the conformity assessment procedures in Article 9, paragraph I.

We, Accriva Diagnostics, Inc., hereby declare that Hemochron® Signature ELITE Instrument meets the provisions of RoHS Directive (RoHS 2) : Directive 2011/65/EU

EC Certification Number
Self Declared

Quality Management System – Certificate Number FM 612089
Issued By: BSI Group America, Inc. Expiry Date: February 28, 2019

Quality Management System – Certificate Number MD 632084
Issued By: BSI Group America, Inc. Expiry Date: February 28, 2019

Accriva Diagnostics, Inc. maintains and operates a Quality Management System according to ISO 13485:2003 / EN ISO 13485:2012.

Name	Steve Worcester
Title	Vice President, Quality and Regulatory Affairs
Date	07/10/2017
Signature	

Attachment 1

Product Group	Catalogue No. / Ref No.
Instruments, Disposables & Controls	
HEMOCHRON Signature ELITE Instrument	ELITE, ELITEINT, ELITEINTDEMO, ELITEINTRF
APTT Cuvettes - HEMOCHRON Jr. Activated Partial Thromboplastin Time (APTT)	J103
Citrate APTT Cuvettes - HEMOCHRON Jr. Citrate Activated Partial Thromboplastin Time (Citrate APTT)	J103C
PT Cuvette - HEMOCHRON Jr. Prothrombin Time Test (PT)	J201
Citrate PT Cuvette - HEMOCHRON Jr. Citrate Prothrombin Time Test (Citrate PT)	J201C
ACT+ Cuvette - HEMOCHRON Jr. Activated Clotting Time Plus (ACT+)	JACT+
ACT-LR Cuvette - HEMOCHRON Jr. Low Range Activated Clotting Time (ACT-LR)	JACT-LR
directCheck Abnormal Controls - ACT	DCJACT-A
directCheck Normal Controls – ACT	DCJACT-N
directCheck Abnormal Controls - ACT-LR	DCJLR-A
directCheck Normal Controls – ACT-LR	DCJLR-N
directCheck Abnormal Controls - PT	DCJPT-A
directCheck Normal Controls – PT	DCJPT-N
directCheck Abnormal Controls - APTT	DCJAPTT-A
directCheck Normal Controls – APTT	DCJAPTT-N
directCheck Abnormal Controls - Citrate APTT	DCJCAPTT-A
directCheck Abnormal Controls - Citrate PT	DCJCPT-A
directCheck Normal Controls – Citrate PT (Normal for Citrate APTT)	DCJCPT-N
Accessories	
Report Maker (Data Management Software)	RPM-CD
Electronic System Verification Kit	HE-J04
Electronic System Verification Cartridge -Abnormal	JEA-QC
Electronic System Verification Cartridge - Normal	JEN-QC
Temperature Verification Cartridge	J-1001

Attachment 2

Standard No.	Title
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13640:2002	Stability Testing of In Vitro Diagnostic Reagents
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
EN 60825-1:2007	Safety of Laser Products - Part 1: Equipment Classification, Requirements, and User's Guide
EN 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential pe1formance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101:Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010:Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use -EMC requirements –Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control, and laboratory use - EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
EN 55011:2009 A1:2010	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement
EN ISO 13485:2003/AC :2009	Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
IEC 60601-1:1988	Medical Electrical Equipment Prut 1: General Requirements for Safety
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 15193:2009	In Vitro Diagnostic Medical Devices - Measurement of Quantities in Samples of Biological Origin - Requirement s for Content and Presentation of Reference Measurement Procedures
EN ISO 15194:2009	InVitro Diagnostic Medical Devices - Measurement of Quantities in Samples of Biological Origin - Requirements for Certified Reference Materials and the Content of Suppo1ting Documentation
EN ISO 15223-1:2007	Medical Devices - Symbols to be used with Medical Device Labels, Labelling and Infom1ation to be Supplied - Prut 1: General Requirements
EN ISO 18113-1:2011	InVitro diagnostic medical devices -Information supplied by the manufacturer (labelling) -Part l: Terms, definitions and general requirements
EN ISO 18113-2:2011	InVitro diagnostic medical devices -Information supplied by the manufacturer (labelling) -Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	InVitro diagnostic medical devices -Information supplied by the manufacturer (labelling) -Part 3: In vitro diagnostic instruments for professional use