Accriva diagnostics

EC DECLARATION OF CONFORMITY

Manufacturer:	Accriva Diagnostics, Inc. 6260 Sequence Drive San Diego, CA 92121 USA Tel: (858) 263-2300 Fax: (858) 875-0603
European Authorized Representative:	MDSS GmbH Schiffgraben 41 Hannover, Germany
Product Group or Family:	HEMOCHRON® Microcoagulation Test System
Product Name(s):	See attachment 1
Device Nomenclature:	See attachment 1
Classification:	"Other" In vitro diagnostic medical device

We, Accriva Diagnostics, Inc., hereby declare that the products listed in Attachment 1 are in conformity with the In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD).

Conformity Assessment Procedure:	IVDD, Annex III, excluding section 6
Notified Body Name:	Not applicable, self-declared
Notified Body Identification Number:	N/A
EC Certificate Number:	N/A
EC Certificate Expiry:	N/A

Additional Information:	Applied Standards:	See Attachment 2
Quality Management System:	BSI, UK EN ISO 13485:2016 Certificate Number: Expiry Date:	 MD632084 2021-07-23

We, Accriva Diagnostics, Inc., hereby declare that Hemochron® Signature ELITE Instrument(s) listed in Attachment 1 meet the provisions of RoHS Directive (RoHS 2): Directive 2011/65/EU.

This declaration of conformity is issued under the sole responsibility of the manufacturer, Accriva Diagnostics, Inc.

(Signature)
Paula Morgan
Vice President, Quality and Regulatory Affairs
Accriva Diagnostics, Inc.

Place: San Diego, CA
Date: 5/7/2019

Attachment 1

Product Name	Catalogue No. / Ref No.	Device Nomenclature	Device Nomenclature Code	Device Nomenclature Term
Instruments, Disposables & Controls				
HEMOCHRON Signature ELITE Instrument	ELITE, ELITEINT, ELITEINTDEMO, ELITEINTRF	EDMA	23 07 10 02	Coagulation Hardware + accessories + consumables + software
APTT Cuvettes - HEMOCHRON Jr. Activated Partial Thromboplastin Time (APTT)	J103	EDMA	13 02 01 02 00	Activated Partial Thromboplastin Time
Citrate APTT Cuvettes - HEMOCHRON Jr. Citrate Activated Partial Thromboplastin Time (Citrate APTT)	J103C	EDMA	13 02 01 02 00	Activated Partial Thromboplastin Time
PT Cuvette - HEMOCHRON Jr. Prothrombin Time Test (PT)	J201	EDMA	13 02 01 01 00	Prothrombin Time (Quick Test)
Citrate PT Cuvette - HEMOCHRON Jr. Citrate Prothrombin Time Test (Citrate PT)	J201C	EDMA	13 02 01 01 00	Prothrombin Time (Quick Test)
ACT+ Cuvette - HEMOCHRON Jr. Activated Clotting Time Plus (ACT+)	JACT+	EDMA	13 02 01 04 00	Activated Clotting Time
ACT-LR Cuvette - HEMOCHRON Jr. Low Range Activated Clotting Time (ACT-LR)	JACT-LR	EDMA	13 02 01 04 00	Activated Clotting Time
directCheck Abnormal Controls - ACT	DCJACT-A	EDMA	13 02 50 02 00	Control Plasmas
directCheck Normal Controls – ACT	DCJACT-N	EDMA	13 02 50 02 00	Control Plasmas
directCheck Abnormal Controls - ACT-LR	DCJLR-A	EDMA	13 02 50 02 00	Control Plasmas
directCheck Normal Controls – ACT-LR	DCJLR-N	EDMA	13 02 50 02 00	Control Plasmas
directCheck Abnormal Controls - PT	DCJPT-A	EDMA	13 02 50 02 00	Control Plasmas
directCheck Normal Controls – PT	DCJPT-N	EDMA	13 02 50 02 00	Control Plasmas
directCheck Abnormal Controls - APTT	DCJAPTT-A	EDMA	13 02 50 02 00	Control Plasmas
directCheck Normal Controls – APTT	DCJAPTT-N	EDMA	13 02 50 02 00	Control Plasmas
directCheck Abnormal Controls - Citrate APTT	DCJCAPTT-A	EDMA	13 02 50 02 00	Control Plasmas
directCheck Abnormal Controls - Citrate PT	DCJCPT-A	EDMA	13 02 50 02 00	Control Plasmas
directCheck Normal Controls – Citrate PT (Normal for Citrate APTT)	DCJCPT-N	EDMA	13 02 50 02 00	Control Plasmas
Accessories				
Report Maker (Data Management Software)	RPM-CD	EDMA	23 07 10 02	Coagulation Hardware + accessories + consumables + software
Electronic System Verification Kit	HE-J04	EDMA	23 07 10 02	Coagulation Hardware + accessories + consumables + software

Electronic System Verification Cartridge -Abnormal	JEA-QC	EDMA	23 07 10 02	Coagulation Hardware + accessories + consumables + software
Electronic System Verification Cartridge - Normal	JEN-QC	EDMA	23 07 10 02	Coagulation Hardware + accessories + consumables + software
Temperature Verification Cartridge	J-1001	EDMA	23 07 10 02	Coagulation Hardware + accessories + consumables + software

Attachment 2

Standard No.	Title
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 23640:2015	In Vitro Diagnostic Medical Devices - Evaluation Of Stability 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 ISO 13485: 2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control , and laboratory use - Part 1: General requirements
EN 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101 :Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-010:2014	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 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 - Requirements for Content and Presentation of Reference Measurement Procedures
EN ISO 15194:2009	In Vitro Diagnostic Medical Devices - Measurement of Quantities in Samples of Biological Origin - Requirements for Certified Reference Materials and the Content of Supporting Documentation
EN ISO 15223-1:2016	Medical Devices - Symbols to be used with Medical Device Labels. Labelling and Information to be Supplied - Part 1: General Requirements
EN ISO 18113-1:2011	In Vitro diagnostic medical devices -Information supplied by the manufacturer (labelling)- Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In Vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) –Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In Vitro diagnostic medical devices -Information supplied by the manufacturer(labelling)-Part 3: In vitro diagnostic instruments for professional use
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